Good Supply Practices for the 21st Century

Marla Phillips, Ph.D., Editor

XAVIER HEALTH

Message from the Director

I am pleased to announce, on behalf of my FDA and industry team members, the release of the highly-anticipated *Good Supply Practices for the 21st Century*, a global tool for industry and regulators.

Completing the GXP Suite: As a result of seven years of focused research, development, testing, and broad stakeholder input, the Good Supply Practices (GSPs) complete the missing piece of the GXP puzzle. These breakthrough supply chain practices provide a solid foundation for the GMP, GCP, GLP, and GDPs, which increase the reliability of your product throughout its entire lifecycle.

Significant Paradigm-Shift in How to Think About Supply Chain Controls: The Good Supply Practice initiative revealed that we, the manufacturers, are either causing, or could prevent, every supply chain failure we experience. So, instead of trying to "fix" our suppliers, it's time to look in the mirror and adopt practices that will result in breakthrough supply chain quality.

Start enjoying the benefits of this work by making a difference in your supply chain performance today!

Marla A Phillips

Director, Xavier Health
Xavier University

ABOUT XAVIER HEALTH

Xavier Health is more than an organization. It is a community of hundreds of FDA officials, industry experts, and thought leaders. Together, the Xavier Health Community believes in:

- **Collaboration:** FDA officials and Industry professionals working in groups, teams and committees towards increasing the confidence we have in medical products and improving the lives of the patients we serve.
- **Finding True Root Cause:** True root causes allow us to shift paradigms through critical thinking and methodical approaches to address complex challenges.
- **Purpose Driven Actions:** A community engaged in purpose-driven initiatives and engaging conferences that are driven by making a meaningful difference.
- **Commensurate With the Need:** Effective implementation that will truly change how we operate today requires a balance of risks and benefits for each organization..
- **Actionable:** Ideas must be more than big. They need to be meaningful and actionable. Xavier Health engages regulators and industry professionals in the development of personal action plans that are ready to be implemented immediately.

Be part of something bigger and make a difference!

Xavier Health Events

FDA/Xavier PharmaLink Conference (March)

Engage in rich discussion with FDA, Chief Quality Officers, and industry experts so you can walk away with solutions to your toughest challenges! The 2019 conference includes:

- FDA Office Hours
- Breakthrough Supply Chain Performance Workshop
- Data Integrity Master Class
- Three days of interactive solution-providing sessions

EU MDR Workshop (March)

Ensure your medical device can be sold after May 2020 in the EU. In 2019, Experts Bassil Akra (TÜV SÜD), Philippe Auclair (Abbott), Gert Bos (Qserve), Oliver Christ (PROSYSTEM), and Kim Trautman (NSF), will lead you through the development of:

- Advanced strategies to effectively work with notified bodies
- Insightful game plans for compiling the data required to certify your products
- Recommendation plans to heighten urgency and gain support from senior leaders

FDA/Xavier MedCon Conference (May)

Over 40 FDA and industry experts with 800+ years of experience share proven solutions that you can implement today. The 2019 conference includes:

- Breakthrough Supply Chain Performance Workshop
- Data Integrity Master Class
- Three days of interactive solution-providing sessions

AI Summit (August)

FDA and tech industries converge—AI solutions for today and tomorrow. Each year, topics fall into the following categories:

- FDA Vision for Artificial Intelligence in our industry
- Foundations of Artificial Intelligence
- AI in Action
- AI Live Demonstrations for hands-on interaction
- FDA/Industry Working team – deliverables, presentations, and new formation

Combination Products Summit (September)

A solution-focused combination like no other! Experience the Xavier Difference:

- One-on-one FDA office hours with the FDA Office of Combination Products leaders, Thinh Nguyen and John "Barr" Weiner
- Led by industry experts who have been instrumental in shaping the combination products regulations and guidances
- Cross-center FDA fireside chat with ORA, CDER, and CDRH
- Primer webinar series

GSP Co-Leaders

Marla Phillips, Co-Leader, 2012-2018
Director, Xavier Health
Xavier University

Dr. Marla A. Phillips joined Xavier University in 2008 as the Director of Xavier Health, where she leads initiatives with FDA officials and Pharmaceutical and Medical Device professionals. Marla began working in the pharmaceutical industry for Merck in 1996 where she took on roles of increasing responsibility, culminating in position of Head of Quality Operations at the Merck North Carolina facility. She holds a B.S. in chemistry from Xavier University, and a Ph.D. in organic chemistry from the University of North Carolina – Chapel Hill.

Jack Solomon, Co-Leader 2013-2018
Senior Consultant, Supply Chain Practice Leader
Core Risks Ltd.

Jack Solomon is Head of Supply Chain Services at Core Risks Ltd., a global provider of specialized consulting services to a variety of business sectors. His primary focus is on supply chain, risk management and due diligence. Prior to joining Core Risks, he spent 30 years in Supply Chain and Finance roles in site and corporate positions in Life Sciences and Technology companies. Jack received his B.S. degree in Finance from Ohio State University and his M.B.A. from Rutgers University.

Troy Fugate, Co-Leader, 2016-2018
Vice President, Operations
Compliance Insight

Troy Fugate utilizes 30 years of hands-on insight into Quality Assurance, Validation, Workforce Development and Training skills to evolve GMPs from a regulation to a value-added habit. Mr. Fugate has been a partner in Compliance Insight since 2001, helping companies around the world, and serves in a variety of roles including: workforce development, strategic compliance initiatives, and FDA mitigation. Mr. Fugate is a proponent of proactive, sustainable compliance solutions.

The full list of FDA and Industry team members is provided in Appendix I.

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Section 1: Executive Summary

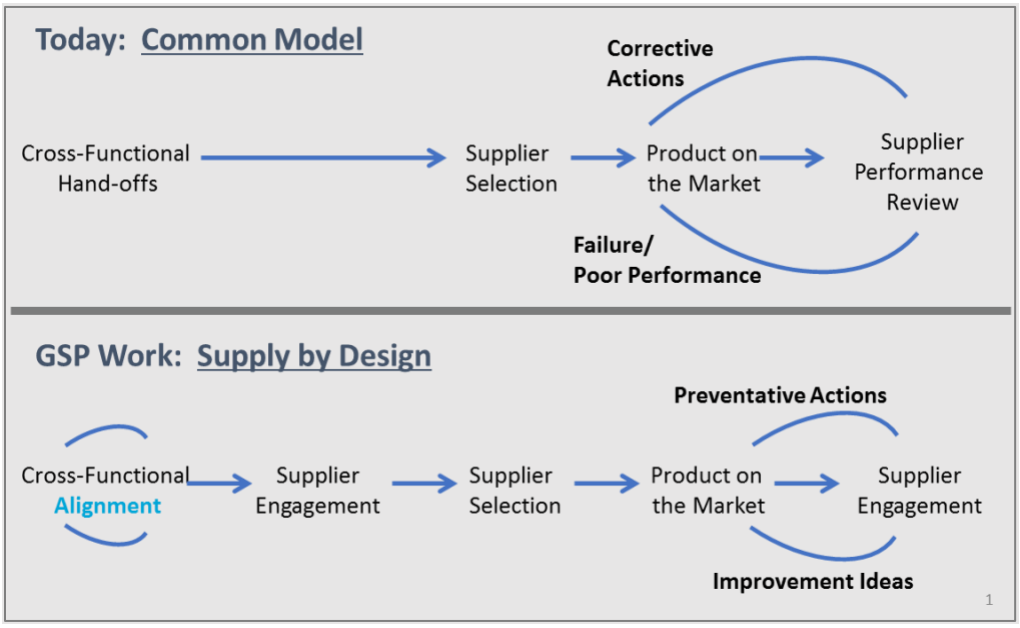
The Good Supply Practices (GSPs) establish a holistic approach to sourcing and supply chain operations that supports patient and business success by reducing risk to internal and external stakeholders throughout the total product lifecycle. Based upon the discovery that the true root cause of supply chain failure starts internally within the buyer's organization, Xavier Health led a team of FDA officials, pharmaceutical professionals, medical device professionals and supplier representatives from 2012 – 2018 to develop four new supply chain concepts that significantly improve supply chain performance for companies of all sizes and complexity. The GSPs provide a practical right-first-time methodology to balance the often-paradoxical priorities of increasing patient safety, optimizing capacity, increasing product quality, and reducing end-to-end cost in a way that is commensurate with the need.

True Root Cause. The GSP work followed the 6 sigma DMADV model (Define, Measure, Analyze, Design, and Verify) using the problem statement, "We are unable to reliably and consistently ensure the supply of incoming materials used in products to serve the Food, Drug, and Device industries." The erroneous belief held across industry that supply chain failures are due solely to poor supplier performance has led to increased supplier qualification requirements, intensive monitoring of supplier performance metrics, and exhaustive supplier oversight models that have not resulted in appreciable supply chain performance improvement. Root cause analyses through the GSP work led to the discovery that all supply chain failures are either caused unknowingly by the companies themselves or could have been prevented, which requires a shift in focus from increasing supplier performance to increasing company performance. By addressing true root cause, industry is able for the first time to truly increase supply chain performance.

Four New Concepts. (1) Supply-by-Design (SbD): The Good Supply Practices in their entirety are grounded in the concept of Supply-by-Design, which protects product quality through an intentional design of the supply chain and minimizes unexpected risk. Each solution provided in the Good Supply Practices is a way in which to execute Supply-by-Design. (2) Cross-Functional Alignment: Gaining internal alignment (i.e. true alignment, not siloed hand-offs) across diverse competing priorities will increase the assurance of patient and business success. (3) Self-Qualification: If companies are causing or could prevent all supply chain failure, then the question must be: "How qualified are *we* to be in this relationship?", which takes companies beyond the one-dimensional approach of supplier qualification. (4) Relationship Risk Mapping: Since all relationships involve more than one entity, then only the overlay of strengths and weaknesses from all entities involved will create an understanding of total relationship risk and enable the company to mitigate weaknesses from both sides.

As illustrated in Figure 1.1, today's supply chain is developed through a series of disjointed siloed hand-offs, which then requires exhaustive resources to mitigate supplier and material failures. Conversely, an intentional supply-by-design (SbD) approach is taken through the GSP processes that is accomplished through cross-functional alignment on material and supplier requirements, which results in reduced failure, cost and risk. This right-first-time approach through cross-functional alignment is a key differentiator of the GSP work.

Figure 1.1: Comparison of Supply Chain Development Model Effectiveness



The GSP work is one of many outcomes from joint initiatives led by Xavier Health with FDA and industry representatives. Xavier engaged FDA from the Office of the Commissioner and the Center for Drug Evaluation and Research (CDER), as well as over 40 pharmaceutical and medical device companies, and 160 suppliers. The subject matter experts spanned multiple levels of management, cross-functional areas, and companies of all sizes (from small family businesses to Top 100 multinational corporations). The GSP work resulted in practical, tool-based solutions designed to be implemented in a way that makes sense for each company and commensurate with the need.

Section 2: Research and Methodology

Background: In August of 2012, Xavier University launched the Integrity of Supply Initiative to determine areas of failure that are increasing the risk of materials and products throughout the

global supply chain, and to develop sustainable solutions tied to return on investment – such as increased safety, improved quality and enhanced reliability – commensurate with the need.

Leaders in the pharmaceutical, medical device, and food industries expressed a unilateral concern over product confidence throughout the total product lifecycle, an unsettling fact for these leaders given that their products affect the lives of millions of people each year. Fueled by the heparin incident of intentional adulteration in 2008, initial efforts for increasing product confidence were focused on improving the confidence of incoming materials, with a belief that supplier performance must be the root cause. As in the heparin case, concern over supplier performance extends deep into the supply chain to include suppliers of the suppliers—which can be challenging to map in legacy supply chains that lack transparency.

The Team: Throughout 2012 – 2018, Xavier Health led a team of FDA officials and industry experts from the pharmaceutical, medical device and food industries that resulted in the identification of an unexpected source of product risk, which has afforded a fresh understanding of why current product and supply chain management methods have not reduced product failures. The team members throughout these 6 years spanned 5 countries, and are listed in Appendix 1 with the position they held during their work on the team.

Research and Methodology: Xavier Health led a robust research and methodology process with the goal of establishing practical supply chain solutions that would result in a meaningful and measurable increase in product confidence. In order to achieve this difference, true root cause of supply chain failures would need to be discovered and supported by data. The process that was followed is described within this section, and examples of the data are provided in Appendix 2.

1. Cross-Functional Interviews. Prior to the first meeting in August 2012, controlled interviews were conducted of cross-functional representatives from the organizations represented on the team, as well as trade associations (IPEC, GPhA, MDMA, and PhRMA) (6) and industry experts—totaling 16 interviews of over 50 individuals. The goal of the interview process was to explore an array of diverse perspectives related to the problem statement, existing gaps, existing solutions, and areas of opportunity. All 16 interviews were conducted by a Xavier University interview team, which utilized a consistent line of questioning, documented responses without bias, and conducted a robust comparison across interviews.
2. SWOT Analysis. A SWOT (strengths, weaknesses, opportunities, and threats) analysis of the interview information was conducted by the Xavier University interview team. The analysis was presented during the Initiative Kick-off Meeting to create an awareness of inherent differences and commonalities across the industries and, therefore, to help identify potential areas of focus. The interview team also identified best practices from

each of the organizations interviewed, and asked the respective team members to present this information during the kick-off meeting. The cross-functional interviews, SWOT analysis, and best practice presentations led to the development of a robust problem statement and an early sense of areas of opportunity.

Through the cross-functional interviews conducted prior to the August 2012 kick-off meeting, it was clear that lack of product confidence was believed to be linked solely to supplier performance. Recognizing that many patient-harm cases were publicized due to the involvement of rogue foreign suppliers economically motivated to contaminate the supply base, it is not difficult to appreciate why industry held this belief. In an effort to improve supplier controls, and therefore reduce product risk, FDA-regulated industries joined in the adoption of the supplier relationship management (SRM) strategy developed by the automotive industry. The SRM approach to supply chain management focuses on increasing oversight of suppliers as a means to reduce risk, but does not traditionally include an assessment of the risk induced in the process by the companies themselves.

In 2011, major food retailers launched a supplier certification program through the Global Food Safety Initiative (GFSI). As a result of this initiative, only suppliers successfully completing the certification process achieved a globally recognized level of acceptability to supply the food industry. The concept of adopting this type of supplier certification process was appealing to the pharmaceutical and medical device industries since it would address their focus of improving supplier operations. This concept was explored during the August 2012 kick-off meeting, during which time the Food industry noted that results of the GFSI approach had not reduced the incidence of food recalls and, therefore, had not alleviated product confidence concern—thus the GFSI approach will not provide the "silver bullet".

3. Cause and Effect Matrix and Pareto Analysis. Once a robust problem statement had been defined, the team was taken through a cause and effect matrix exercise using the following critical customer requirements: visibility of supplier information across industries, supplier awareness of roles/responsibilities in the supply chain, cost effectiveness, full supply chain knowledge and oversight, protection of company brand/assets, and reliable/safe materials. Pareto analyses were conducted per organization, which then allowed for comparison between companies, between industries, and between companies and regulators. Surprisingly, results from all comparison groups led to a similar rank-order of the 19 identified causes, which led to an unexpected paradigm shift yielding a fresh understanding of why current product management methods and strategies have not satisfactorily reduced product failures.

Although one could interpret the problem statement as implying that due to uncertainty in the confidence of incoming materials, the lack of final product confidence must be linked to poor supplier performance, the gap analysis conducted by the manufacturers pointed to themselves as the source of this lack of confidence, not their suppliers. The paradigm shift required great pause to internalize how this outcome could be possible.

Assessment of the cause and effect matrix data revealed that manufacturers either unknowingly increase the potential for error or can control/prevent many aspects of product confidence failure. Three main themes emerged from the cause and effect matrix data as to areas of improvement needed by the manufactures:

1. Manufacturers do not understand the variability in their own products and processes well enough to know what is needed from their suppliers.
2. Manufacturers often circumvent their own supply chain development and management processes, which leads to suboptimal decisions.
3. Manufacturers do not develop relationships with their suppliers that engender trust.

Theme 1: Manufacturers do not understand the variability in their own products and processes well enough to know what is needed from their suppliers. The original assumption at the outset of the Integrity of Supply Initiative was that suppliers cannot consistently supply what is needed. However, it was discovered through our research that manufacturers often do not know what specifications are actually needed, do not involve suppliers in development discussions, do not explore the full expertise of suppliers, do not understand their own process well enough to know how the incoming material will impact their product, and do not ask for the process capability of their suppliers – a key variable that is introduced into the process and product.

Manufacturers often replicate specification requirements for commonly used incoming material from product to product, or rely on compendial requirements without understanding the impact to individual final products. A key success factor for this theme is to involve the right functional groups upfront and understand how to effectively engage suppliers for successful product and process development.

Theme 2: Manufacturers often circumvent their own supply chain development and management processes, which leads to suboptimal decisions. Many manufacturers have supplier selection and supplier approval processes in place; yet demands on speed to market often result in circumvention of these processes. Additionally, it has been found that supply agreements often conflict with the requirements of other agreements (i.e., Quality Agreements)

and drive the wrong behavior, as it is difficult to satisfy both sets of expectations. Time constraints or convenience often override the use of methodical supplier identification processes designed to ensure the right suppliers are selected based on vast risk-based criteria including capability, capacity, cost, and culture. As a result, years of effort follow to "control" suppliers that never should have been included in the supply chain. Although manufacturers report the use of risk-based decisions, it was found that the inclusion of key risk factors such as economics, financial viability, geopolitical implications, and culture were often missing. Risk-based decisions are typically made within internal silos, and therefore lack cross-functional visibility. Without internal alignment and awareness, decisions are made with detrimental impact to the products and company, and ultimately pose potential for harm to the patients they serve.

Theme 3: Manufacturers do not develop relationships with their suppliers that engender trust. Many discussions throughout the Integrity of Supply Initiative have centered on behavior. For example, customers historically operate without caring what the cost or disruption is to the supplier, or how the supplier profit margins are impacted. Yet, there is a lack of realization that this churn increases opportunity for error, thus decreasing the ability of the supplier to be reliable for the manufacturer. Importantly, the data revealed the significant importance of recognizing the supplier as a valued partner, rather than one needing to be controlled. Instead of increasing controls over supplier operations, manufacturers need to assess how their own actions and behaviors prevent their suppliers from consistently supplying reliable material.

Viewing the supplier as a valued partner and taking ownership of product confidence failures will allow manufacturers to view supplier relationships through a different lens. A truly collaborative relationship where partners work together to foster mutual growth is certainly more desirable than one where relationship management strategies are designed to enable one partner to control the other. In light of this paradigm shift, one can see how traditional and modern supplier relationship management strategies have not alleviated the concern of product confidence failures.

A further shift in thinking is for manufacturers to view their suppliers as customers first. The supplier is the customer, or recipient, of the requirements, needs, and wants of the manufacturer. If the manufacturer considers the supplier as a customer in this light, then the manufacturer will work to ensure that their "customer" is satisfied both upfront in how they are engaged and regarded, as well as their satisfaction with the on-going relationship and growth. This type of approach will ensure manufacturers regard their suppliers as equal entities, and that they are aware of the impact of their own performance on their suppliers, thus increasing the likelihood of product success.

4. Focus Group Input. Eight focus group sessions were conducted in the 2013-2014 timeframe to corroborate the research findings by a wider array of experiences. Focus group input was gathered during the following conferences: FDA/Xavier University PharmaLink Conference (2013 and 2014), FDA/Xavier University MedCon Conference (2013 and 2014), Association of Food and Drug Officials Conference (2013), ExcipientFest Americas Conference (2014), FDA/PDA Regulatory Conference (2014), and the Great Lakes cGMP and Regulatory Science Forum and University of Illinois Conference (2014). In all cases, the focus group session corroborated the findings and identified a strong desire to acquire a "step-change" in supply chain performance. Not once did a focus group member express either the lack of need for the research or question its accuracy in identifying the main issues.

   Presentation of the Good Supply Practices is on-going through invitations to present during national industry conferences across pharma and device, as well as invited presentations during FDA workgroup meetings. The outcome has been that the presentations have gained continued feedback to support the findings and direction of the research and solution development. Importantly, there has never been an instance to date whereby someone has voiced that the work is off-target or not valued.

5. Voice of the Customer. The DMADV process (define, measure, analyze, develop, and verify) is the disciplined approach that was employed throughout the initiative, which includes a strong "Voice of the Customer" component. In the spirit of the supplier-is-customer analogy, "Voice of the Customer" surveys were given to suppliers for the food, pharmaceutical, and medical device industries. The suppliers chosen were those that would typically be viewed as "Key Suppliers" either by the criticality of the material being provided (i.e., function in the final product, cost of the material, risk of volume to supply the need, etc.), or significance of the business relationship. Additionally, the team chose suppliers that supply other industries such that the suppliers would have a broader perspective on how the FDA-regulated industries might differ from best practices in their view.

   The responses provided by the suppliers through the Voice of the Customer survey corroborated the findings of the manufacturers themselves in that the manufacturers unknowingly increase the potential for error or can control/prevent many aspects of product confidence failure. It is not surprising, then, that without recognizing the role the manufacturer plays in product failure, SRM has not alleviated concerns of product confidence. Upon further review, it was found that the intent of SRM is about determining and communicating needs and expectations to a supplier, measuring

performance, and invoking actions for compliance. At the higher end, SRM is about developing suppliers so they perform for the benefit of the buying company/organization. Additionally, tying the concept of "strategic partners" in SRM with the need to manage and control those "partners" continues to alienate the large base of suppliers that exist for the true benefit of the industry they serve. In contrast, through the Integrity of Supply Initiative, manufacturers have embraced the role they play in product confidence failures and are working collaboratively with suppliers to design practices in full recognition that suppliers are equal partners with manufacturers, not "lesser" entities needing to be controlled. It is through this paradigm shift that a step-change in thinking will drive a focus on practices that can truly increase product confidence.

All 162 responses corroborated the findings of the team and importantly did not identify an "elephant in the room" that the team had missed. The insight gained through the survey was further explored through a focus group meeting led by Xavier University representatives between the team and eight suppliers in order to ensure the context of the survey responses was fully understood. It was at this point in the initiative that the suppliers were integrated in the initiative through formal representation on the team.

Appendix 2 contains pie charts from the supplier survey along with explanations of what the results reveal.

6. Solution Design and Feasibility Studies. The team consisting of FDA officials, pharmaceutical professionals, medical device professionals, and supplier representatives collaboratively developed 11 pragmatic solutions that are outlined in Section 3A. During the development process, the team initiated feasibility studies with companies of varying sizes and complexity to verify the value of the solutions. In each case, the participating companies expressed that the Good Supply Practices revealed gaps in their processes that exposed their companies to risk. In one case, a new company indicated that the Good Supply Practices offered them an entire suite of solutions to use as their supply chain development and management practices, and indicated that they previously had not been able to find such tools to support their operations.

Key Differentiators. Through the Integrity of Supply Initiative, 4 new concepts have been developed (Figure 2.1) that differentiate this work from other work in publication, and lead to a meaningful and measurable impact.

Figure 2.1: 4 New Concepts Established through the Good Supply Practices

(1) Supply-by-Design (SbD): The Good Supply Practices in their entirety are grounded in the concept of Supply-by-Design, which protects product quality through an intentional design of the supply chain and minimizes unexpected risk. Each solution provided in the Good Supply Practices is a way in which to execute Supply-by-Design.

(2) Cross-Functional Alignment: Gaining internal alignment (i.e. true alignment, not siloed hand-offs) across diverse competing priorities will increase the assurance of patient and business success.

(3) Self-Qualification: If companies are causing or could prevent all supply chain failure, then the question must be: "How qualified are *we* to be in this relationship?", which takes companies beyond the one-dimensional approach of supplier qualification.

(4) Relationship Risk Mapping: Since all relationships involve more than one entity, then only the overlay of strengths and weaknesses from all entities involved will create an understanding of total relationship risk and enable the company to mitigate weaknesses from both sides. It is through this granular level assessment that companies can identify the right supply chain partner for the material in question that best supports the product, business and patient.

Section 3: Setting the Foundation

Before racing to implement changes in any organization, each company must set the foundation to ensure sustainable success is realized. In this section, an explanation is provided on how to use the Good Supply Practices since every company is in a different position on the supply chain development and management continuum and has different scales of operation (some have 10-100 suppliers, while others have over 10,000 suppliers, etc.). Perhaps the most important solution each company must implement in order to experience any level of success is to (1) establish the right cross-functional team for the business. Aligning (truly *aligning*) cross-functionally will prevent the continuous stops and starts that occur in today's supply chain management models and is critical to every aspect of supply chain operations. As companies make decisions on what to do and not do, (2) knowledge management plays a key role in maintaining the "tribal knowledge" that is so important to assess the validity of assumptions on an on-going basis, and to decrease the likelihood of wasting time, money and other resources in the future. Since every company has varying levels of complexity, the (3) supply chain risk management triage will provide companies with an example of how to determine where to start. And finally, prior to assessing the strengths and weaknesses of another company, it is imperative to understand one's own strengths and weaknesses. The (4) Self-Qualification scoring model provides companies with a mechanism through which to assess one's own strengths and weaknesses, and is aligned with the supplier requirements model provided in Section 4B, which can then be overlaid through the Relationship Risk Map in Section 5C.

Enjoy the journey!

3A. The Big Picture and How to Use the GSPs

The Good Supply Practices provide 11 practical tools for each company to use in a way that makes sense for the complexity of products, operations and business of each company. It is recommended that each company assess each tool, and modify the tools such that they are fit for purpose. The Xavier Health team of FDA and industry representatives worked to provide examples of what to discuss and how to assess each of the operations covered through the Good Supply Practices. For example, our goal was not to simply indicate that a cross-functional team should be established, but rather, to give guidance on how, when and why. Taking this example further, the cross-functional team formation tool lists 17 different functional groups, what each group needs from the supplier selection process, what each can contribute to the supplier selection process, and then how to score the likelihood of including each one through discussion with the functional group. Each company should modify this tool to list the actual functional

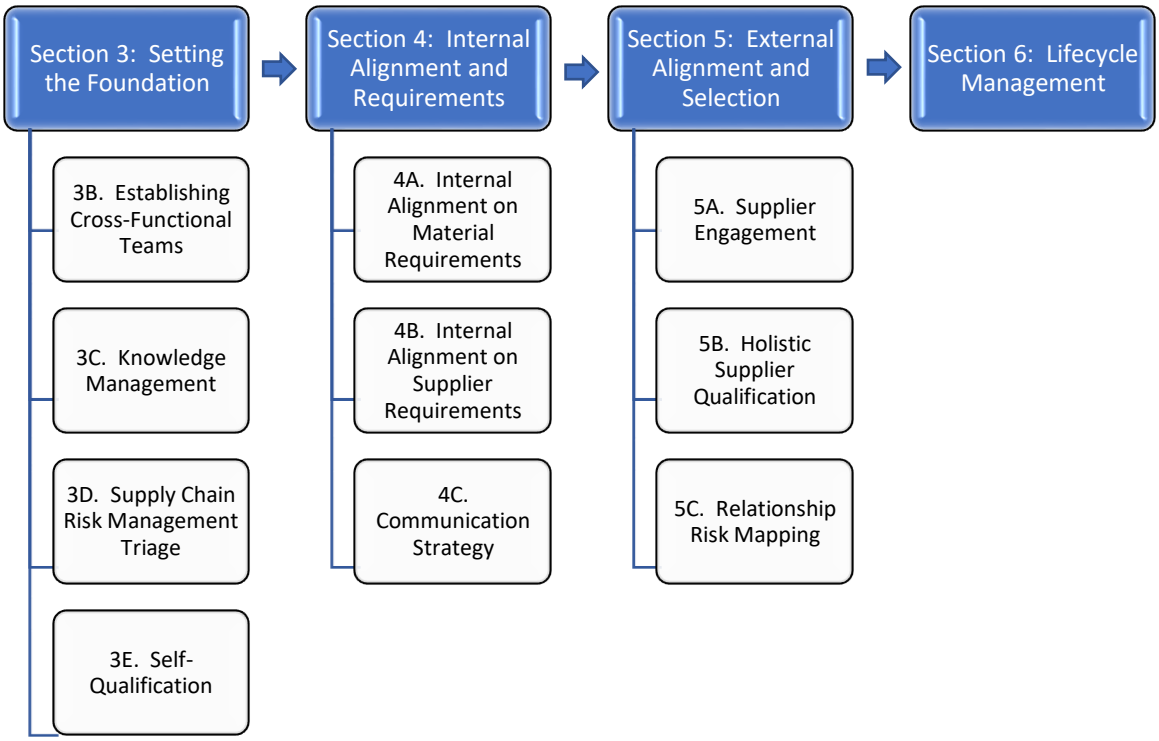
groups within their organization and determine any modifications that need to be made regarding what each group needs from and contributes to the supplier selection process. This tool, as is true for all tools in this document, provides great information from which to work, instead of a blank piece of paper.

Note: It is important that each company operates in accordance with local regulations, guidances and regulatory expectations. The Good Supply Practices provide each company with a mechanism for supporting operations in accordance with global regulatory requirements.

In order to effectivly use the Good Supply Practices, the Big Picture of the construct is helpful to understand. The Good Supply Practices are divided into 4 major sections in sequential order of implementation, as depicted in Figure 3A.1.

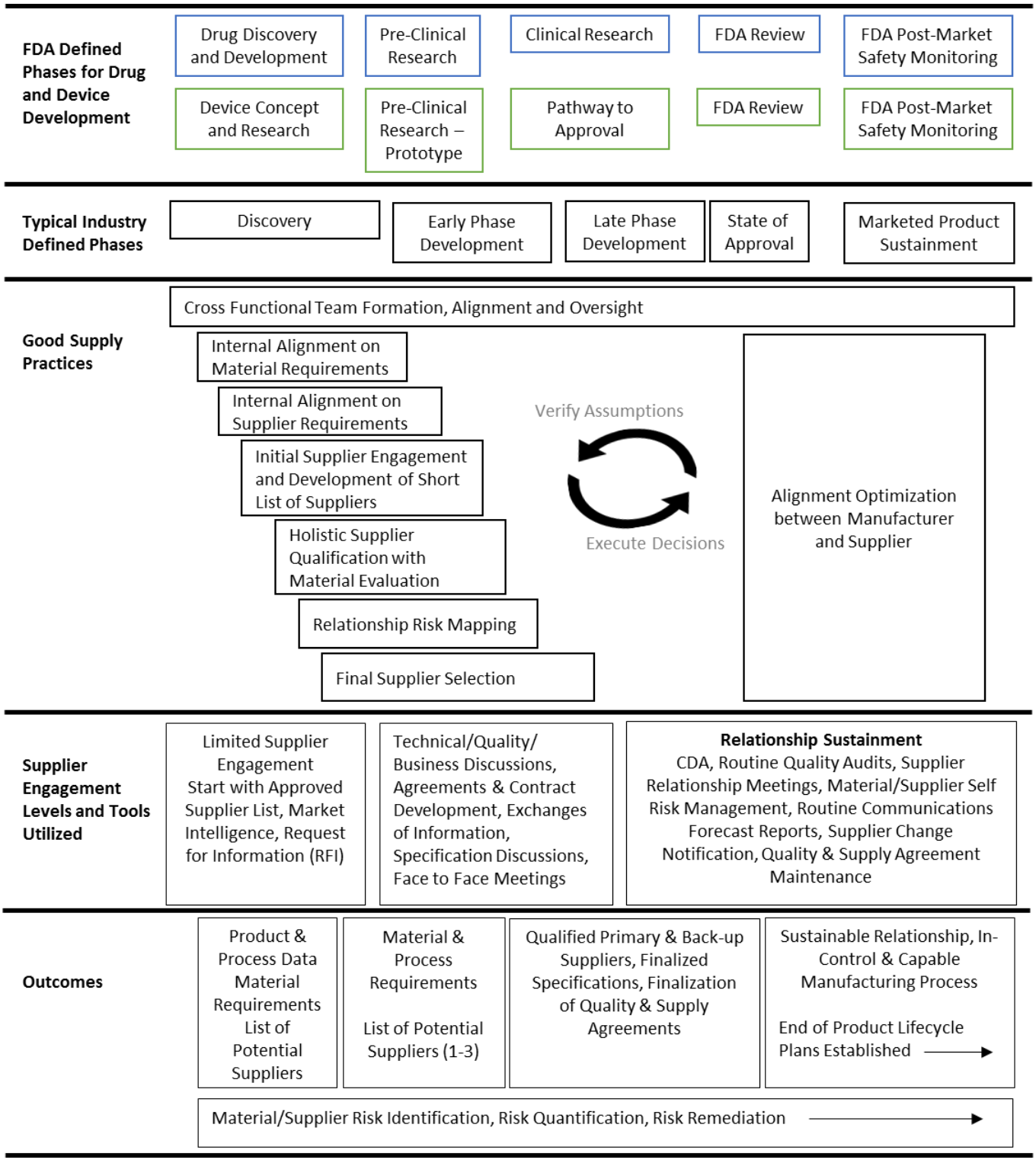
- Section 3 enables each company to establish a foundation that will support all supply chain development and management decisions such that each decision is sustainable, captured, and is in context with each company's own strengths and weaknesses.
- Section 4 provides guidance on how to establish internal alignment prior to racing to engage the supplier and making decisions. This internal alignment (true *alignment*) will prevent the repeated stops and starts that occur throughout today's supply chain development and management operations.
- Section 5 branches out to the purpose-driven external engagement of the supplier in a way that is grounded in the decisions established during the internal alignment processes of Section 4. It is important to engage the supplier as a subject matter expert after each company's internal cross-functional groups have aligned on priorities, criticality and requirements. Discussions that ensue with the supplier then include input from the supplier in order to refine the initial requirements established by the cross-functional team.
- Section 6 then provides guidance on how to manage the on-going lifecycle of the supply chain as a living model.

Figure 3A.1: Organization of the Good Supply Practices



In order to demonstrate how and when the Good Supply Practices fit within the construct of the product development lifecycle, swimlanes of operation were developed as provided in Figure 3A.2. Notice the intentional delay of Good Supply Practices implementation from the initial days of product research and discovery. Research and Development groups need time for discovery, trial and error before the implementation of formal discussions and decisions can and should be made. Additionally, it is important to note that the supply change management process is a living cycle that continually (1) assesses original assumptions, (2) assesses performance of self, supplier and materials, and (3) engages the supplier as a subject matter expert in the assessment of that performance. This is noted in Figure 3A.2 with the cyclical arrows.

Figure 3A.2: The GSP Swimlanes [Note: also provided in Appendix 3 for future reference throughout the document].



In order to provide a Big Picture understanding of the relevance of each GSP Solution, Table 3A1 provides a description of each solution, where the solution can be found wihtin this Good Supply Practices document, and a brief description of the outcome from each solution.

Table 3A1. Outcome of Each GSP Solution

GSP Solution	GSP Section	Outcome of Each GSP Solution
Cross-Functional Team Formation for alignment on material requirements	Section 3B	Documentation of functional areas to include
Cross-Functional Team Formation for alignment on supplier requirements	Section 3B	Documentation of functional areas to include
Knowledge Management	Section 3C	Types of information to be captured throughout the supply chain operations process
Supply Chain Risk Management Triage	Section 3D	Documentation of risk and impact of material and supplier, and determination of risk ranking
Self-Qualification Risk	Section 3E	Documentation of the risk score per category and overall
Internal Alignment on Material Requirements	Section 4A	Documentation of critical material requirements per material
Internal Alignment on Supplier Requirements	Section 4B	Documentation of the importance rating for each selection criterion per material to source
Outcome of Multi-Sourcing Strategy decision	Vignette	Documentation of the number of suppliers needed for each material
Communication Strategy from Manufacturer to Supplier	Section 4C	Documentation of what information is critical to share with each supplier, who shares it and when.

Communication Strategy from Supplier to Manufacturer	Section 4C	Documentation of what information is critical to receive from each supplier, who needs to receive it, and when it is needed.
Engaging the Supplier	Section 5A	The suppliers are engaged as SMEs to provide input on specifications and material performance for intended use.
Holistic Supplier Qualification - Proof of Capabilities for Material and Supplier	Section 5B	An evaluation of material and supplier stated capabilities versus demonstrated capabilities
Relationship Risk Mapping of Self and Supplier strengths and weaknesses	Section 5C	Documentation of risk score of each manufacturer/ supplier relationship
Final Supplier Selection Decision	Section 5C	Documentation of the supplier selection decision and rationale
Lifecycle Management	Section 6	Documentation of on-going performance versus initial assumptions and assessments

So where can you start?

Each company is in its own position on the maturity continuum of systems and processes, and that place ebbs and flows over the course of time as (1) key subject matter experts come and go, (2) new systems are adopted, (3) new products are developed that are beyond the familiarity of the organization, (4) mergers and acquisitions occur, etc. Each company also has its own living culture and personality, so it is important to implement anything new in the way that makes the most sense for the organization. Here are some suggestions on how your company can begin benefitting from the 11 solutions provided through the Good Supply Practices:

- **Example 1:** You are a very large company with 10,000 – 50,000 suppliers, and you have supply chain practices in place that are very complex or even advanced. You could do any of the following to first demonstrate success and ROI, then gradually move into the other solutions to continue benefitting from these practices:
    - Develop a cross-functional team (Section 3B) that is charged with aligning on future decisions related to your supply chain, using your current supply chain practices. New learnings will be discovered through this alignment process that

can be spread across your product lines and divisions for powerful ROI. This alignment also prevents the stops and starts experienced in today's supply chain operations.

- Develop a cross-functional team (Section 3B) that is charged with aligning on the requirements needed (Section 4B) for a supplier that is not performing well for you right now. Use this process to identify the source of the failure and areas of misalignment so the failures can be mitigated.
- Conduct a self-qualification (Section 3E) to identify the areas of risk you are inducing into your own supply chain operations, and to understand the offsetting strengths you need from your suppliers.
- The next time you need to identify a new supplier, align on the requirements each relevant cross-functional group has for the supplier selection process (Section 4B). This information can also be used to assess the supplier's ongoing performance against those requirements.

- **Example 2:** You are a small to midsized company with roughly 1,000 suppliers. Your systems may be in place, but the practices are not being used consistently across your company and throughout the total product lifecycle. Perhaps the most impactful place for you to start is:
  - Develop a cross-functional team (Section 3B) that is charged with aligning on the requirements needed (Section 4B) for a supplier that is not performing well for you right now. Use this process to identify the source of the failure and areas of misalignment so the failures can be mitigated. Also, recognize as a team the value each member's perspective brings to ensuring the right decisions are being made. This could also alert the cross-functional members to the importance of following your established processes.

- **Example 3:** You are a start-up company and do not have supply chain practices established yet. You can use the Good Supply Practices as your supply chain practices. As you work together as a team, just note the points made throughout this document about using the practices in a way that is commensurate with the need (for example, a spreadsheet can serve as your supply intelligence repository) and in a way that makes sense for your company (for example, you might have 3 people representing most if not all of the functional groups). Think through the Good Supply Practices in chronological order, and also apply them retrospectively if you have already made supply chain decisions you would like to verify.

3B. Setting the Foundation - First Things First: Establishing the Right Cross-Functional Teams

Purpose

Many of the solutions presented in this Good Supply Practices document require cross-functional alignment and collaboration in order to optimize success. This section can be used as a guide for companies to determine which specific functional areas to include on project teams for all development and lifecycle activities. The objective of forming cross-functional teams is to provide all functional areas a vehicle through which to align on key requirements and assumptions so as to make the best possible decisions within the mission/vision/values framework of the company.

By utilizing cross-functional teams, the company can better align needs and expectations across all disciplines. This will help eliminate unintended consequences caused by conflicting goals and misunderstandings. Balancing the needs, requirements and preferences across the company helps avoid overemphasis on a single or few factors (e.g., cost and personal goals), as well as underrepresentation of unrecognized critical factors. In the event that one element, such as speed or cost, significantly overrides all other factors, the resulting risks can be identified, understood and mitigated.

Scope

This section can be used to assist organizations in establishing the right cross-functional teams for any activity throughout the product and supply chain lifecycle. It is recognized that aligning on requirements too early in the development lifecycle may stifle innovation, as the research and development functions need opportunities to experiment. Once the pharmaceutical formulation or medical device concept are developed, then this might be the right timing for many organizations to form the cross-functional team as described herein. Each organization is different; however, be wary to not delay cross-functional team formation to the point that revising decisions results in financial burden and timeline delays.

Many teams will require supplier involvement. External alignment with suppliers is addressed in Section 5A of this document.

Background

In order to increase the robustness of product and supply chain lifecycle management (from development forward), it is important to involve subject matter experts from the appropriate functional areas (those affecting or affected by product and supply chain decisions) in order to balance individual/department objectives and to align individual/department goals with goals of the overall organization. Historically, product and supply chain development has occurred in functional silos through a series of hand-offs, which can expose the organization and the patients served to unnecessary risk (e.g., safety & efficacy issues, product delays, and unnecessary costs).

Early cross-functional involvement will provide a forum to 1) uncover risks and opportunities, 2) quantify & qualify the risks, and 3) examine potential mitigating options and implications before finalizing product specifications and supplier selections. Robust cross-functional teams allow for the best possible decision–making process to occur within the framework of the mission, vision, and values of the company. It is important to note that cross-functional team alignment continues to add value and protect the organization even after product launch. All work should be commensurate with the need, but each company should keep in mind that post-market changes (even improvements), may require extensive time and cost to implement – thus making "right first time" an important outcome.

Process:

Step	Description	Cross-Reference
1	Identify a list of functional areas in your company	Appendix 5
2	Each functional area to provide an overview of the goals of their functional work	Appendix 5
3	Each functional area to provide examples of how their involvement can benefit the material and/or supplier requirements discussions	Appendix 5
4	Each functional area to provide examples of what they need from the material and/or supplier requirements discussions	Appendix 5
5	Determine with each functional area if that functional area will be included in the material and/or supplier requirements discussions	Appendix 6
6	Identify with each functional area the appropriate timing for when to engage their functional representative	Appendix 3; Appendix 4
7	Document all assumptions and decisions in the Supply Chain Intelligence Repository through the Knowledge Management Process.	Section 3C

The process outlined within this section provides an actionable pathway and tool for each company to determine which functional groups make the most sense for their organization to

include on cross-functional teams for various purposes. In small companies, one person may handle multiple functions, while large companies may need to include multiple representatives for each function on the team. Some functional areas may indicate that they do not need to be directly involved, but instead, will either provide information needed or another functional area will gather information on their behalf. This type of orchestration is perfectly acceptable and will vary from company to company.

In order to determine which functional groups to include on the cross-functional team, it should be noted that some decisions may be easy (e.g., Quality needs to be involved in the development of the Quality Agreement), but the timing of when to include each functional area may not be as obvious. Additionally, the benefits of including certain functional areas are not as obvious to those who are often making the decisions.

All of these scenarios are addressed through the process provided herein. Importantly, instead of "requiring" specific functional groups to be involved, the process will help each company make the best decision for their organization.

In this section of the Good Supply Practices document, a useful tool and scoring mechanism have been developed to support the decisions to be made by each company. In Appendix 5, a table has been created that lists 14 Functional areas down the left-hand column. For each functional area, examples are provided of what the main goals are of that functional area that affect supplier and/or material requirements decisions. Examples are then provided of what that functional area typically needs from the supplier related to supplier and/or material requirements decisions. And finally, examples are provided of what that functional area can often contribute to the supplier and material requirements decision process. By providing this information, it has been found that the needs and benefits of some functional areas have historically not been realized, resulting in missed opportunities and risks.

Importantly, the Team Leader should involve the cross-functional representatives directly in order to ensure each functional role is accurately represented, instead of relying on assumptions. Each company should use the table provided in Appendix 5 as a guide in order to create an accurate chart that applies to their organization.

After the potential contributions and needs of each functional area are identified, the company needs to determine the appropriate representation on the cross-functional team. In order to assist in this process, a scoring mechanism has been developed and is available in Appendix 6. Through this scoring mechanism, each of the 14 functional areas provided in Appendix 5 are listed. The team leaders who are establishing the cross-functional team are to ask each functional group if (1) they feel their involvement has been missed, and (2) they feel they are not

included at the right time. It has been found that unrecognized risks and benefits are uncovered through these conversations that are very powerful. The team leaders, with each functional group, are to document the likelihood of involving each functional group on the cross-functional team going forward. Again, it is important to lead activities in a way that is commensurate with the need. It is acceptable to not include each functional group on each team, but it is important to gain the concurrence of those functional groups before excluding them.

Once the functional groups are identified, it is critical that all team members are capable of, and empowered to, represent their respective functions, and team members must be prepared to discuss all issues related to their functional areas. In some situations, the skills required to perform specific functional tasks on a day-to-day basis may differ from the skills needed to be effective on a cross-functional team. Therefore, education, training and individual coaching may be required for individuals before they participate on cross-functional teams (e.g., high-performance work teams, and problem solving techniques).

In order to maximize effectiveness, the Team Leaders need to establish the protocol for the Project Team, for example:

- Determine meeting frequency
- Publish minutes that will document all agreements, assumptions, action items, and the status of action items
- Identify how best to document the decisions and output of this team
- Agree upon a process to use for resolution of issues
- Define teams goal(s) and how to measure success
- Clearly define roles and responsibilities
- All functions present their respective needs and how other functions affect their success
- Identify conflicting goals, quantify/qualify impact

The company should assign an independent, strong team leader who is able to facilitate each project, ensure deadlines are met and maintain the focus on organizational goals vs. individual goals. It is suggested that this assignment be made by cross-functional alignment from management levels above the team participants. However, if this is not possible, then the team should agree upon a leader who has the experience necessary to understand multi-functions across the total product lifecycle of the product, has strong leadership skills, and works to include the ideas and experience of the remaining team members. There are multiple options for team leadership/facilitation, as provided in Table 3B.1.

In order to improve the effectiveness of each team, companies should identify potential barriers to success. The Good Supply Practices research identified challenges companies face when implementing this type of process. The following are common challenges:

- Many Companies do not have cross-functional alignment in the early stages of development, and it can be difficult to change later in the lifecycle.
- Typically, the individuals involved in the development, launch and ongoing commercialization of a product have different and/or conflicting goals. Therefore, it is important to align all goals at the earliest possible stage. Documentation of this alignment is important for team success.
- Organizational structure, corporate culture, and commercial objectives inhibit or create barriers to timely and complete communication necessary for a successful supplier relationship.
- Different skill-sets are required, and this may require education and training.
- There can be resistance to give up existing authority/control to a cross-functional team.
- Some individuals have stronger personalities or a higher level of expertise than others, and this can create an overemphasis on the wrong factors

Table 3B.1: Pros and Cons of Team Leader Functional Areas.

Who	Pros	Cons
Regulatory Affairs	Owns the regulatory strategy through which the product, process, and suppliers are approved throughout the lifecycle of the product. Drives the requirements and timeline for approval.	Historically is not connected to important business drivers, and tends to remain focused on regulatory compliance.
Project Manager or independent 3rd party	Unbiased & independent Potential for greater acceptance	Requires additional resources (Project Managers) or 3rd party support
Supply Chain	Can add independent business approach	May overemphasize functional area goals (i.e. cost reduction) Requires trained resources May divert resources from other work
Other functional area	Expertise on a specific portion of work	May have limited scope and lack overall business perspective May overemphasize functional area goals (i.e. speed to file) Requires trained resources May divert resources from other work

The Good Supply Practices research identified Successful Practices that improve the likelihood of team success:

1. Align all goals at the earliest possible stage. Focus on organization goals vs. individual goals. Documentation of this alignment and rationale should be conducted as discussed in Section 3C.
2. In order to support the aligned goals, it is strongly recommended that the organization consider the adoption of shared objectives tied to the performance incentives program. Without this level of alignment, teams will struggle to put the team goals ahead of their own functional area goals, which will unravel the progress of the team.
3. Early cross-functional collaboration will give all parties a better understanding of the interrelationship of all goals across the organization, which in turn will result in better decisions. Refer to Section 4A and Section 4B for examples of when to begin cross-functional team involvement for material requirements and supplier requirements, respectively.
4. A strong leader needs to ensure the team decisions are balanced and in the best interest of the overall organization.
5. Agreement on a communication strategy, combined with controlled communication with suppliers, reduces risk and improves the Integrity of Supply.
6. It is critical that all team members are capable of, and empowered to, represent their respective functions, and all team members must be prepared to discuss all pertinent issues. This is most successful when management levels above the team members cross-functionally align on the team roles and responsibilities, and charter.
7. Provide training, coaching and support to prepare individuals for new roles and responsibilities on teams.
8. Establish a process for escalation to help keep projects on track and mitigate risks.

Throughout the development and implementation of the cross-functional team, each organization should ensure that all work is commensurate with the need (do not form a team just to form a team). The teams may refer to the Lifecycle Matrix provided in Appendix 4, which captures some of the decisions that need to be made by cross-functional teams when (1) initially establishing the supplier and material requirements, (2) when changes need to be made to the supply chain or materials, and (3) during the lifecycle review. Additionally, some organizations may find that different teams may be needed for different work, while other organizations use the same team throughout. Senior Leaders should assess the effectiveness of the teams to ensure the desired outcome of balancing benefits and risks is achieved.

All assumptions and decisions made while establishing an effective cross-functional team should be documented in the Supply Chain Intelligence Repository through the Knowledge Management Process provided in Section 3C.

3C. Setting the Foundation through Knowledge Management

Purpose

As companies continue to expand outsourcing activities, identify new sources for materials and services, and engage in acquisitions and mergers, it becomes increasingly difficult to rely on informal and disjointed systems to retain undocumented information about suppliers, materials and services. In order to reduce risk to the business, patients and product quality, companies need to establish a process for knowledge management, which requires the information to be accessible, complete, accurate and current.

Scope

This section covers information related to supply chain development and maintenance, suppliers, materials, services, product development, and impact of materials on the final product. This list is not meant to be all-inclusive, since each company will need to determine which functions, processes and decisions are truly relevant. The intent of this section is to ensure key information, assumptions and decisions are captured real-time to provide a source of intelligence that supports current decisions and provides a basis for future decisions. The knowledge management process is intended to span the total product lifecycle.

Background

A robust process for effective knowledge management can lead to more productive, efficient and effective supply chains that reduce risk to product quality. Documentation of assumptions and decisions helps to support more robust discussions with suppliers, and enables an organization to discuss product and supply chain development objectively. Too often, companies are resistant to the expertise of suppliers due to undocumented rationale as to the decisions that had been made prior to engaging the supplier. Additionally, a robust knowledge management process enables internal cross-functional groups to align on requirements for the good of the overall business. Information captured can be used to improve decision making based on a holistic review of the historical information, and enables every individual to make decisions beyond their own experience level for the betterment of the company. Importantly, a well designed knowledge management process protects and propagates the intellectual property of the company.

Process

Step	Description	Cross-Reference
1	Form Cross-Functional Team to align on how best to establish the Knowledge Management Process	Section 3B
2	Determine relevant sources of information to retain	Current Section
3	Establish user group authorities and responsibilities	Current Section
4	Provide access to, and training on, repository to support business success	Current Section
5	Identify a process to ensure the timely update of the repository on a continual basis	Current Section

Cross-functional team formation. The knowledge management process and repository should be created and maintained through cross-functional alignment on how best to establish a repository for the good of the overall organization across the total product lifecycle. Suggestions on how best to create a cross-functional team are provided in Section 3B of this document. The cross-functional team should align on the following:

- Types of supplier relationship categories and risk/benefit of each designation
- How much time and effort to put into each category of relationships
- What types of information to maintain (refer to Appendix 7 for examples to consider)
- How to maintain information
    - Frequency of updates (e.g., real-time, annual reviews, etc.)
    - Controls for data integrity
- How to use the information in the repository
- Information owners and responsibilities

Supplier and Item Segmentation and Categorization. Maintaining accessible, complete, accurate and current information for every aspect of the total supply chain can be resource intensive. Therefore, companies could develop a process for differentiation and prioritization based on risk (as provided in Section 3D) in order to determine how to develop a knowledge management process that is commensurate with the need.

The repository can include a ranking and categorization of suppliers, starting with information from the Approved Sourcing List (ASL), and should include information that goes beyond minimum cGMP requirements. The ranking should be based upon firsthand knowledge, such as performance criteria and cross-functional input, as well as from other information available to the company. The repository can include suppliers under evaluation, but not yet audited and/or approved for use in commercial production. The amount and type of information will depend

upon the impact and risks of the materials and services provided by each supplier as provided in Section 3D (Supply Chain Risk Management Triage). Appendix 7 includes some examples of information to consider for inclusion. The internal alignment on material and supplier requirements processes (Section 4A and Section 4B, respectively) can also be used as guides to determine the type of information to include. The categories covered in the supplier requirements section are the same as the categories used for the self-qualification process (Section 3E), and are as follows:

- Supplier Operating Systems and Business Capability
- Relationship Alignment
- Quality and Regulatory Compliance Systems
- Supplier Product and Process Technical Capability

The supplier and self-qualification processes allow each company to map the strengths and weaknesses of each relationship as described in Section 5C. It is important to document the assumptions and decisions made when using scoring mechanisms such as these, as well as the mitigation strategies identified. Importantly, the lifecycle review of processes such as these should be documented to identify the effectiveness of the original decisions, as well as any changes needed to the assumptions and decisions.

Critical factors that need to be considered. In many cases, the company needs to work closely with suppliers throughout the product life cycle, beginning with early development. Therefore, it is important for the company to identify and document suppliers with whom sensitive information can be safely shared, and to track this in the repository. An appropriate communication strategy can be developed through the use of Section 4C of this document. Additionally, identification of strategic suppliers (i.e., one that represents the highest level of alliance/relationship) is the highest designation, which involves preferential treatment for the supplier and the customer. The strategic partnership requires alignment of goals and expectations, as well as transparency and support from senior management at both companies. Early involvement of strategic suppliers can facilitate a shorter development cycle and greater commercial success (reference timing in Appendix 3). Therefore, it is important to identify and document in the repository suppliers that meet these criteria.

Use of the Repository. This repository should be employed when making any supplier related decision. For example, the product development group (e.g., Research and Development and Engineering), can use the repository when identifying potential suppliers early in the development process. The repository can also provide information on alternate sources, as well as a comprehensive assessment of all supplier experiences across the total enterprise. It is

critical to maintain the accuracy of the information in the repository by adding information as it becomes available, and to use this information when making decisions.

The management of the supply chain intelligence repository must ensure the integrity and protection of the data such that the information is reliable and can be trusted. This includes determining an approval process for adding data/information to the repository, and policies against deleting or changing the data/information. Additionally, a system should be developed to cross-reference the location of information. For example, any given raw material or component aspects that are considered during process development may exist in several different documents or systems. When revisions are required, a matrix enables integration across multiple systems. Depending on the size and complexity of the information, the supply chain intelligence repository can be as basic as a simple spreadsheet/document or as comprehensive as a database, such as a Supplier Relationship Management system.

The supply chain intelligence repository should be viewed as a living system and should house all relevant decisions, assumptions and outcomes to support current and future decisions.

3D. Setting the Foundation through Supply Chain Risk Management Triage

Purpose:

To provide a practical triage assessment process that enables manufacturers to identify the greatest areas of threat to patient safety and business viability from internal, product, and external supply chain risks. The triage process provides a methodology for manufacturers to prioritize the use of resources for assessing, monitoring and mitigating supply chain risks in a way that is commensurate with the need.

Scope:

Supply Chain Risk Management is an intentional process that is used to assess risk across product lines, materials, suppliers and the entire enterprise, such that product quality is optimized and risk is minimized. The supply chain risk management triage process includes the impact of risk from the finished product itself, third party goods and services (i.e. equipment, contract services, spare parts, etc.), and internal systems. Importantly, supply chain risk management is optimally linked to the enterprise risk management (ERM) system and insurance programs so as to provide a more holistic view of risk to the product, patient and business. Organizations typically find it impractical to manage all suppliers in each supply chain with the same degree of resources (i.e. time, effort, money), so this section establishes a methodology for estimating risk impact, and using this information to prioritize mitigating actions.

Background:

Supply chain risks in the life science industries have grown exponentially for a variety of reasons, e.g., product complexity, globalization, outsourcing, competition, geopolitical risks, fraud, cost pressure, rapid changes in technology, pressure for quick results, etc. Additionally, the impact of risk to patients has been amplified by the growth in orphan therapies that provide treatment to patients from a single manufacturer. As a result, disruption in supply and/or an increase in risk to the product supplied often carries an unacceptable impact to patients and the business.

Despite the criticality of a well-orchestrated and living supply chain risk management process, supply chain risk management is frequently neglected or ineffective. When supply chain risk management is addressed, it is often not properly integrated into other business processes and is frequently a one-time event. Historically, companies have assessed supply chain risk based on cost; however, this section provides a more holistic assessment methodology that combines multiple risk factors and the linkage to patient and business impact. Each company needs to develop priorities based on the impact to all stakeholders: patient, public, employees and shareholders. When measuring impact, it is important to focus on the impact to safety, efficacy, continuity of supply, and business/financial performance, and not on the cost/spend or volume. Low-spend items are often ignored, but they can impact multiple product lines and have a significantly greater impact to patients and the overall business than high-spend items.

Supply Chain Risk Management is a living process, not an event. Risk changes over time, and therefore, assumptions and decisions must be constantly monitored and updated. Successful supply chain risk management holistically integrates these risks into an overall enterprise risk management (ERM) program, as well as into the overall end-to-end supply chain strategy. In order for this process to be effective, the process must be led by a cross-functional team, and should be included in the corporate culture and decision-making processes. Companies that have a formal integrated risk management program are more prepared to avoid and/or manage safety and quality disruptions in supply, which can result in a significant competitive advantage.

Process:

Step	Description	Cross-Reference
1	Form Cross-Functional Team to conduct the Supply Chain Risk Management Triage	Section 3B
2	Create supply chain maps for all finished products to levels that are achievable/practical	Current Section
Risk Triage Process:		
3	Part A – Product-Related Risk Impact	Current Section

4	Part B – Material-Related Risk Impact	Current Section
5	Part C – Supplier-Related Risk Impact	Current Section
6	Part D – Determining the Triage Outcome	Current Section
Managing the Risk Triage Outcome:		
7	Develop risk remediation and mitigation strategy	Current Section
8	Document all assumptions and decisions in the Supply Chain Intelligence Repository through the Knowledge Management Process	Section 3C
9	Monitor and review assumptions and decisions on an on-going basis	Current Section

A common process for supplier and Item Segmentation and Categorization[1] involves risk categorization of suppliers (e.g., strategic, tactical, commodity, key, etc.), and materials/items (e.g., single source, sole source, etc.) or on a combination of site and material specific information (e.g., approved, qualified, disqualified, and do-not-use).

Cross-Functional Team Formation. In order to increase the assurance that supply chain risk management is developed and managed from a holistic perspective, a cross-functional team should be established as provided through the process in Section 3B. Each team member needs to be prepared to identify supply chain risks from their respective functional areas so as to minimize impact to patients and the overall business. This information can be gained through the supply chain intelligence repository (Section 3C), experience and external sources.

Quantifying risk is an inexact science at best. Therefore, it is not always possible to prioritize based on pure numbers. Some business acumen needs to be applied, which is why the formation of an experienced cross-functional team is critical to increasing the validity of assumptions made throughout the risk triage process. The cross-functional team should evaluate each risk element in Parts A, B and C of this section as it relates to potential impact to the patient and business. The following factors should be considered when quantifying each risk:

1. Exposure/severity: measured in terms of the amount of impact and degree of damage, which can be determined through the following examples of inputs:
    - Time to Recovery (TTR)

[1] Note: much has been written about methods for accomplishing segmentation and categorization. In addition to the suggestions provided herein, companies should utilize the existing available information and tools to develop a process commensurate with specific needs, and consistent with quality systems and control requirements.

- Number of people impacted
- Number of occurrences
- Cost to recover
- Lost revenue/profit
- Other financial implications
- Patient safety/efficacy/availability
- Employee safety
- Environmental and social responsibility
- Reputation
- Key customer impact
- Intellectual property loss

2. Velocity: how quickly a risk may affect the company, and whether there is time to react/respond.
3. Likelihood: probability of a risk event.
4. Effort to mitigate: resources or cost to implement mitigating actions to avoid or reduce the impact.
5. Time to mitigate: elapsed time required to implement mitigating actions to avoid or reduce the impact.

Creating Supply Chain Maps. The cross-functional team should orchestrate the creation of supply chain maps that ideally include all suppliers as far upstream as possible. Often, problems are the result of suppliers further up the supply chain, so it is no longer acceptable to include only tier 1 suppliers (i.e. suppliers who supply directly to the company). Tier 2 suppliers (i.e. suppliers who supply to the company's tier 1 suppliers) and beyond must be considered. Once the supply chain is understood, risks can be identified, which enables companies and suppliers to trace the source of supply back to raw materials in the event of failure in order to identify root causes and implement effective corrective actions and preventative actions.

Since it may not be achievable or practical to map every supply chain through to the source material provider, then the team should at least create supply chain maps that include all tier 1 suppliers. Where possible, the team should create maps to tier 2 suppliers and beyond. Through the development of the supply chain maps, and in conjunction with the supply chain risk management process described within this section, the company may identify supply chains that require full knowledge through to the source material provider. This section provides a triage process for companies to use when establishing a methodology for estimating risk impact in order to prioritize resource utilization and mitigating actions.

The Risk Triage Process

Part A. Product-Related Risk Impact. After supply chain maps are created for each product, the cross-functional team should score how product-related risks impact patients and the business as provided in Table 1. Table 1 provides examples for how the team can assess the impact of product-related risk, but this table should be designed by the team in a way that makes the most sense for the products and business of the company. One point to note is that the examples provided in Table 1 include inherent product risks, as well as risks to patients and the business.

Table 1. Scoring Product-Related Risk Impact

Product-Related Risk	**Impact of Product-Related Risk** (Low Impact = 0, Slight Impact = 3, Moderate Impact = 7, High Impact = 10)
Manufacturing Complexity • Pharma: biologic, vaccine, sterile, nonsterile, etc. • Device: Class III, Class II, Class I, etc.	Score based on the impact of the amount of risk due to the complexity of the manufacturing process
Product Sensitivity • Sterility, temperature sensitivity, light sensitivity, etc.	Score based on the difficulty in maintaining and assuring conditions to protect product sensitivity.
Stock-out risk to patients • New product, orphan product, etc.	Score based on the impact that a stock-out would have to patients.
Financial risk to the business • High cost of discards, loss of market share, impact to shareholders, etc.	Score based on the financial impact that risks would have to the business.
Overall Impact Score:	**Minimum = 0; Maximum = 40**

Once the scoring process is complete, the team will have a way to differentiate the risk level of various products based on the resulting impact. The cross-functional team can use the scoring outcome to delineate high, medium and low risk products/product lines. The team should then group the products accordingly in the Risk Management Triage Flowchart provided in Appendix 8.

Part B. Material-Related Risk Impact. After product-related risk impact is determined, then the materials within each of the products (listed in the supply chain maps) should be

assessed. Table 2 provides examples for how the team can assess impact of material risk, but this table should be designed by the team in a way that makes the most sense for the materials and business of the company.

Table 2. Scoring Material-Related Risk Impact

Material-Related Risk	**Impact of Material-Related Risk** (Low Impact = 0, Slight Impact = 3, Moderate Impact = 7, High Impact = 10)
Used in patient and/or business critical products (irrespective of material cost)	No = 0; Yes = 10. Based on product assessment provided above.
Degree of use across product lines (irrespective of material cost)	Score as low impact if the material is isolated to few products; Score as high impact if the material is used across product lines
Available inventory (internally and/or externally) irrespective of material cost. Consider supplier's reject/discard rate	Score low if internal inventory is acceptable to meet market demand and/or if inventory is easily sustained (multi-sourced, etc.)
Criticality of the material to the finished product. Consider variability in process capability impacting final product	Score low if the material does not play a critical functional role in the finished product.
Material performance based on information in the supply chain intelligence repository (Section 3C)	Score low if historical performance is acceptable
Financial impact - Cost of material and/or service, cost and time of alternate source	Score low if financial impact is low
Overall Impact Score:	**Minimum = 0; Maximum = 60**

As noted in the Background portion of this section, companies have historically assessed supply chain risk based only on cost; however, this section provides a more holistic assessment methodology that combines multiple risk factors and the linkage to patient and business impact. Each company needs to develop priorities based on the impact to all stakeholders: patient, public, employees and shareholders. When measuring impact, it is important to focus on the impact to safety, efficacy, continuity of supply, and business/financial performance, and not only on the cost/spend or volume (this factor is important, but is just one facet of the total impact). Additionally, low-spend items are

often ignored, but can impact multiple product lines and can have a significantly greater impact to patients and the overall business than high-spend items.

Once the material-related risk impact scoring is complete, the team will have a way to differentiate the risk level of various materials based on the resulting impact. The cross-functional team can use the scoring outcome to delineate high, medium and low risk materials. In the Risk Management Triage Flowchart provided in Appendix 8, the materials should then be grouped according to the high, medium and low designations given, under the appropriate product risk categories. Since many materials are often used in multiple products, the materials will need to be listed under each relevant product risk category.

Part C. Supplier-Related Risk Impact. After the product-related and material-related risk impact is determined (Parts A and B above), the cross-functional team should determine the level of which the supplier performance is known. In order to determine the level of known supplier performance, the cross-functional team should reference the supply chain intelligence repository as described in Section 3C, as well as include experience and external information (e.g., the team becomes aware that the supplier has been issued a Warning Letter from a regulatory body, etc.). If the supplier is an existing supplier, then the outcome of the Holistic Supplier Qualification Process in Section 5B (which should be captured in the Supply Chain Intelligence Repository) can provide a useful resource. However, note that it cannot be assumed that the supplier performance will be the same if the supplier only supplies different materials from the material in question.

Examples of how supplier performance can impact the overall resource utilization determination are as follows (refer to the Risk Management Triage Flowcharts in Appendix 8):

- Example 1. Product-related impact is low, Material-related impact is high. If the supplier performance is unknown or unacceptable, then the resource utilization should be increased compared to the same scenario with suppliers that have acceptable performance.

- Example 2. Product-related impact is high, Material-related impact is medium. If the supplier performance is acceptable, then the resource utilization could be decreased compared to the same scenario with suppliers that have unknown or unacceptable performance.

Part D. Determining the Triage Outcome. After the product, material and supplier risk impact are each determined sequentially, then the cross-functional team can work collaboratively to group suppliers into resulting Red, Yellow and Green categories. The

Advanced and Basic Flowcharts in Appendix 8 can be used as a guide, but each company will have a different outcome based on: (1) sophistication of controls and monitoring in place, (2) depth of knowledge of the products, materials and suppliers, and (3) risk culture.

The first step is to determine a rank prioritization of which scenarios lead to higher risk priority. For example, a high risk product with high risk materials and unknown or unacceptable supplier performance is considered the highest risk in the Appendix 8 flowcharts. As a result, this grouping of suppliers is given a designation of "N" in the Advanced Flowchart, or "F" in the Basic Flowchart. The team should work through each scenario accordingly to prioritize the risk ranking of each group. Once the risk prioritization is complete, then the team can categorize the groups into categories such as Red, Yellow and Green. Each category (i.e., Red, Yellow, Green) still maintains the risk prioritization within it as shown in Appendix 8, such that the team is able to prioritize the resource utilization within each category. The level of sophistication of this exercise needs to be commensurate with the sophistication of systems, controls and culture of the company. As such, each company can use the Advanced or Basic Flowcharts in Appendix 8 as appropriate, or develop their own system to achieve a similar outcome.

- **Automatic Risk Elevation:** There are scenarios the cross-functional team should identify that fall outside of the flowchart triage process. For example, a high risk scenario that would not be captured by the flowchart is as follows: a supplier supplies multiple materials to a company that cut across many, if not all, of the company's products. The materials may be high, medium and/or low risk. So instead of being a high-volume material that is flagged through the flowchart process, this would be a "high-volume supplier" that might not be detected due to the variety of materials supplied for a variety of products. If this supplier has a shift in capability of supplying materials, or a cross-cutting failure that impacts all of the materials supplied, then the resulting impact to the company would be high. The cross-functional team should do an assessment to identify if this scenario exists, as well as others that might not be captured through the flowchart triage described in this section.

Managing the Risk Triage Outcome

Once the Risk Triage process is complete, the cross-functional team needs to align on the resource utilization that is appropriate for each category of risk. The choices of the actions to be taken are generally recognized as the following:

Mitigate	Some risks are unacceptable and are mitigated by the company to lessen the risk itself and/or its impact.
Transfer	Some unacceptable risks can be transferred to other entities or mitigated through other entities.
Accept	Some risks are determined by the company to be acceptable without mitigation, and therefore, the company accepts the risk.

Unacceptable risks must be addressed to avoid or lessen the potential impact to patients and the business. One course of action is to mitigate the risk so as to remove the risk itself, or lessen the impact of the risk. For example, one course of action would be to build resilience into the supply chain by the following examples: (1) multi-sourcing the material, (2) conducting additional studies on the product to better understand the impact of variability, (3) discussing material alternatives with the supplier, (4) discussing the appropriateness of the testing and specifications of the materials with the suppliers, and (5) increasing the controls in place, such as real-time monitoring of external factors, tracking supplier process capability, man-in-the-plant, etc. The cross-functional team should ensure that full action plans are developed that are established by the appropriate subject matter experts. The following should be included in those plans:

- Assign owner/person responsible
- Establish due dates - depending on complexity, may need to include milestones
- Establish follow up communications and meetings
- Monitor progress on actions - As part of an ongoing Risk management program, progress should be tracked and results published
    - Ongoing status meetings
    - Review progress on all activities
    - Discuss issues and adjust as required
    - Confirm/update priorities and resource allocation
    - Follow up with suppliers to confirm progress on their commitments and to verify risks have not changed.

In some cases, unacceptable risks can be transferred to another entity. For example, if the supplier process capability is critical to minimize variability, then the company can transfer financial risk of discard to the supplier. Another example is the utilization of insurance to offset financial loss related to a variety of risks. When risk is transferred, the company needs to understand the remaining exposure, and needs to continue monitoring the validity of assumptions made relative to exposure, severity, probability and detectability.

Risk identification and quantitation, as mentioned previously, is not an exact science. As such, some low risks might not even be identified by some companies as a risk. This indicates that the company has accepted those risks to the point of not even recognizing that they are risks. In other circumstances, companies recognize low risks, but intentionally determine to not address the risks. By default, then, the company has "accepted" those risks. An example of the type of risk a company might choose to accept is when the risk has low impact, and occurs with low frequency. Another example is when that same risk occurs with high frequency, but due to the low impact, the company chooses to manage around the risk (this is referred to as a nuisance risk). When risk is accepted, the company needs to understand the exposure, and needs to continue monitoring the validity of assumptions made relative to exposure, severity, probability and detectability.

The cross-functional team can establish a process to verify the effectiveness of the overall supply chain risk management process, and determine if changes need to be made to how those risks are managed. Risk decisions need to be monitored for continued acceptability and changes. Once a risk is mitigated, the new level of that risk needs to be evaluated. As time evolves, a variety of changes occur that could affect the assumptions that were originally documented. The team needs to evaluate previous decisions and assumptions for continued validity, and take action when needed. Metrics to consider for monitoring risk management suitability are:

- % of high risk suppliers in the supply chain versus the total
- % of single and/or sole sourced suppliers in the supply chain versus the total
- Year over year comparison of Financial impact related to supply chain risk
- Supplier related performance metrics (e.g., quality and delivery) as provided in Section 4B
- Etc.

All assumptions and decisions made while aligning on supply chain risk management should be documented in the Supply Chain Intelligence Repository through the Knowledge Management Process provided in Section 3C.

3E. Setting the Foundation through Self-Qualification

Purpose:

To provide a methodology for establishing and understanding the level of risk brought by the company to each supplier relationship. Importantly, since each relationship involves at least two entities, the risk of the relationship can only be understood if the risk brought to that relationship from each entity is understood. The outcome of the self-qualification process is to be used in

conjunction with the holistic qualification of the supplier and material as outlined in Section 5B, in order to develop a relationship risk map as described in Section 5C. The relationship risk map is an overlay of the self-strengths and weaknesses with the supplier strengths and weaknesses. This mapping process allows the cross-functional team to identify the best-fit supply chain partners, and any internal and external mitigation actions needed to reduce supply chain risk.

Scope

The self-qualification process provided within this section is designed to be used by a cross-functional team such that: (1) a baseline risk level related to the company's supply chain practices is established, (2) mitigation actions can be identified to reduce the company's areas of risk, (3) the company's risk can be assessed against the risk of its supply chain partners, and (4) the company's risk level can be monitored and trended at a predefined frequency. The self-qualification process can be conducted throughout the total product lifecycle of its product development, and across all levels of supply chain maturity. Ideally, the outcome of the self-qualification process will lead to mitigation actions that reduce supply chain risk, increased awareness of risk imposed by the company, and a better understanding of factors that influence supply chain success.

Background

Historically, supply chain failure has been attributed to poor supplier performance, and has resulted in vastly increased resources expended on trying to improve, verify, and certify supplier practices. These efforts, however, have resulted in little to no improvement in the reduction of supply chain risks. Through the development of the Good Supply Practices, it has been identified that all of the supply chain failure a company experiences is either caused by, or could have been avoided by the company itself (Section 2 and Appendix 2). As a result of this finding, the Good Supply Practices are targeted at improving the supply chain practices of the company, and includes an assessment of self-risk. If the company truly is part of the risk equation, then including a self-qualification assessment of the risk brought to the relationship by the company is critical. The question being addressed is: "How qualified are we to be in this relationship?"

The self-qualification process provided herein covers the following four categories of risk: (1) Operating Systems and Business Capability, (2) Relationship Alignment, (3) Quality and Regulatory Compliance Systems, and (4) Product and Process Technical Capability. The reason each of these categories is included in the self-assessment is based on the gap analysis conducted by the companies of what caused failure across a supply chain process map (Section 2 and Appendix 2). Each of the failures in the gap analysis pointed to broken or non-existent practices found in a typical supply chain management process, and were then grouped by theme into the above listed categories. The self-qualification process includes questions to be scored by the

cross-functional team within each category to highlight the criticality of those practices, drive the desired behaviors across the enterprise, and mitigate supply chain risk.

Process:

Step	Description	Cross-Reference
1	Form Cross-Functional Team to conduct the self-qualification process	Section 3B
2	Align cross-functionally on the questions to include in the Self-Qualification assessment such that the assessment is most appropriate for the company's business, products, supply chain complexity and supply chain maturity.	Current Section
3	Align cross-functionally on the mitigation plans and scoring levels per category.	Current Section
4	Align cross-functionally on the scoring of each question within each category.	Current Section
5	Document all assumptions and decisions in the Supply Chain Intelligence Repository through the Knowledge Management Process.	Section 3C
6	Monitor and review assumptions and decisions on an on-going basis	Current Section

The self-qualification process provided herein is to be conducted by a cross-functional team as established in Section 3B. It is important for the cross-functional team to recognize the criticality of scoring the performance of the company as candidly as possible in order to attain supply chain risk reduction. This candid scoring needs to be understood and supported by senior management in order to model and drive the desired behavior.

The cross-functional team must assess the questions within the Self-Qualification Scoring Mechanism provided in Appendix 10 to ensure that the questions are applicable to the business of the company, as well as the supply chain maturity of the company and supply chain complexity. The questions can be revised or deleted, and other questions can be added such that the assessment makes the most sense for each company. The scoring mechanism provided in Appendix 10 is the culmination of industry and supplier input from a cross-functional vantage point, and therefore, will provide each company with a solid starting ground.

The Self-Qualification Scoring Mechanism provided in Appendix 10 is divided into four separate categories based on a cross-industry gap analysis of supply chain failures. The separation of questions into categories enables each company to identify strengths and weaknesses by theme/category, as well as to determine acceptable scoring ranges with associated mitigation and escalation actions. It is important that the team does not use the scoring mechanism to simply

compare scores over time to show improvement, but rather, to associate the score with a level of perceived risk that has mitigating actions identified to reduce that risk. The scoring mechanism in Appendix 10 provides sample scoring ranges and mitigation steps to help the company create the best scheme for their business, products and supply chain.

As previously mentioned, the self-qualification assessment contains four categories of risk questions that are as follows: (1) Operating Systems and Business Capability, (2) Relationship Alignment, (3) Quality and Regulatory Compliance Systems, and (4) Product and Process Technical Capability. Each question within each category is to be scored by the cross-functional team to ensure a more holistic view of the risk is assessed.

Operating Systems and Business Capability:

> The questions included in this section are intended to assess the business and operating understanding the company has of its supplier. For example, does the company have quality agreements in place with at least Key Suppliers, and is the agreement a living and practical document. It was discovered that typical companies do not respect the business of their suppliers such that forecasts are changed frequently and without regard to the business of the supplier, and suppliers are not paid on-time. These behaviors create risk to the ability of the supplier to supply the desired material to the company on-time and of the quality needed.

Relationship Alignment:

> As in any relationship, treating each other with respect leads to a stronger more trustworthy relationship. Supply chain relationships are no different in this regard. As such, the self-qualification includes an assessment of how trustworthy and respectful the company is for and to its suppliers. Questions in this category center on meaningful and consistent dialog from representatives who have the authority and responsibility to convey the desired information. An assessment of the company's understanding of the needs of their supply chain partner are included, as well as the existence and effectiveness of a performance review by the supplier of the company.

Quality and Regulatory Compliance Systems:

> An interesting gap in successful supply chain practices is the existence of systems established by the company to ensure the supplier has the systems in place to support the company requirements. Instead, the company would typically penalize the supplier for not having systems in place after the company signed an agreement indicating that the supplier was acceptable. Additionally, this category of questions includes an assessment

of the adequacy of resources the company has to conduct successful supply chain practices.

Product and Process Technical Capability:

> In many circumstances, it was found that companies do not possess the requisite understanding of their own product and process well enough to know what is needed from the supplier and material being provided. This category of questions helps a company identify what gaps might exist in their understanding of finished product process and controls, technical transfer success rates, and the process capability of the supplier.

The outcome of the Self-Qualification process is also to be used to create the Relationship Risk map provided in Section 5C, which will enable the company to determine if actions need to be taken regarding existing supplier relationships and/or which supply chain partners are best suited for the company.

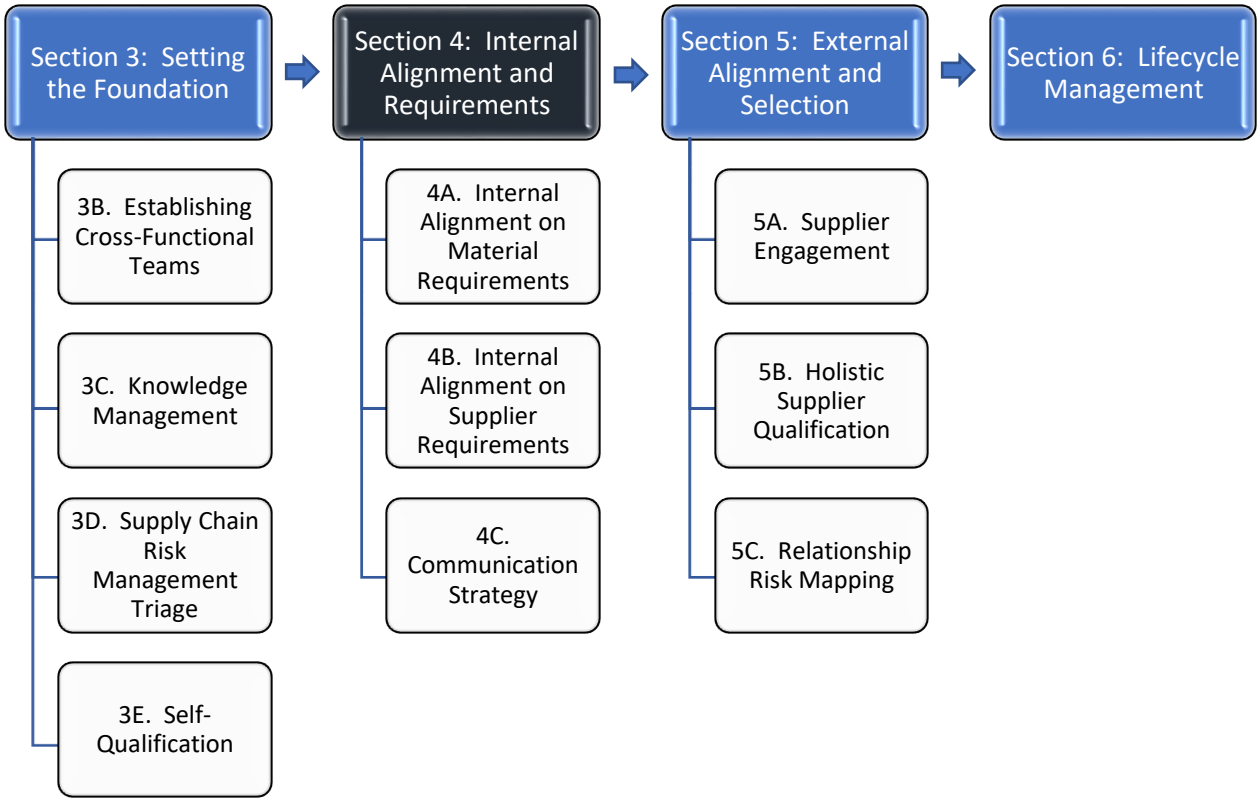
As a direct outcome of the Self-Qualification process, the cross-functional team should prioritize the risks and mitigation actions to develop an appropriate and practical corrective action plan. The team should develop a process to ensure the corrective actions are implemented and are effective. The team should also establish a frequency by which to repeat the self-qualification process so as to monitor changes and trends. All assumptions and decisions made while aligning on the self-qualification assessment should be documented in the Supply Chain Intelligence Repository through the Knowledge Management Process provided in Section 3C.

Section 4: Internal Alignment and Requirements

This section is designed to enable the company to cross-functionally align on material and supplier requirements early in the product development cycle and prior to engaging the supplier. Refer to Figure 4.1 below as a reference for where the Internal Alignment activities occur in the overall Good Supply Practices. It is recognized that the Research & Development (or Technical Operations) group needs to have time to identify new potential products and conduct some preliminary assessments for initial viability. However, soon after this early phase of development, a cross-functional team needs to be established (Section 3B) to support the lifecycle success of the product. Importantly, the company needs to establish what it believes is critical versus non-critical, criteria and specifications for materials it believes are needed to support the finished product, and requirements it believes are necessary during the supplier selection process. Once this understanding is gained by the cross-functional team, and the communication strategy is developed (Section 4C), then the supplier can be engaged in a more

meaningful way (Section 5A). Alignment on internal requirements is not intended to be a process of "setting" the requirements, but rather, will foster insightful dialog between the company and suppliers around what the requirements should be based on the input of supplier subject matter expertise and company knowledge/experience.

Figure 4.1: Organization of the Good Supply Practices



A. Internal Alignment on Material Requirements

Purpose:

To provide a roadmap for establishing internal alignment on requirements for material attributes, specifications, and characteristics to support consistent final product performance. The outcome of this process is to be used in conjunction with the internal alignment on supplier requirements outlined in Section 4B prior to engaging the supplier in material and supply chain discussions. The purpose of internal alignment is to ensure requirements are first understood from key internal stakeholders, followed by alignment on the prioritization of those requirements. This will result in more effective and streamlined discussions with the supplier once the supplier is engaged as described in Section 5A. After engaging the supplier, the decisions made on material

requirements in this section will support the supplier qualification process described in Section 5B, which leads to the ultimate supplier selection decision.

Scope

This section includes a process for internal alignment on material requirements that can be used to assess the appropriateness of those requirements throughout the total product lifecycle, and is to be conducted prior to engaging the supplier. Importantly, this process can be used when (1) developing the material requirements for the first time, (2) supporting a change to the material needed in the finished product, and (3) assessing the effectiveness of the material through lifecycle management review. The information provided in this section is not meant to be all-inclusive, but rather, is to serve as a tool to support the decisions to be made by each company as to what information is relevant to its own operations. The intent of this section is to ensure a cross-functional team aligns on key material requirements to support the success of the finished product.

Background

During the product development process, the importance of identifying and understanding critical material requirements is often overlooked. Historically, companies identify materials needed for the finished product, then work to identify readily available supply of those materials and utilize standardized test methods to verify quality for immediate use. These activities are completed without first understanding what is actually needed. Additionally, suppliers are often engaged before the company has a preliminary understanding of what material requirements are necessary to support consistent product function. Functional areas within a company typically do not communicate with each other to align on what material requirements are critical from the perspective of their functional role (quality, hazard limits/controls, environmental concerns, cost, impurities, etc.), which eventually leads to a disjointed approach to setting material requirements with the supplier. As a result, the supplier (1) receives conflicting information from different functional areas within the company, (2) is asked to meet requirements that are not necessary or achievable, and/or (3) is not given enough information to be able to provide guidance on what might actually be needed for proper function within the finished product.

The likelihood of finished product success for the benefit of the patient and business can be increased through an intentional assessment of how the material affects the finished product, what attributes of the material are critical to the finished product, and what test methods can best assure material function, quality, and efficacy. Through this type of intentional assessment,

discussions with suppliers can be more robust, and can finalize the requirements that are necessary and critical, and can lead to specification development that makes sense for the intended use. The material can then be assessed on an ongoing basis (as described in Section 6) to ensure proper function within the finished product, and to identify unacceptable variability that might otherwise have gone undetected.

The information provided in this section is intended to enable a company to establish a process for material requirement development that will support successful finished product performance throughout the product lifecycle.

Process:

Step	Description	Cross-Reference
1	Form Cross-Functional Team to conduct the material requirements evaluation process	Section 3B
2	Align cross-functionally on a process to follow to material requirement evaluation	Appendix 11
3	Gain an understanding as a cross-functional team of the final product requirements and critical materials	Current Section
4	Gain an understanding as a cross-functional team of the critical quality attributes of each critical material	Current Section
5	Identify tests that can assure the performance of each critical quality attribute to support discussions with suppliers	Current Section
6	Develop preliminary specifications for materials to support discussions with suppliers	Current Section
7	Document all assumptions and decisions in the Supply Chain Intelligence Repository through the Knowledge Management Process.	Section 3C
8	Monitor and review assumptions and decisions on an on-going basis	Current Section

Each company should align cross-functionally (Section 3B) on its material requirements in order to increase the assurance of finished product success, and to best identify supply chain partners who can support those requirements. A process through which to identify, control and maintain material requirements is provided in this section. In order to determine company readiness, the team should use Appendix 11 to identify which process steps might already exist, versus those that need to be developed. If possible, the Research and Development team should start the product development process using materials supplied from suppliers listed on the approved supplier list. If this is not possible, then the team should document that a viable, agreed upon supplier will need to be identified prior to starting trials in humans, if not sooner.

Prior to aligning on the internal requirements for each material, the team must understand the intricacies of the final product and the critical quality attributes of the finished product. The team can gain this information through sources such as the research and development team, technology operations team, and the supply chain intelligence repository (Section 3C - for additional information on previous/current information on product performance if this is an extension of a current product, etc.). Subject Matter Experts should provide as much information as is known about the following information to the team:

- Finished Product overview – formulation or product design, and how it works in or for the body
- Critical finished product function in the body
- Critical quality attributes of the finished product
- Assumptions and decisions related to materials chosen
- Desired function of each material

Key Concept: Recognizing that these discussions are occurring during early stage development, the subject matter experts will only be able to share what is known, but the team should be aware that many iterations of product development will be occurring during this time. As a result, it is critical to document decisions and assumptions related to those decisions, and to be prepared to support the success of the product development team with agility. One goal is to prevent using materials during product development that are chosen simply because they are available. Often, these materials are used in finished product that is included in clinical trials or human factor studies, etc. that become part of a formal regulatory filing. Once this occurs, it is difficult to course-correct to use a material and/or supplier that is better suited for the needs of the product and company. Also note that changing material requirements may necessitate a change in the supplier. The team should not assume that the current supplier is best suited for the new requirements.

Internal Alignment on Requirements. Once the intricacies of the final product are understood, and the desired material performance is outlined, the cross-functional team should align on material criticality. Material criticality assessments include considerations of the material function in the finished product, as well as to the production of the finished product. Some materials ensure the manufacturing process can consistently produce finished product that meets specifications (such as glidants), other materials functionally bind the finished products, while others may ensure the active ingredient of the product becomes bioavailable.

The criticality of the material should include an understanding of how each raw material and its variability affect the critical quality attributes of the product. The impact of material variability on the finished product should be assessed throughout the product development cycle, since this involves knowledge gained later in the process, such as an understanding of supplier process

capability and any material nuances known by the company and/or suppliers (e.g., seasonal differences of some materials, such as sugar). One tool that can be applied progressively for specification refinement during the development program is the Design of Experiments (DoE) approach. A number of resources exist to explain the utility of DoE in the pharmaceutical product and medical device industries. The tool can begin to reveal various process parameters that can impact the output quality of an intermediate or product and thus provide an indication as to requisite specifications that may lead to a successful outcome. Appropriate consideration should also be afforded when deciding between standard specification grades of material (e.g., ACS, USP or other similar grades). Such grades of material can often be more readily available than custom specified materials.

Since contract services are used widely across the pharmaceutical and medical device industries, it is important for the company to assess the raw material selection and attribute identification/control processes employed by contract research and/or manufacturing organizations. The company should ensure these practices meet regulatory expectations, but also the rigor necessary to protect and support product success.

Once the critical attributes of the materials are identified, the company needs to determine testing that is appropriate to ensure the critical attributes meet the identified requirements. The testing criteria for each raw material should be reviewed with a technical team. The testing criteria should not be decided by choosing attributes only from the certificate of analysis provided by the supplier. Rather the key attributes which are important for product quality should be discussed and a determination should be made of which attributes require specification development. Additionally, effective sampling regimens should also be considered and determined based upon the extent of experience and knowledge of the raw materials and what characteristics of the material (e.g., impurities) may have direct and deleterious impact upon the quality of the product.

The team should align on the attributes, testing and sampling requirements prior to engaging the supplier, such that the team has an initial understanding prior to receiving advice and input from the supplier. The company can better understand the pros and cons of the advice being offered by supplier subject matter experts, and will increase the likelihood that decisions made early in the product development cycle will support the ongoing success of the product. Internal alignment gained on material requirements is to be used in conjunction with the internal alignment on supplier requirements provided in Section 4B. Importantly, the effectiveness of decisions made regarding materials and specifications should be evaluated on an ongoing basis. Input from the supplier regarding material requirements is addressed in the Supplier Engagement section (Section 5A) and will be evaluated through the material evaluation process provided in Section 5B. Through lifecycle management (Section 6), material performance is evaluated, along with input from the supplier on feasibility and appropriateness of the material

requirements. This process increases the success of the finished product throughout the product lifecycle.

All assumptions and decisions made while aligning on material requirements (including a specification change control process) should be documented in the Supply Chain Intelligence Repository through the Knowledge Management Process provided in Section 3C.

4B. Internal Alignment on Supplier Requirements

Purpose:

To provide a roadmap for establishing internal alignment on a holistic set of criteria used for the selection of suppliers. The outcome of this process is to be used in conjunction with the internal alignment on material requirements outlined in Section 4A prior to engaging the supplier in material and supply chain discussions. The purpose of internal alignment is to ensure requirements are first understood from key internal stakeholders, followed by alignment on the prioritization of those requirements. This will result in more effective and streamlined discussions with the supplier once the supplier is engaged as described in Section 5A. After engaging the supplier, the decisions made on supplier requirements in this section will support the supplier qualification process described in Section 5B, which leads to the ultimate supplier selection decision.

Scope:

This section includes a process for internal alignment on supplier requirements that can be used to assess any supplier or service throughout the total product lifecycle. Importantly, this process can be used when (1) developing a supply chain for the first time, (2) supporting a change to an existing supply chain, and (3) assessing the effectiveness of an existing supply chain through lifecycle management review. The information provided in this section is not meant to be all-inclusive, but rather, is to serve as a tool to support the decisions to be made by each company as to what information is relevant to its own operations. The intent of this section is to ensure a cross-functional team aligns on key supplier requirements to support supply chain success.

Background:

Due to the global complexity of research, development, clinical and commercial supply chains, it is generally not practical to conduct a thorough assessment of all necessary goods/services or suppliers. Additionally, the term “supply chain” technically includes all suppliers from the most

basic source of materials leading to the finalization of the material ultimately supplied (i.e., your supplier's supplier's suppliers, etc., also known as tiers 1, 2, 3, etc. suppliers). Due to the often impossibility of assessing all suppliers, Section 3D provides a risk triage mechanism by which each company can determine where to focus its resources such that risk is limited as much as possible. It is important to note, however, that there are historical examples of impact to patient and business risk that were caused by a supplier or material that otherwise appeared to be of very low risk. In order to offset the likelihood of unanticipated risk events, each company should employ multiple methods by which to assess and surveille the direct and indirect influences on their supply chains (such as the global economy, weather patterns, political forces, etc.), and subsequently adjust risk determinations and mitigation strategies as necessary. This type of information should be included in the supply chain intelligence repository through established knowledge management practices discussed in Section 3C.

Historically, companies have conducted supplier requirement evaluations against a limited set of risk categories, and have not gained cross-functional alignment on the importance of each risk. Typically, requirements have centered on cost of doing business, current capacity and quality compliance. However, patient and business success are both dependent on a larger array of criteria as provided within this section.

Process:

Step	Description	Cross-Reference
1	Form Cross-Functional Team to conduct the supplier requirement evaluation process	Section 3B
2	Gain an understanding as a cross-functional team of the final product requirements and material requirements to support successful supplier selection.	Section 4A
3	Determine which goods/services and suppliers to include in the evaluation process	Section 3D
4	Align cross-functionally on a complete list of requirements to evaluate using the provided template as a starting point.	Appendix 12
5	Align cross-functionally on the relative importance of each requirement based on the goods/services to be provided	Appendix 12
6	Identify potential suppliers to evaluate from the Approved Sourcing List, the supply chain intelligence repository, and external sources of information	Section 3C
7	Cross-functionally evaluate the potential suppliers against the identified requirements that were determined to be important	Appendix 12
8	Create a list of prospective suppliers	Current Section

9	Document all assumptions and decisions in the Supply Chain Intelligence Repository through the Knowledge Management Process.	Section 3C
10	Monitor and review assumptions and decisions on an on-going basis	Current Section

Each company should align cross-functionally (Section 3B) on its supplier requirements, goals and expectations in order to identify the appropriate selection criteria against which to evaluate the goods/services of a supplier. However, prior to aligning on the internal requirements for each supplier, the team must understand the intricacies of the final product and requirements of the material to be supplied (Section 4A). The team can gain this information through sources such as the research and development team, technology operations team, and the supply chain intelligence repository (Section 3C - for additional information on previous/current performance of the material in other products). If possible, Subject Matter Experts should provide as much as is known regarding the following information to the team:

- Finished Product summary, including use, market, competition, key success factors
- Finished Product risks, e.g., technical complexity, limited availability
- Key attributes for purchased materials
- Self-risks, e.g., lack of time to gain full understanding of specification requirements or alternatives, lack of technical understanding of different purchased materials

Internal Alignment on Requirements. Once the intricacies of the final product and materials are understood, the cross-functional team can align on which suppliers to include in the evaluation process through a supply chain risk management triage process, such as that provided in Section 3D. Annual spend is often used to prioritize the amount of effort given to suppliers and material. Although many high spend goods and services also have a high impact, this method fails to consider low spend items that can have a significant impact on the integrity of supply. Focusing on the impact, rather than spend, reduces the risks associated with low spend items.

Following the completion of the risk triage process, and the material requirements have been identified internally (Section 4A), then the template provided in Appendix 12 can be used for each company as a starting point to identify holistic requirements that are pertinent to their product, supply chain, and business. The team can begin by reviewing the examples of criteria provided in the template, but then should determine if any of the requirements should be removed or revised, and if any additional requirements should be included. It should be noted that the examples provided are not intended to be all-inclusive. This process establishes a pathway to identify and score the relative importance of a holistic set of requirements for the supplier selection process, which also provides the basis for determining meaningful supplier performance metrics going forward.

The holistic requirements have been divided into four categories as follows so that the areas of supplier strengths and weaknesses can be easily identified and compared to self-strengths and weaknesses for optimal supplier selection decisions and mitigation strategies:

1. *Supplier operating systems and business continuity.* The ability of the supplier to support speed to market, meet lead time demands, respond to changes in demand, long term operational and financial viability, future capacity, systems to manage enterprise risk, etc.

2. *Relationship alignment.* It is important that the supplier is socially responsible, willing to sign various agreements prior to contract finalization, shares market intelligence, and meets the strategic needs of the company culture, commitment, and trust. [Note: it is important to identify which agreements must be signed to limit business and patient risk, and ensure business continuity. The timing of when to communicate these requirements and gain agreement is discussed in Section 4C].

3. *Quality and regulatory compliance systems.* The supplier has controls in place for material traceability, non-quality related compliance (REACH, RoHS, EH&S, Ethics and Labor, etc.), and control over their own supply chain.

4. *Supplier product and process technical capability.* The supplier has specific technical expertise, acceptable process capabilities, direct experience with the material in question, and demonstrated process improvements to afford future economies of scale.

Internal Alignment on Relative Importance. The cross-functional team should evaluate the list of requirements per category, and determine the relative importance of each requirement to the ultimate quality assurance of the final product and business continuity. Through the use of the template provided in Appendix 12, the team should score each requirement as a 0, 3, 7 or 10 as instructed in the appendix. When assigning relative importance, the team should focus on what is required for the business versus criteria that are nice to have or address individual goals. The value of this exercise is the discussion, since it provides an opportunity for each team member to help others understand the importance of their criteria and vice versa. It is important to document rationale, assumptions and decisions using the knowledge management process established by your company (refer to Section 3C for guidance).

Identification of Potential Suppliers. Once the requirements are identified and scored, the cross-functional team is then able to identify potential suppliers that might meet these requirements. The team should identify potential suppliers starting with the Approved Supplier List (ASL), followed by an assessment of the supply chain intelligence repository (Section 3C) and external

sources. The potential suppliers should be evaluated against the requirements that have been established by the cross-functional team through the template in Appendix 12. As a reminder, the supplier has not been engaged yet at this point, since it is important to establish internal alignment prior to engaging with the supplier. Therefore, performance against some requirements might not be known by the company during this process. The company can gain insight by determining if the company has previous or current experience with the supplier, if there is any information in the supply chain intelligence repository (Section 3C), or through external intelligence gained. Otherwise, the company should leave the requirement blank, and then fill-in further once the supplier is engaged. The team can determine which suppliers form the strongest list of potential suppliers to take forward in the process, with the goal of identifying no more than 3 if possible. This "short list" of suppliers will offer enough diversity to determine which supplier is the best fit for the company, while keeping the process manageable from a resource perspective (time and money).

The effectiveness of the supplier identification process is evaluated during the Holistic Supplier Qualification (Section 5B), and should be monitored throughout the product lifecycle as described in Section 6. Additionally, the company will gain an understanding of "fit" through the early supplier engagement process (Section 5A), which will lead the company to identify the best possible supplier match to meet the needs of the product and company (Section 5C – Relationship Risk and Mapping).

It is important to note that an evaluation of supplier capabilities versus requirements is a process that can be employed while establishing an initial supply chain, making a change to the supply chain and assessing the effectiveness of the supply chain during the lifecycle management review. This lifecycle management process is provided in Section 6. All assumptions and decisions made while aligning on supplier requirements for a successful supply chain should be documented in the Supply Chain Intelligence Repository through the Knowledge Management Process provided in Section 3C.

Additionally, each company should also use the supplier evaluation process for single and/or sole sourced materials, since it provides internal alignment on the strengths and weaknesses of the supplier relationship, thus enabling the company to develop an appropriate mitigation plan. The following vignette is offered to assist companies in recognizing the benefits and risks associated with multi-sourcing, such that the best strategy can be developed for each company.

Vignette: Single Source versus Multi-Source

Purpose: Dual sourcing, or multi-sourcing, is commonly used to manage capacity and mitigate supply risk. It is important to recognize that supply risk management is a broad and complex process, and multi sourcing is just one of the tools that can and should be considered. The purpose of this Vignette is to provide a perspective on the benefits and risks of a multi-sourcing strategy so the user can best determine when and why to use this approach.

Defining Multi-Sourcing: The term multi-sourcing has two very different meanings, so it is important for the purpose to be made clear by the user when exploring the use of multi-sourcing as part of the supply strategy.

1) Multi Sourcing as a Capacity Management Tool. In this case the strategy requires that sufficient capacity is available as the sum of the capacities of multiple sites or suppliers.
2) Multi Sourcing as a Risk Management Tool. In this case the strategy requires that sufficient capacity is available from each individual site or supplier when required to mitigate a supply issue at another site or supplier.

Benefits of Multi-Sourcing: The most fundamental and compelling purpose for multi-sourcing as a supply strategy is to ensure sufficient capacity is available when no individual supplier or supply site has sufficient capacity to meet the needs of a customer.

As a risk management strategy, multi-sourcing is often employed as mitigation for high impact/low frequency risks that interrupt supply from an individual supplier. These events may include those that cause catastrophic damage to the site, compliance failures leading to regulatory action, or cessation of part or all business activities of the supplier for financial or strategic reasons.

It is important to the success of this strategy to consider the lead-time required to complete all activities needed to establish the additional source. Notably, an early decision to multi-source can mitigate this lead-time risk, while also providing transparency to the primary supplier(s), which can build the strength of the ongoing relationship.

A multi-sourcing strategy can work well in conjunction with other risk management approaches, such as the systematic identification and mitigation of risks and the use of inventory coverage to allow for changes in source. An effective multi-sourcing strategy enables an organization to operate with the agility needed to manage the complexity of today's global supply chains.

Additionally, the use of multiple sources can establish a positive competitive dynamic if managed properly, which can be leveraged to drive additional value to both parties via performance and cost improvements.

Risks of Multi-Sourcing: Although multi-sourcing is widely viewed as having a risk reduction affect, if not managed appropriately, the organization could in fact be at greater risk. Greater risk may occur since the user is often unaware of strategies employed by the suppliers, which create vulnerabilities. For example, if the additional capacity required to be truly multi-sourced is not being reserved by the additional sources, then true multi-sourcing is not achieved, and the risk of catastrophic failure has not been mitigated. This vulnerability is often not known by the user until the user necessitates the capacity of the additional sources. Therefore, clarity of the multi-sourcing purpose is critical, and the overall risk management strategy must require the additional source to guarantee redundant capacity.

Additionally, dividing supply volumes between two or more suppliers could be viewed negatively by existing suppliers, and could undermine leverage for both performance and cost improvement outcomes. This means that whereas the high impact/low frequency risk of catastrophic failure has been mitigated, the management of low impact/high frequency risks may be sub-optimized due to the loss of leverage on performance. On cost, if multiple suppliers are reserving enough capacity to cover the needed volume so that catastrophic failures can be mitigated (true multi sourcing for risk management), then the cost of access to that capacity will likely be factored into the contract. It may also be the case that each source requires a specific volume commitment, or percentage volume, which then undermines the ability to leverage volume in negotiations.

The cost of, and cycle times for, establishing multiple sources and the resource and change management processes required to maintain equivalence between suppliers is often underestimated by the user. As a result, the impact and cost of not maintaining equivalence can be high.

A final risk factor to consider is related to infrequently manufactured products. Infrequently manufactured products elevate risks to process capability and reliability of execution, which is exacerbated by the diluted volumes allotted to each supplier involved in the multi-sourcing strategy. suppliers may experience a lengthened learning curve when supporting infrequent production, which cannot be address through a multi-sourcing strategy, and in fact may deepen the risks.

Mitigating the Risks of Multi-Sourcing: Ultimately, multi-sourcing for capacity or risk management reasons is intended to ensure the user meets the foundational business objective of most supply organizations - the long-term security of supply to patients and customers. Collaborating with existing supply partners to explore available mitigation strategies can drive alignment between the organization, and can also result in the development of more robust solutions. Communication of the risk management strategy, along with the rationale, enables the organizations to work together toward additional risk mitigation. For example, if a sufficiently

strong partnership environment can be established, then the learning curve for infrequently manufactured products may be accelerated through information sharing.

4C. Internal Alignment on Communication Strategy

Purpose:

To create a comprehensive approach for the development of a strategic communication plan between manufacturers and suppliers. The foundation of this strategic plan is reliant upon the partnership level between the two entities, which is rooted in historical experience, performance and demonstrated trust. This section of the Good Supply Practices document provides a tool for the manufacturer and supplier to use that guides each entity through an assessment of the benefits and risks of several common types of information that could be shared during the partnership, such that each entity is able to determine the appropriate strategy for their organization and the partnership at hand. The goal of the communication strategy is to ensure that each entity is able to make informed and intentional decisions about what to communicate such that each business is protected, and each partnership is able to grow based upon demonstrated trust.

Scope:

During product and supply chain development phases of the total product lifecycle, a cross-functional team should be established as discussed in Section 3B that will assess material requirements and possible supplier partnerships to fulfill the identified needs. This cross-functional team should also align on the type of information to be shared with the supplier, the timing of the information to be shared with the supplier, and the information needed from the supplier based upon the categorization of the supplier partnership. The communication strategy is to be developed prior to engaging the supplier, and is to be reassessed throughout the partnership lifecycle to ensure the strategy is effective and is meeting the needs of both entities. Additionally, the supplier should establish a communication strategy for each of its customers, and is therefore included in the scope of this section.

Background:

During the research and development stage of the Good Supply Practices, gaps, risks and areas of opportunity related to communication content and timing between manufacturers and suppliers were identified. Examples of issues related to communication between the partners include:

- Customer not sharing critical information needed by the supplier, such as intended use
- supplier not sharing critical information, such as changes made to the material, process, or organizational leadership
- Customer not providing sections of the regulatory filing that pertain to the operations being performed by the supplier
- Point of contact from the customer or supplier not being the person who has the responsibility or authority to provide an adequate response
- Communication from either party not being conveyed in a timely manner
- The information shared is not agreed upon by key functional areas and/or leadership levels in the organization, and therefore, results in false-starts, lost time, expense, etc.
- Actual capacity at the supplier

Through research, it was determined that frustration experienced by both parties related to limited, inconsistent, and at times, inaccurate information is widely felt across the pharmaceutical and medical device industries. It was also recognized that the information to be shared by each party is not established through a strategic process. On the contrary, the type information to share and its timing is often determined by individual preferences and historical precedence. This type of approach poses many risks to the business and stakeholders of the organization. As a result, this section of the Good Supply Practices is designed to assist organizations in identifying the type of information to share or not share based on an understanding of the risks and benefits of each. Importantly, the level of transparency must be based on the level of demonstrated trust between the organizations, and should be considered an asset of the company.

Process

Step	Description	Cross-Reference
1	Form a cross-functional team that is responsible for the communication of the information from relevant functional areas with suppliers (or customers).	Section 3B
2	Identify potential information that could be shared with the supplier (or customer).	Appendix 13; Appendix 14
3	Identify the risk level of each relationship, such that communication is based on the level of established trust.	Section 3D
4	Identify the risks of sharing the information	Appendix 13; Appendix 14
5	Identify the benefits of sharing the information	Appendix 13; Appendix 14

6	Determine if the information is currently being shared.	Appendix 13; Appendix 14
7	Determine the probability of sharing the information going forward	Appendix 13; Appendix 14
8	Review the effectiveness of the communication strategy	Current Section
9	Document all assumptions and decisions in the Supply Chain Intelligence Repository through the Knowledge Management Process.	Section 3C

Information is a key asset to each organization that is often not handled with appropriate stewardship. Individuals historically do not have the training needed to identify and understand the significance to the overall business of information sharing, handling and storage. The Knowledge Management section of this Good Supply Practices document (Section 3C) provides insight on how to maintain knowledge and information so as to propagate continuity of decisions and assumptions made historically. In addition to knowledge management, however, the type of information to share and not share needs to be thoughtfully established by the organization through a communication strategy for each partnership based on the risk of each relationship.

The Communication Tool in Appendix 13 provides a methodology to support the development of a communication strategy by manufacturing organizations, whereas the Communication Tool provided in Appendix 14 supports the development of a communication strategy that can be used by the supplier. The tables in these two appendices provide examples of information that could be shared with the partner in each relationship, such as:

Potential Information to be shared by the customer	**Potential Information to be shared by the Supplier**
Forecast/Inventory strategy	Actual flexibility in schedule
Long Term Demand	Actual capacity
Intended Use	Changes made to the process
Regulatory filings	DMF or other regulatory filings
SOPs/Work Instructions/Test Methods	SOPs/Technical specifications
Cost/Profit	Cost/Profit
Master batch or device records	Master batch or device records
Other Suppliers	Regulatory inspection results

Importantly, the cross-functional team established in Section 3B needs to align on the information to be shared based on an understanding of the risk level of each relationship (Section 3D provides an overall supply chain risk management triage process). The risk level is determined through a combination of the strengths and weaknesses of each organization, as identified through Self-Qualification (Section 3F) and the Holistic Supplier Qualification process (Section 5B), resulting in an overall Relationship Risk (Section 5C). It is important for each

organization to recognize internal risks and gaps instead of wholly focusing on the risks and gaps of the other entity in the relationship. For example, if the finished product type and/or material are new to the manufacturer, then the manufacturer needs to rely more heavily on the expertise of the supplier. In this situation, information sharing between the two organizations regarding the product and process is critical, and therefore requires a level of trust that will enable adequate information sharing. Additionally, the manufacturer needs to recognize the criticality of this requirement when choosing the right supplier partnership, as discussed in Section 4B.

The cross-functional team should assess the relevant appendix (Appendix 13 for customers, or Appendix 14 for suppliers) for examples of the types of information that could be shared in order to identify which of the examples are applicable to their operations, as well as to identify additional types of information to include. The team should then align on the risks and benefits related to sharing each type of information with the other entity in the relationship. This exercise will then allow each organization to make informed and intentional choices of what to share based on the balance of benefits and risks. However, this balance can only be understood if the risk of the relationship is understood first, as described in Section 5C.

Relationship trust could be established based on a multitude of inputs, such as whether the manufacturer and supplier have engaged in business before, duration of the relationship, how each party treats third party data, management stability or turnover, demonstration of competency, operating in mutual interests, admission of error and speedy recovery, integrity in other aspects of the business such as contract respect, GMP compliance, EHS conscientiousness, etc.

Once the communication elements are identified, a strategy needs to be established by the cross-functional team to identify when to share to share the information, and who is authorized to share that information. One aspect of customer-supplier relationships that is a point of frustration is not having access to a point of contact who has the authority and expertise to answer questions and provide information. The cross-functional team should carefully determine how to establish a point of contact plan that will optimize business efficiency. Establishing agreements early in the supplier selection process (even prior to finalization) will increase the alignment of expectations and likelihood of gaining official approval when needed. Based on knowledge of the level of relationship trust, the team should determine when to communicate the agreements that were determined in Section 4B to be necessary to support the business (e.g., Quality Agreement, Supply Agreement, Service Level Agreement, Confidentiality Agreement, Code of Conduct, etc.).

The cross-functional team should assess the effectiveness of the communication strategy related to the information being shared with the other entity, as well as the information needed by the

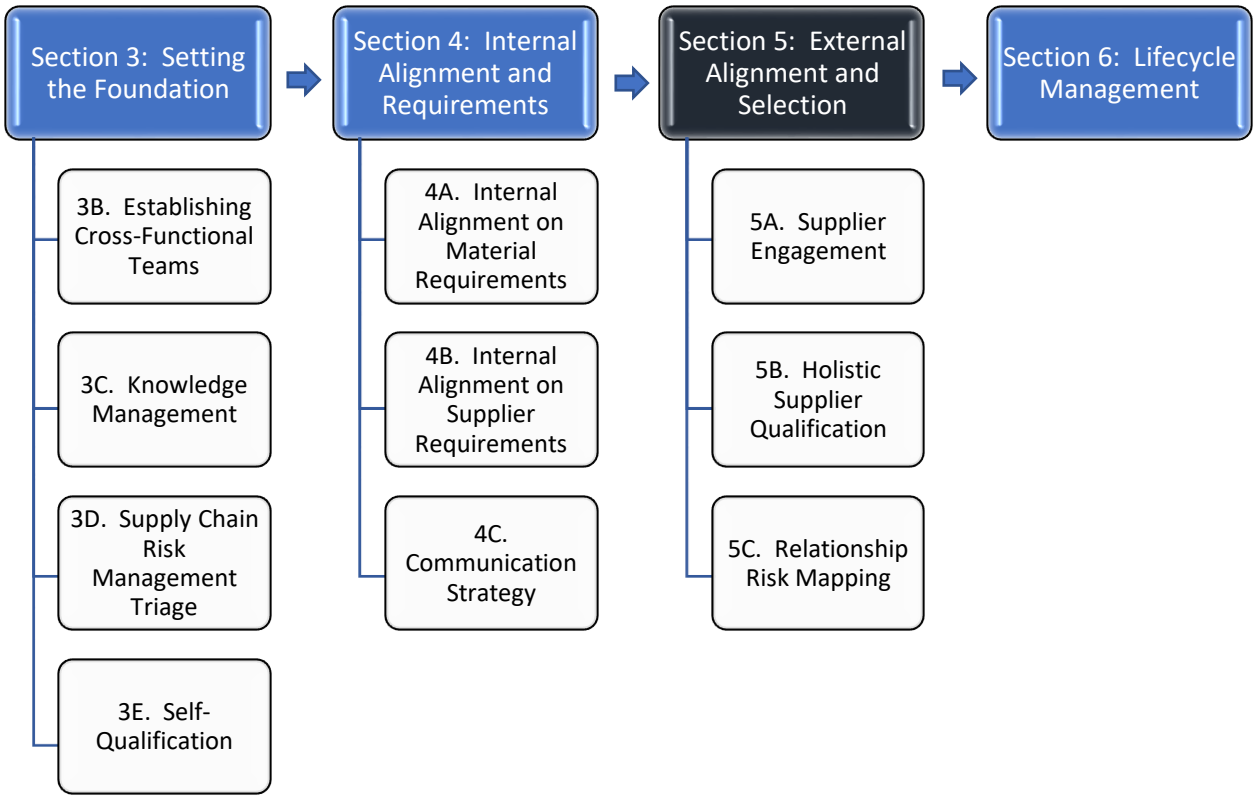
other entity. The effectiveness should be assessed against the accuracy and timeliness of the information shared. The outcome of an effective communication strategy is an effective business relationship as well as increased efficiency and accountability across complex supply chains.

All assumptions and decisions made while establishing an effective communication strategy should be documented in the Supply Chain Intelligence Repository through the Knowledge Management Process provided in Section 3C.

Section 5: External Alignment and Selection

This section is designed to enable the company to effectively engage external partners on material and supplier requirements early in the product development cycle after internal alignment is gained. Refer to Figure 5.1 below as a reference for where the External Alignment activities occur in the overall Good Supply Practices. It is recognized that internal alignment on material (Section 4A) and supplier (Section 4B) requirements is conducted early in the product development cycle. As a result, the assumptions and decisions will likely need to evolve as product development understanding evolves. Additionally, once suppliers are engaged (Section 5A) and share subject matter expertise, it might be identified that internal assumptions and decisions were not correct or complete. The cross-functional team must be prepared to manage the process with agility in order to best support product and company success. Throughout this process, it is critical for the cross-functional team to document decisions, assumptions and changes in the supply chain intelligence repository through the knowledge management process (Section 3C) so as to provide future insight on why decisions were made.

Figure 5.1: Organization of the Good Supply Practices.



5A. External Alignment - Supplier Engagement

Purpose:

To provide a purpose-driven process for engaging suppliers throughout the product development and commercialization lifecycle. This process is to begin after internal alignment is gained through a cross-functional team (Section 3B) on requirements for materials (Section 4A) and suppliers (Section 4B). Additionally, the cross-functional team should develop a communication strategy (Section 4C) prior to engaging the supplier such that there is an understanding of what can be communicated, and who should communicate the information with the supplier, as well as what information is needed from the supplier.

Scope

It is recommended within this section that supplier engagement should begin after early phase research into product viability. Although early engagement is desired, too early is not beneficial.

For example, the Research and Development/Technical Operations teams need to have time to innovate before engaging internal cross-functional teams and external suppliers. Ideally, engagement with suppliers occurs during early phase development (as depicted in Appendix 3 – The GSP Swim Lanes) after internal alignment is gained by a cross-functional team (Section 3B) on material (Section 4A) and supplier (Section 4B) requirements. Engagement of suppliers should continue throughout the product development lifecycle so as to ensure supplier capabilities continue to be sufficient to support new learnings gained during product development. Additionally, as greater understanding of the product and process is gained by the company, supplier subject matter experts can provide input on the appropriateness of the materials and specifications, which may require changes to improve finished product success. Supplier engagement should continue throughout commercialization scale-up, launch and routine commercial manufacturing.

Background

Successful material and supplier identification requires understanding the manufacturing process of both the finished product and material being supplied. Early engagement with the supplier will allow the best opportunity for an increased understanding of available materials that meet the intended use, material performance, material variability, and impact of the material on the critical quality attributes of the finished product. This supplier subject matter expertise is powerful, yet often neglected. Pharmaceutical/device companies and suppliers have indicated that communication between the two entities has historically not been effective, and does not occur in manner in which suppliers have the ability to influence decisions made regarding usage of the materials they provide. It has been identified that when engagement does occur, timing often has precluded the supplier's input into problem solving and their ability to influence decisions regarding material implementation.

The supplier engagement practices provided within this section address the following examples of gaps that are provided in Appendix 2:

- Typically, there is not cross-functional agreement on a supplier engagement strategy, which creates confusion, mixed-messages, and conflicting messages - all of which create risks to safety, efficacy and availability
- Many key suppliers are willing to share process capability with companies, but very few companies ask to see the supplier's process capability
- Very few companies make use of suppliers' knowledge and capabilities
- Suppliers are often engaged too late in the process to have impact
- Companies do not understand when information is truly confidential and tend to over-share or under-share information
- Companies tend to focus on spend instead of impact

- Communication between companies and suppliers has not been effective or timely
- Suppliers are not involved as subject matter experts on an ongoing basis

An effective process for improving supplier engagement is provided within this section, which addresses when and why to engage the supplier throughout the total product lifecycle.

Process:

Step	Description	Cross-Reference
1	Form Cross-Functional Team for the supplier engagement process	Section 3B
2	Gain cross-functional alignment on material requirements	Section 4A
3	Gain cross-functional alignment on supplier requirements	Section 4B
4	Develop a communication strategy through the cross-functional team	Section 4C
5	Identify who should engage with the supplier	Section 4C
6	Determine when to engage with the supplier relative to the product development lifecycle, and why	Current Section
7	Document all assumptions and decisions in the Supply Chain Intelligence Repository through the Knowledge Management Process.	Section 3C
8	Monitor and review assumptions and decisions on an on-going basis	Current Section

The cross-functional team should include personnel with authority to represent the company when making critical decisions. Critical and non-critical materials will likely require a different level of engagement that the cross-functional team should define through the risk management triage process provided in Section 3D. The cross-functional team should have the ability to provide the supplier with key information (such as intended use of the material, critical quality attributes of the product, technical capabilities needed from the supplier, filing timing, forecasts, etc.) that will enable both the supplier and the company to successfully support the finished product and sustain the material or service in the supply chain. If the information cannot be provided, then the cross-functional team must understand risk to the finished product and establish a mitigation strategy to manage the risks.

Appendix 3 provides a swim lane diagram to illustrate when it is recommended for supplier engagement activities to begin relative to the product development lifecycle. As shown in the diagram, engagement does not start until the company has generated a short list of potential suppliers through internal alignment on supplier requirements (Section 4B), which includes internal alignment on material requirements (Section 4A).

Any information related to risk that can be provided to the supplier through the Communication Strategy (Section 4C) will empower the supplier to better understand selection criteria against which they are being assessed, such that the supplier is able to address the needs of the company. Although risk is the ultimate responsibility of the company, the supplier should certainly be provided as much information related to risk as possible to ensure both supplier and company have the best opportunity to mitigate risk factors and successfully supply the material that meets the needs of the product.

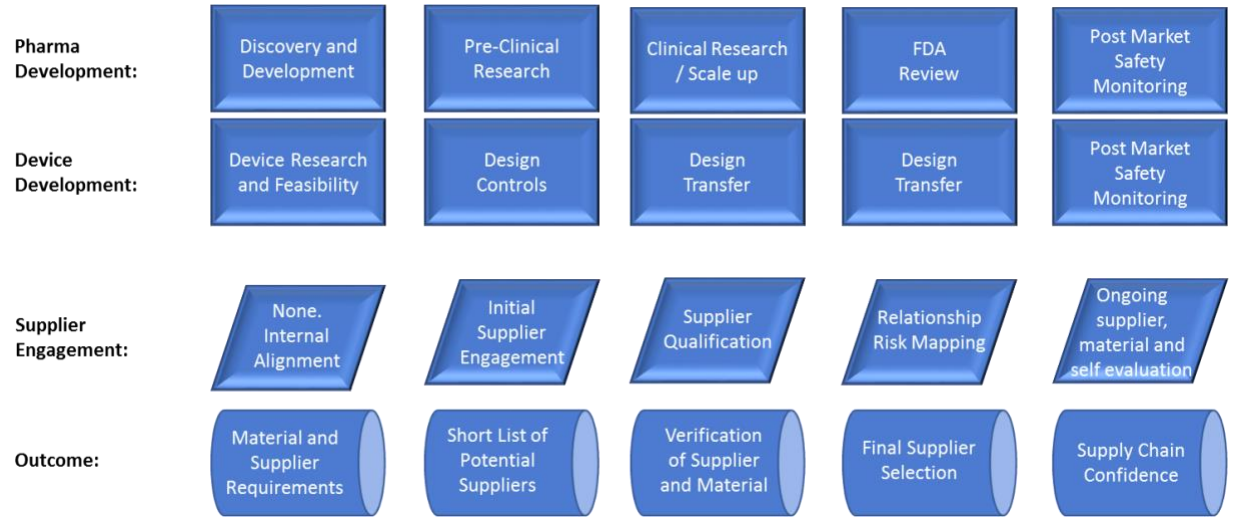
The desired outcome of a successful supplier engagement includes:

- Understanding the suppliers' stated needs and technical capabilities
- Alignment and agreement with supplier on expectations
- Agreement with supplier on terms in various agreements and contracts
- Alignment with supplier on initial material requirements and specifications
- A respectful company-supplier relationship

Company/Supplier Engagement Phases

Supplier engagement is described herein from the point of establishing a material or service during Research and Development activities, through the course of scale-up, and ultimately commercialization. In Figure 5A.1, an overview of supplier engagement milestones relative to the various manufacturing phases is provided. It should be noted that there is intentionally much overlap of activities throughout the development lifecycle, and many aspects that can impact manufacturing timelines (such as capacity constraints, studies needed to support regulatory filings, and manufacturing complexity). The supply chain intelligence repository (Section 3C) should be consulted prior to engaging the supplier to determine if the supplier is already supplying the desired material or other material to the company, and if there are notes on supplier and material performance. A supplier that provides the material in question might already be qualified and listed on the Approved Supplier List. It should be noted that supplier qualification is based on the performance of the supplier related to a specific material, and not based on the supplier as a whole. Experience has shown that a supplier may not be able to perform well for supplying a new/different material despite excellent performance related to a current material supplied.

Figure 5A.1. Supplier Engagement Milestones



Prior to having any technical discussions with suppliers, the company and supplier will determine when a confidentiality agreement (CDA) should be put in place. suppliers and companies may elect to develop separate CDA's for different stages of material usage (e.g., due diligence, development, pre-commercial, etc.). This allows for information sharing between the company and supplier such that critical information sharing can occur without risk to either party's intellectual property.

Discovery / Early Development Supplier Engagement

During early phase development, companies often rely on readily available materials irrespective of purity or grade. The company should document usage and performance of materials, as well as decisions and pertinent information that will aide in establishing the usage of the material in commercial production. Experience has shown early supplier engagement results in an increased likelihood of relationship and finished product success. As provided in Section 4A and Section 4B, however, the cross-functional team needs to align internally on material and supplier requirements prior to engaging the supplier.

Once engaged, the company should discuss with the supplier the following considerations:

a. Do the small-scale samples of material being used in Research and Development represent the most recent materials available? Does the source of material represent the most recent technology available for the type of material? Are there more appropriate grades of material available that the company should be using that inherently contain material attributes more aligned to usage?

b. Does the distributor know the original manufacturer of the material? Is the original manufacturer qualified and willing to source to the company when commercialization takes place? Is supplier capable of achieving specialized needs imposed by the company? Are the specifications in alignment with the supplier's process capability?
c. What testing is performed by the original material manufacturer, the distributor, and the company? Are the test method identical, and is the supplier willing to share the test methods with the company? Does that company require additional test attributes based on the usage of the material in the process.

The company and supplier engagement activities might be minimal during the early research phase, but external alignment on agreements (e.g., Quality Agreements and Supply Agreements) and capabilities are critical to the product development and regulatory timelines. The company should be prepared to provide details of material usage to the supplier, in order to prepare the supplier to understand if their material and services are suitable for the application, especially in preparation of bidding for contracts and providing the company details of their capabilities. Suppliers should be made aware of the company's acceptance criteria so that the supplier can advise the company of better materials that might be available or different requirements that might be better suited for the intended use.

Process Development; Scale Up and Supplier Engagement

As a company moves into a scale-up phase, the company will begin to optimize the manufacturing process, including evaluation of material and supplier options. The company will be faced with a need to begin 'locking down' many aspects of their process as they move towards regulatory registration and commercialization. Identification of materials will be a priority. Potential supplier lists will be evaluated and shortened as companies have the ability to determine via large scale manufacturing runs which materials are the best fit. In some cases, it will be necessary to seek new suppliers that can meet the needs of the commercial process. Additionally, some materials, such as drug delivery devices, drug storage components, and other materials not used in discovery and bench scale batches, will be evaluated for the first time. In addition to the ability to utilize and evaluate materials within the process, the company will begin to utilize such tools as due diligence audits, questionnaires, and detailed discussions with the supplier. In a due diligence audit, the company will evaluate the supplier facility, and will likely focus on specific technical and quality aspects outlined in Section 4B to allow the company to determine if the supplier and supplier assets are appropriate for future use. Importantly, the company and supplier should be working collaboratively to finalize appropriate material specifications for intended use in the finished product and process.

Late Stage Development and Supplier Engagement

As the company moves into final pre-commercialization processing, many aspects of the finished product process will be finalized including final selection of materials and suppliers. During this phase of product development, regulatory submission activities and will include material and supplier information and data.

In this phase of product development, if not sooner, the company and supplier should work together to outline the necessary supplier activities and requirements that need to take place prior to commercialization. Quality agreement templates and supply agreements should be provided to the supplier to ensure the supplier agrees with the content and requirements, while providing ample time to negotiate before approval. Routine quality audits of the supplier facility should begin so that there is time to close any audit observations or quality system gaps to support finished product success. Design of Experimentation (DOE) studies should be underway to understand material variability and the impact to the finished product process, in conjunction with awareness and understanding of the supplier's process capability. Specifications should be finalized with input by the supplier, who is the subject matter expert of their own material. By having the specification discussion, in conjunction with sharing intended use, the supplier can provide expert guidance. If the supplier disagrees with the specifications, then the company should document the supplier's input and scientifically why the company is not accepting the supplier's recommendation.

Manufacturing forecasts related to material inventories should be provided to the supplier and agreed to in advance of commercial production. By this phase, supplier qualification should be near completion as outlined in Section 5B. Formalized communication channels between the supplier and company should be established, which is often captured within the Quality Agreement. The supplier needs to know who to contact for change notifications, supplier deviations and other non-routine communiques, and should be given contact information and access to the appropriate representatives within the company. This reduces company risk by ensuring supplier concerns are addressed by those with the experience, responsibility and authority to manage the questions and situations.

Preparing for Commercialization and Process Validation and Supplier Engagement

As the company prepares for commercialization and process validation, supplier qualification (Section 5B) should be complete. Quality agreements and supply agreements should be in place and approved. As the manufacturing process is moved into the commercial facility, certain material requirements may need to be refined and finalized. These requirements could include aspects such as dispensing requirements, pallet requirements, finalization of sample plans, and sampling details such as material ID samples and all aspects related to receipt of materials. The cross-functional team should ensure at this stage that all cross-functional requirements are being

met. If the requirements are not being met by the supplier, then the team should determine next steps, including discussions with the supplier and mitigation strategies.

Commercial Processing and Supplier Engagement

Once routine manufacturing begins, the company and supplier should continue to work together on a routine basis. A means to ensure the relationship remains healthy is establishment of Supplier Relationship Meetings (SRM). The SRM should be scheduled commensurate with the need that was identified through the supply chain risk management triage process in Section 3D. As described in Section 6, the cross-functional team can use the lifecycle management tool to guide performance discussions with the supplier. Importantly, this process includes an evaluation of the company's performance related to impact to the success of the relationship, material provided by the supplier, the finished product and overall business. The SRM provides a platform for both company and supplier to work on continuous improvement activities, to update forecasts and inventory levels, and to discuss deviations, complaints, and audit observations.

Throughout commercial manufacturing, suppliers should expect routine audits to take place, Quality Agreement reviews, periodic questionnaires, and periodic performance evaluations to be completed. These activities are to be conducted by the cross-functional team in a way that is commensurate with the need based on the risk management triage outcome (Section 3D).

Successful implementation of a material within a product or manufacturing process requires extensive knowledge of both the manufacturing process for the product and the material being implemented. Early engagement of the supplier will allow the best opportunity for successful and sustained usage of the material and best suiting the needs of the patient. All assumptions and decisions made during supplier engagement should be documented in the Supply Chain Intelligence Repository through the Knowledge Management Process provided in Section 3C. The success of the company-supplier relationship needs to be monitored on an ongoing basis as both organizations are living entities that change in leadership, culture, capabilities and needs over time. The supplier capabilities compared to what was determined to be relatively important by the cross-functional team (Section 4B) should be assessed at a predetermined frequency, as well as when for-cause circumstances arise (e.g., significant known change in leadership). This Lifecycle Management process is further described in Section 6.

5B. External Alignment - Holistic Supplier Qualification (with Material Evaluation)

Purpose:

To create a cross-functional holistic approach to material/service evaluation, supplier qualification, and supplier selection. Through this holistic approach, the cross-functional team is able to ensure internal and external requirements are fulfilled by both entities as appropriate, including applicable regulatory requirements. This section includes decision tree processes to assist companies in determining the acceptability of the material, and the qualification state of the supplier. This decision tree process results in the following possible outcomes for the supplier qualification state: supplier is qualified, supplier is qualified with restrictions, or supplier is disqualified. The holistic qualification process is used by the company to verify the actual performance of the material and supplier versus the stated performance that was identified during internal alignment activities (Section 4).

Scope

The holistic supplier qualification process is designed to be used by the company throughout the total product lifecycle, and for different triggered reasons, such as: (1) initial qualification of a supplier during product development, (2) when changes occur to the material and/or supplier, and (3) when evaluating existing suppliers and materials throughout the product lifecycle (Section 6). During internal alignment activities (Section 4), the cross-functional team aligns on important requirements for the material (Section 4A) and supplier (Section 4B). The supplier is then engaged (Section 5A) to discuss the requirements and the supplier's ability to meet those requirements, resulting in a short list of suppliers for the company to evaluate. Through the holistic supplier qualification process, the performance capabilities of the supplier are evaluated versus the capabilities that were stated by the supplier during initial supplier engagement discussions.

Background

Historically, supplier qualification has been conducted as a disjointed exercise by various functional groups working independently. Criteria identified by these functional groups to assess supplier performance is limited in scope – often focusing on regulatory and technical criteria, as well as price. Companies and suppliers have indicated that supplier selection failures often occur as a result of examples such as: (1) companies circumvent their own supplier qualification and selection processes, (2) companies do not engage their suppliers as subject matter experts, (3) material variability is not evaluated for impact on the finished product, (4) the criteria against

which suppliers are evaluated are limited in scope, and (5) communication of priorities from the company to the supplier is often conflicting, and not delivered by the point of contact who has the authority needed to resolve questions. This type of outcome is not surprising since the company has historically operated without internal alignment on the criteria needed to ensure the material and supplier are the right fit for the company as a whole, and for the specific product in question.

Companies expend tremendous resources developing, tracking and trending supply chain metrics, developing supply chain risk dashboards, and conducting audits of suppliers. However, all of this activity is typically conducted from the vantage point of one functional area, which creates a myopic view of each supply chain partner. This disjointed approach leaves the company vulnerable to unidentified risks, and to an underperforming supply chain. The company then typically expends more resources to do more of the same activity, and the cycle is repeated.

Through the Good Supply Practices, companies gain cross-functional alignment on material requirements (Section 4A) and supplier requirements (Section 4B), followed by meaningful supplier engagement (Section 5A), such that supply chain risk can be reduced and supply chain performance increased. Specifically, through the cross-functional internal alignment process on material requirement development, the impact of material variability on the finished product is more fully understood such that the necessary supplier capability requirements are identified. Additionally, the following categories from Section 4B are used to identify a holistic set of supplier requirements: (1) Supplier Operating Systems and Business Capability, (2) Relationship Alignment, (3) Quality and Regulatory Compliance Systems, and (4) Supplier Product and Process Technical Capability. By having the cross-functional team determine the relative importance of each criteria within each category, it is more likely that the final list of requirements will robustly represent the best interests of the business, product quality/safety, and the patient.

After the supplier is qualified, the company must continue to assess the total relationship, including self-performance and supplier performance, throughout the total product lifecycle. This process is described in the Lifecyle Management section (Section 6), and should engage the supplier as a subject matter expert to ensure input is gained on the appropriateness of specifications, the ability of the supplier's process to continually meet specifications, suitability of the material for the intended use, and satisfaction from both entities with the company-supplier relationship. Historically, poor supplier performance was assumed to be due to supplier inadequacies. However, the company must recognize the impact of their own procedures, processes and practices on the ability of the supplier to perform to ensure the root cause is truly addressed. Self-Qualification (Section 3E) and Relationship Risk (Section 5C) are to be used in

conjunction with the supplier qualification process to provide the company with a holistic assessment of the source of risk to the business, product and patient.

Process:

Step	Description	Cross-Reference
1	Form Cross-Functional Team to conduct the holistic supplier qualification process	Section 3B
2	Cross-Functional alignment on Qualification Plan	current section
3 or 4	Material Evaluation	current section
4 or 3	Supplier Evaluation	current section
5	Supplier Qualification determination	current section
6	Document all assumptions and decisions in the Supply Chain Intelligence Repository through the Knowledge Management Process.	Section 3C
7	Monitor and review assumptions and decisions on an on-going basis	Current Section

Sequence of activities

The sequence of activities provided in this section is situational and may vary under different circumstances. The actual sequence should be determined during internal alignment and stated in any documents related to the qualification process or plan. For example, some work conducted during the early stages of development may be used as part of the qualification process. Additionally, the order in which suppliers and materials are qualified may vary such that in some cases the company may start reviewing a supplier first, and in other cases, the material. Therefore, it is essential that early work and decisions are well documented (Section 3C).

Cross-functional alignment on Qualification plan

Internal alignment regarding material suitability and holistic qualification of suppliers can only be achieved through the involvement of cross-functional teams (Section 3B). The objective of this alignment is to provide all functions a forum through which to gather sufficient information to make the best possible decisions. The team should agree upon and complete the following:

1. Determination of Target Relationship Level: decided based on the type of material/service and business case, such as Strategic, Critical, Commodity, Leverageable, etc.
2. Develop sourcing strategy and qualification plan including e.g. objectives, activities, timeline, roles and responsibilities etc.

3. Establish a communication strategy as provided in Section 4C such that the cross-functional team agrees upon what information to share with suppliers, how, by whom, and when. The team should work to ensure the suppliers still under consideration are being informed about the qualification process and their status.
4. Determine when to involve suppliers in decision-making, e.g., success factors, setting of specifications, etc.
5. Identify timing of on-site evaluations, how best to consolidate on-site evaluations, and which cross-functional representatives should conduct the conduct the evaluations. The timing of on-site evaluations is situational and need to be discussed with the cross-functional team. Note: it is also possible that some of this work is completed during the supplier engagement stage (Section 5A).
6. During and/or after completion of the on-site evaluation, the team should discuss progress and/or results with the Supplier. Document eventual supplier action items/findings and other supplier commitments. Create and track the agreed upon action plan, and ensure actions are closed. Include specific controls and systems to be implemented and utilized as part of the ongoing management process.

Once the qualification plan is developed by the cross-functional team, then the qualification process can begin.

Holistic Qualification Process – Material and Supplier Evaluation

The short list of suppliers identified through the Supplier Engagement process (Section 5A) should be engaged based on the qualification plan developed above by the cross-functional team. The cross-functional team should evaluate each supplier on the short list by (1) comparing the supplier capabilities against the material requirements identified through internal alignment in Section 4A (refer to the scores established in Appendix 11), (2) comparing the supplier capabilities against the supplier requirements identified through internal alignment in Section 4B (refer to the scores established in Appendix 12), and (3) through discussions with the supplier during supplier engagement (Section 5A). The cross-functional team should use the tools in Appendices 11 and 12 to document how the supplier compares against what the team identified as important. The gaps between desired requirements and actual performance provide an indication of risk to the business, finished product and patients. These gaps will also assist in identifying the most viable supply chain partners; however, final decisions should be based on a comparison of the strengths and weaknesses of the supplier and company through relationship risk mapping as described in Section 5C.

In order to conduct the material and supplier evaluations against desired requirements, the following on-site evaluations may be needed, as determined previously during the internal

alignment process for supplier requirements provided in Section 4B. As previously stated, the timing of the following activities is situational, and may have been completed or determined not necessary. Importantly, the cross-functional team should establish how best to combine as many of the following activities into a single on-site evaluation visit.

1. Supplier Quality and Regulatory Compliance: Quality audit including review of regulatory compliance and an assessment of the quality control laboratory, and testing methods of incoming materials. The assessment should be based on critical material parameters identified during product development and confirmed during the internal alignment on material requirements (Section 4A), and discussed with the supplier during engagement (Section 5A).

   The company and supplier should ensure that the tests to be performed are understood and agreed upon so as to not inadvertently use two different methods (one used by the supplier for release, and one used by the company upon receipt). Both entities should identify any specific equipment that might be needed during material production, incoming receipt, in-process testing and final stages of finished product manufacturing. Additionally, required documentation, testing, and certificates should be identified for inclusion in the material specification.

2. Raw material/Item Verification: Verify that the material fulfills the requirements identified through the internal alignment on material requirements process (Section 4A). If the supplier has not been included in determining the specifications, discuss with supplier and align expectations. Specifications could be included as attachments in agreements signed separately by the supplier to simplify the process if any future deviations would occur. If samples are available, agree upon the scope of work for determining how the material will be evaluated, what work will be done with the material in the finished product (or intermediate stage), and how the material will be evaluated in the finished product.

3. Supplier Technological Capability: Process Audit including technical capability and capacity assessments (e.g. equipment, staff capability and availability). Manufacture trial batches of finished product with the material under protocol to determine if the material is acceptable against preapproved acceptance criteria. If the material and/or supplier is not acceptable, discuss the results with the supplier and options such as:

   - Have supplier modify the material, if possible, and repeat the trials
   - Modify the finished product specifications, if possible, and repeat the trials
   - Identify alternative material and/or supplier and re-initiate the selection process

4. Supplier Social Responsibility: review supplier´s integrity statement or code of conduct to ensure it is aligned with the company's guidelines,

5. Supplier Business Capability and Alignment, and Supplier Operational Capability: Review of business and operational systems and transactional processes, and any other systems required to assess supplier's ability to satisfy selection criteria. Ensure the supplier has the capacity and technical capability to scale up manufacturing of the material according to the forecasted demand communicated to the supplier during the supplier engagement process (Section 5A).

   If not already completed, review the supplier´s financial status (if public) to ensure the supplier demonstrates healthy financial performance. Ensure the supplier has a Business Continuity Management system that provides processes for crisis management and recovery planning to handle incidents that could potentially cause supply disruptions. The outcome of the supplier performance against the identified requirements from Section 4B, along with the supplier's business continuity plan, should provide indication of the need for a second source to be qualified to mitigate the risk of potential delivery disruptions affecting the company and impacting patients. Other risk mitigating activities could also be considered, such as safety stock and improved contract terms.

6. Communication Alignment: review data to be shared by the company and to be obtained from the supplier, discuss point of contact from each entity, critical information needed by each company, timing, and all other expectations and needs.

7. Agreements required: negotiation of agreements required depending on the material/service and business case (Note: these agreements should have been provided to the supplier during the initial supplier engagement stage (Section 5A) such that the agreements can be finalized during the supplier qualification stage).

Supplier Qualification Determination

Once the material and supplier evaluations are complete, the cross-functional team will determine if each supplier meets the requirements needed for qualification versus the desired requirements established through the internal alignment processes in Section 4A and Section 4B. The flowcharts provided in Appendix 16 can be used to guide the cross-functional team towards determining which materials and suppliers are qualified. Importantly, the supplier performance must be viewed in context with the ability of the supplier to consistently produce material that meets the desired requirements. Based on this critical aspect, the flowcharts are designed to assess the acceptability of the material, followed by the ability of the supplier to consistently produce the material in a way that meets specifications and criteria. The flowchart process

results in the following possible outcomes for the supplier qualification state: (1) supplier is qualified, (2) supplier is qualified with restrictions, or (3) supplier is disqualified.

The cross-functional team must assess the strengths and weaknesses of all qualified suppliers against those of the company in order to identify the best-fit supply chain partner. This assessment is conducted through the relationship mapping and final selection process provided in Section 5C.

Supplier Disqualified/Not Qualified:

When a supplier is disqualified after having been qualified, or does not reach a qualified state, all information should be captured in the supply chain intelligence repository (Section 3C) to ensure future decisions regarding such supplier are informed.

Supplier Qualified with Restrictions:

Circumstances exist in which there are no alternative suppliers on the market for a specific material (e.g., unique intellectual property, sole sourced material, suppliers do not supply regulated industry, etc.), but yet the supplier does not fulfill the qualification criteria established by the company. In these circumstances, the company should first investigate alternative solutions, including alternate suppliers and/or different materials. If alternatives are not available, then the cross-functional team should consider escalating the issue to senior management to ensure the appropriate levels of management are informed. A decision to move forward with the supplier should be made after conducting a risk/benefit analysis for the patient/consumer, identifying mitigation actions that could reduce or eliminate risk, and in some cases, contacting regulatory authorities for consultation.

An additional risk assessment should be conducted to decide what level of oversight the company needs to perform to ensure the supplier can be conditionally qualified to ensure that the material specifications are consistently fulfilled, and change control requirements are established. The company could consider one or more of the following control measures based on risk of the supplied material:

- Company to invest in the supplier's people, processes and equipment.
- Company to invest in the quality management systems of the supplier.
- Company to provide man-in-the-plant oversight at the supplier.
- Supplier to provide company with process analytic data in real time during the manufacture of the material to be supplied.
- Supplier to provide production, inspection and test data to company for review and approval prior to material release.
- Supplier to submit representative samples of manufactured materials to company for analysis and approval before shipment of material.

- Company to increase the frequency of on-site surveillance audits of the supplier.

If the supplier is qualified with restrictions, an assessment should be conducted (including audits) during the first year or two of the relationship to ensure the supplier's capabilities are fully understood and to determine if and when the conditions imposed on the supplier can be lifted. If materials are purchased from the supplier on an infrequent basis, this analysis may take longer than 1-2 years.

In some circumstances, a supplier may refuse to allow the company to conduct audits or to customize the manufacturing and testing processes to meet the company's requirements, which results in the company's inability to qualify the supplier. Although there may be no evidence that the supplier is not acceptable, the company is not able to verify the regulatory compliance of the supplier processes and systems, and acceptability of material variability. In these circumstances, most mitigation actions identified above are not possible (e.g., increased audits, man-in-the-plant, receiving information and samples from the supplier, etc.). The company could consider conducting extensive material characteristic testing on initial batches of material so as to identify possible future changes in the material that could lead to impact to the finished product. This extensive testing should be conducted for-cause and at a predetermined frequency.

The management of suppliers qualified with restrictions should be a part of the company´s quality management system for supplier/purchasing controls. All information, decisions, results and assumptions should be documented in the supply chain intelligence repository (Section 3C) to support future decisions regarding the supplier and/or material.

Supplier Qualified:

When the supplier and material satisfactorily meet the requirements of the company, the supplier will be deemed qualified by the company. The company will make a final decision on supplier selection after conducting a map of the relationship risk (Section 5C) between the strengths and weaknesses of the supplier (through the holistic qualification process) and the company (through the self-qualification process in Section 3E). All information, decisions, results and assumptions should be documented in the supply chain intelligence repository (Section 3C) to support future decisions regarding the supplier and/or material. The ongoing performance of the supplier will be monitored by the company following the process outlined in Section 6 – Lifecycle Management.

5C. External Alignment - Relationship Risk Mapping

Purpose:

To establish a mechanism through which a company can overlay the strengths and weaknesses of an existing or potential supplier with the strengths and weaknesses of its own operations across four categories of risk in order to identify the best supplier partners for each supply chain. The goals of this process are fourfold: (1) to choose which supplier best meets the supply chain needs of the company through an informed decision, (2) to monitor the relationship performance of existing suppliers, (3) to identify supply chain partners that offset the weaknesses of the company, and partnerships in which the company can offset the weaknesses of the supplier, and (4) to establish appropriate mitigating actions that address true root cause of each risk for each relationship.

Scope

The relationship risk mapping includes an assessment of company and supplier operations across four categories of risk: (1) Operating Systems and Business Capability, (2) Relationship Alignment, (3) Quality and Regulatory Compliance Systems, and (4) Product and Process Technical Capability. The relationship risk map is developed from the scoring outcome of the Self-Qualification assessment (Section 3E) and the Holistic Supplier Qualification (Section 5B), and must be evaluated by a cross-functional team (Section 3B) to ensure the resulting decisions are robust. The relationship risk assessment can be conducted throughout the total product lifecycle, across the entire supply chain, on legacy supply chains, for the development of new supply chains, and when a change to any supply chain is needed.

Background

Through the research conducted during the development of the Good Supply Practices (Section 2 and Appendix 2), it was recognized that companies often circumvent good supply chain development and management practices due to (1) ease of using suppliers already being used by the company, (2) lack of a cross-functional supply by design process to strategically develop a supply chain that will meet the needs of the finished product, the patient and the business, and/or (3) lack of supply chain processes in general. Most companies recognize that supplier qualification is an expectation of many regulatory agencies, and therefore, have some type of supplier qualification program that varies in sophistication across the industry. The result of the supplier qualification typically leads to the decision on which supplier to choose.

Based on the findings of the Good Supply Practices research, it was recognized that the companies themselves either cause or could prevent all risk in their own supply chain. This realization shifted industry paradigms from solely focusing on qualifying and certifying

suppliers, to discovering the root of risk in their own supply chain practices (see "Self-Qualification" in Section 3E).

The Holistic Supplier Qualification (Section 5B) and Self-Qualification (Section 3E) provide a detailed understanding of supplier and self strengths and weaknesses. Although both the supplier and self strengths and weaknesses can be tracked separately for mitigation and improvement, the power of this information comes through the overlay of the two. For example, since both the supplier and self risks are assessed against the same four categories, then an overlay of the Holistic Supplier Qualification and Self-Qualification scoring outcomes on a spider diagram (Appendix 17) can visually quantify areas of risk in the overall relationship. This powerful process enables the company to choose the supplier that best fits the needs of the company, the product, the patient and the business.

Process:

Step	Description	Cross-Reference
1	Form Cross-Functional Team to conduct the relationship risk mapping process	Section 3B
2	Determine which scores from each category to map onto the relationship risk map from the Holistic Supplier Qualification and Self-Qualification processes	Current Section
3	Create and Understand the Relationship Risk Map	Current Section
4	Final selection of supplier	Current Section
5	Document all assumptions and decisions in the Supply Chain Intelligence Repository through the Knowledge Management Process.	Section 3C
6	Monitor and review assumptions and decisions on an on-going basis	Current Section

A cross-functional team should be developed (Section 3B) to create the relationship risk map in order to ensure the risks mapped to the spider diagram make the most sense for the company, the risks are fully understood, and the final supplier selection includes a diverse perspective across the total enterprise.

Starting with the End in Mind – the Spider Diagram and How it Works:

- As shown in Appendix 17, a spider diagram has spokes that radiate out from the center, where the center is "0", and the value on each line (i.e. spoke) increases in specified

increments up to "100". Based upon the way in which the spider diagram is used for the relationship risk map, the level of strengths of each organization is mapped such that "0" is the lowest score and least desirable, whereas "100" is the highest score and most desirable (if a company chooses to map weaknesses instead of strengths, then lower scores would be more desirable).

- Each spoke represents one of the four assessment categories used in the Holistic Supplier Qualification (Section 5B) and Self-Qualification (Section 3E) processes: (1) Operating Systems and Business Capability, (2) Relationship Alignment, (3) Quality and Regulatory Compliance Systems, and (4) Product and Process Technical Capability.
- On any given spoke, differences between the strengths of "Self" and each "Supplier" can be visually compared quickly and quantitatively. Different colors are used for each entity so as to quickly recognize the differences. Lines can be used to connect the data points on each spoke (as represented in Appendix 17) to show the connectivity of performance of a single entity across each of the four assessment categories.
- The presentation of data in the spider diagram enables the company to determine which supplier best offsets company weaknesses, while identifying areas that might require mitigation to increase the level of performance of the supplier in any particular category.

Determination of Which Scores to Map:

Supplier Scores to Map: Through the Internal Alignment on Supplier Requirements process provided in Section 4B, the cross-functional team worked collaboratively to determine the relative importance of various supplier performance requirements to the product, supply chain and business. These scores were added to the scoring tool provided in Appendix 12 in the "Relative Importance" column. The cross-functional team then scored the actual performance of the supplier against the requirements determined to be important through the Holistic Supplier Qualification process provided in (Section 5B). These scores were added to the scoring tool provided in Appendix 12 in the "Does Supplier Fit Your Need" column. Theoretically, the scores from every requirement could be mapped onto the spider diagram shown in Appendix 17; however, the cross-functional team should determine which supplier requirements are the most meaningful to the company in order to identify which scores to map to the spider diagram. The team should consider which requirements would differentiate supplier performance in a way that might guide mitigation strategies, and/or obviate strengths that would overcome challenges that have been difficult to manage. For illustrative purposes, the supplier scores highlighted in orange in the Appendix 12 tool are the scores that were mapped onto the spider diagram in Appendix 17.

Self Scores to Map: Through the Self-Qualification process provided in Section 3E, the cross-functional team worked collaboratively to assess the performance of the company against

requirements that lead to strong company-supplier relationships. These scores were captured in Appendix 10. Theoretically, the scores from every requirement could be mapped onto the spider diagram shown in Appendix 17; however, the cross-functional team should determine which self requirements would highlight important strengths needed to enable the supplier to supply material that consistently meets the business needs. For illustrative purposes, the self scores highlighted in orange in the Appendix 10 tool are the scores that were mapped onto the spider diagram in Appendix 17.

Create and Understand the Relationship Risk Map

Once the cross-functional team has identified which supplier and self scores would provide differentiating information between itself and the short list of suppliers, the team should map the scores per category onto the spider diagram per entity (i.e. "Self", "Supplier 1", "Supplier 2", etc.) as shown in Appendix 17. Importantly, the scores need to be normalized against the total possible prior to adding them to the spider diagram. For example, if the team chooses to include 2 requirements from the Operating Systems and Business Capability category, and the sum score from those 2 requirements is 18, then the score to map is the percent of the total possible, which is 90%. As a comparison, if the team chooses to include 7 requirements from the Relationship Alignment category, and the sum score from those 7 requirements is 40, then this would appear to be higher than the performance of the Operating Systems and Business Capability category score of 18. However, the percentage of 40 out of a total possible score of 70 is only 57% for the Relationship Alignment, which is clearly weaker than the 90% performance in the Operating Systems and Business Capability category.

Once the spider diagram is created, the cross-functional team can make the final supplier selection by quantitatively comparing the strengths and weaknesses of each supplier against its own strengths and weaknesses on a granular level per category of performance. Here is information that can be gleaned from the spider diagram provided in Appendix 17:

1. Self: the company has a strong quality and regulatory compliance history, it is not strong in product and process technical capability (perhaps a new product type for this company), the operating systems and business capability is average which indicates weakness in forecasting and respecting the frozen period of making changes to the order demands, and the relationship alignment is above average which indicates relative strength in communicating with the supplier in a timely and effective way.

2. Supplier 1: the quality and regulatory compliance history is above average, it has above average product and process technical capability, it is weak in operating systems and business capabilities which indicates limited ability to meet the ebb and flow of order

demands, and is above average in relationship alignment which indicates relative strength in communicating with customers in a timely and effective way.

3. Supplier 2: the quality and regulatory compliance history is weak, it is below average in product and process technical capability, it is above average in operating systems and business capabilities which indicates reasonable ability to meet the ebb and flow of order demands, and is weak in relationship alignment which indicates poor performance in communicating with customers in a timely and effective way.

4. Supplier 3: the quality and regulatory compliance history is weak, it has weak product and process technical capability, it is weak in operating systems and business capabilities which indicates limited ability to meet ebb and flow of order demands, and is strong in relationship alignment which indicates relative strength in communicating with customers in a timely and effective way.

Based on the information provided in the spider diagram the company could make several decisions depending on the situation and the needs of the company. The following examples of how to select the best-fit supplier from the spider diagram are provided to guide the cross-functional teams on how to have robust and meaningful discussions based on the data:

1. Choose Supplier 1: The cross-functional team could choose Supplier 1 if the criticality of technical capability is high to support the success of the finished product. If this decision is made, then the company will need to mitigate the lack of flexibility in capacity and/or inventory management so as to support the ability of the company to keep the product on the market. One such mitigation might be to identify a second source to manufacture a certain portion of the required inventory.

2. Choose Supplier 2: The cross-functional team could choose Supplier 2 if the ability to maintain supply is critical for the company. If this decision is made, then the team can visually see that it will need to support the supplier's quality systems by methods such as investing in their people, processes, equipment, and training, and perhaps providing a man-in-the-plant resource until compliance can be improved. Additionally, on-going meetings with the supplier can be initiated to ensure communication of critical information is timely and effective, while including these requirements in the Quality Agreement.

3. Choose Supplier 3: The investment required to consider selecting Supplier 3 would likely outweigh the benefit of choosing this supplier if alternate suppliers are available. If, however, there are no other suppliers available, then the cross-functional team can use the outcome of the spider diagram to identify mitigation strategies for the poor quality

and regulatory compliance, poor technical capability and poor operating and business capabilities.

Many tools can be used to delineate risks across an enterprise and across entities. The company may choose a tool other than a spider diagram to accomplish a visual quantification of relationship differences, but the spider diagram is provided as a model that is effective and can serve as a thought-starter for companies that might prefer a different approach. Importantly, the tool used should provide a level of granularity that will enable the company to choose the supplier that will best fit the needs of the product, patient and business.

Final Selection of Supplier

Through the use of the spider diagram in Appendix 17, or other comparable tools, the cross-functional team is able to make an informed final supplier selection. Each of the suppliers on the short list that have been evaluated through the Holistic Supplier Qualification process (Section 5B) should have been engaged throughout the evaluation process as described in Section 5A. As a result of this engagement, various agreements and contracts should have been discussed between the company and supplier, such that finalization can be accomplished at this point almost as a formality. Prior to finalization, the following considerations should be made:

- If, as a result of the spider diagram or other, the company has invested in manufacturing equipment/tools placed at the supplier site, it is recommended to have an agreement covering terms regarding ownership, use and service/maintenance.
- The company and supplier must agree upon acceptance criteria for material/services going forward
- The company must develop and share with the supplier any triggers that would result in a change to the qualification status of the supplier.
- Ensure that the required qualification data has been collected, reviewed and approved e.g. material and supplier evaluation requirements, any other relevant questionnaires including e.g. applicable regulatory requirements and certificates, etc.
- Ensure that the Quality Management System and Purchasing Control related activities have been completed according to the company's Quality Management System.
- Add the supplier to the company's Approved Supplier List. Note that a supplier is qualified per material. Controls should be put in place to ensure only qualified materials can be purchased from each qualified supplier.

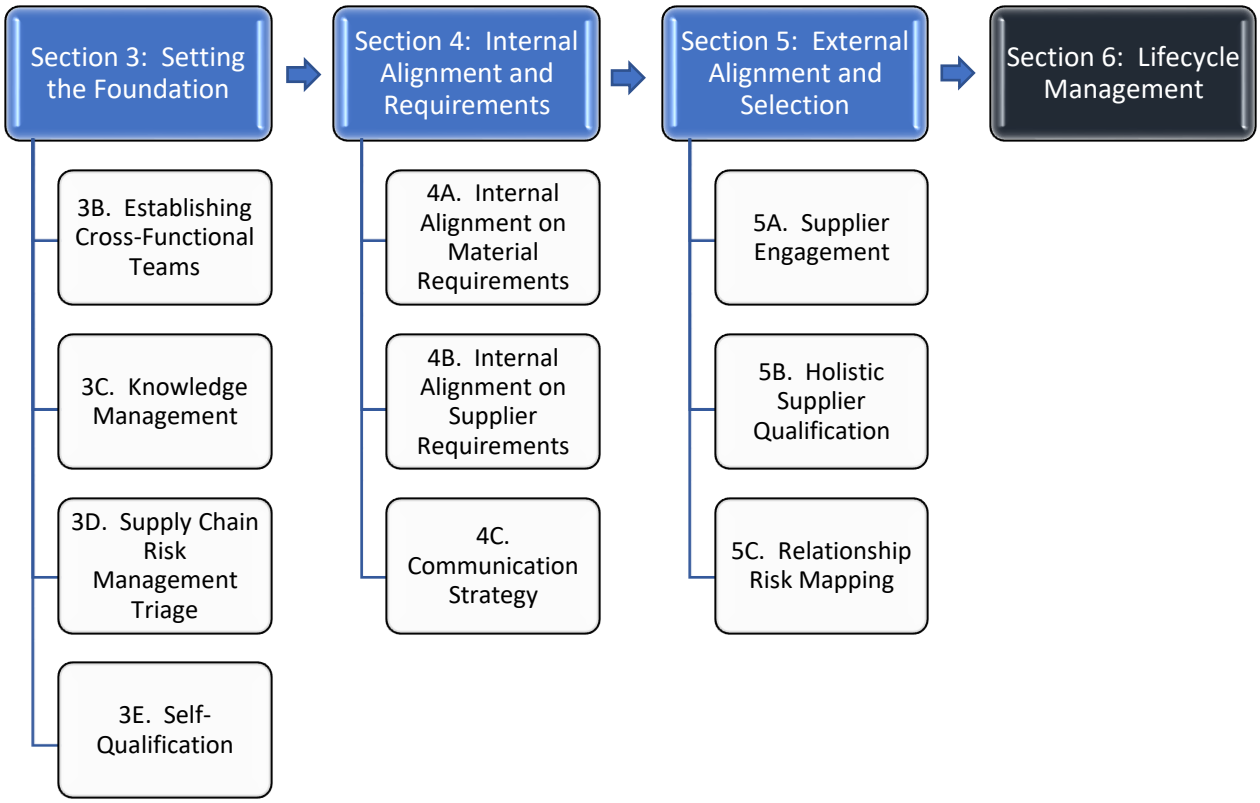
All information, decisions, results and assumptions should be documented in the supply chain intelligence repository (Section 3C) to support future decisions regarding the supplier and/or material. As stated previously, the final supplier selection should be added to the Approved Sourcing List such that informed decisions can be made throughout the enterprise, and across the total product lifecycle, regarding the appropriate use of suppliers. The ongoing performance of the supplier will be monitored by the company following the process outlined in Section 6 – Lifecycle Management.

Section 6: Lifecycle Management

Purpose:

To establish a living process for practical establishment and monitoring of supply chain performance across the total product lifecycle. Refer to Figure 6.1 below as a reference for where the Lifecycle Management activities occur in the overall Good Supply Practices. This process will guide companies through successful use of the Good Supply Practices during development of the initial supply chain, management of changes to the supply chain, and monitoring of supply chain performance on an ongoing basis. Through the documentation of all information, decisions, results and assumptions in the supply chain intelligence repository (**Section 3C**), future decisions regarding the supplier and/or material by any appropriate functional area within the company are supported during any point throughout the total product lifecycle – thus establishing an effective Lifecycle Management process.

Figure 6.1. Organization of the Good Supply Practices.



Scope

The Lifecycle Management process begins with effective development of the initial supply chain in a way that supports the needs of the finished product throughout the intended lifecycle of that product. The criteria established for initial assessment of the material, supplier and self performances are used to determine if changes to the supply chain will be at least as effective as the initial supply chain, and to monitor the performance of the supply chain on an ongoing basis. Effective lifecycle management involves cross-functional team participation and alignment to ensure there is a robust identification and assessment of risks, and a clear understanding of risk impact to the product, patient and business.

Background

The research conducted during the development of the Good Supply Practices (Section 2 and Appendix 2) indicated that companies typically do not establish supply chains through a Supply-by-Design methodology whereby suppliers and materials are chosen through cross-functional alignment against a robust set of critical success factors. The initial establishment of the supply chain is the beginning of the supply chain lifecycle, and is therefore, the foundation to be used by the cross-functional team in assessing all future changes and supply chain performance

monitoring. Often, companies simply "select suppliers" instead of working to "establish supply chains". Historically, this ineffective approach has occurred when companies establish supply chains through disjointed cross-functional efforts (often as hand-offs rather than through alignment), or by having just a select few functional areas identify suppliers based on cost, technical capability and/or quality. The criteria used to identify suppliers by these functional areas often varies, and is dependent upon the expertise of the individuals involved in the process. Through the Good Supply Practices, practical processes are provided for companies to successfully implement intentional Supply-by-Design principles that lead to robust supply chain development.

Once a supply chain is established, companies typically have limited cross-functional involvement in the assessment of changes needed to the material and/or supplier, and even less cross-functional involvement in lifecycle monitoring of supply chain performance. As noted throughout the Good Supply Practices, supply chain performance has historically been assessed solely on the performance of the supplier without recognizing the impact of self-risk on the ability of the supplier to consistently supply materials that meet the needs of the product, patient and business (Section 3E).

The information provided in this section is intended to enable a company to increase the assurance of supply chain success throughout the lifecycle of the product.

Process:

Step	Description	Cross-Reference
1	Form Cross-Functional Team to conduct the lifecycle management process	Section 3B
2	Process for supply chain assessment when a material change is needed	
3	Process for supply chain assessment when a supplier change is needed	
4	Process for supply chain assessment at a predetermined frequency throughout the lifecycle of the product	
5	Document all assumptions and decisions in the Supply Chain Intelligence Repository through the Knowledge Management Process.	Section 3C
6	Monitor and review assumptions and decisions on an on-going basis	Current Section

In order to ensure some level of consistency, the company should consider having high level guidelines established for the individual cross-functional teams to follow when determining functional areas to include throughout the lifecycle of the product, how to determine criteria to assess when changes to a material are needed, how to determine criteria to assess when changes to a supplier are needed, and the frequency at which lifecycle monitoring should occur. The guidelines should enable the teams to determine what is most appropriate for the product and supply chain, but should be directive enough to provide guidance that meets the needs of the company overall.

In general, the functional areas involved in establishing the initial supply chain should determine which functional areas need to be involved in future material changes, supplier changes and for lifecycle management review. The team may determine that only a subset of functional areas needs to be involved for the total process, while maintaining linkage to the remaining functional areas on an as-needed basis. In some cases, small companies may have multiple functional areas combined under a single leader, and thereby continue to involve all functional areas going forward. Importantly, the team should consider how best to maintain involvement from the development technical areas so as to ensure scientific impact to product performance, safety and quality is understood when changes are necessary. The decision of which functional areas to include going forward should be documented in the supply chain intelligence repository (Section 3C) and might benefit from senior level management agreement.

Material Change

A material change may be identified throughout the product lifecycle from a number of sources, such as (1) the supplier notifies the company of difficulties in maintaining the material requirements desired by the company, (2) the supplier notifies the company of new materials available that perform better than the current material, (3) the company recognizes material performance concerns in the finished product, (4) inventory level demand exceeds the availability of the current material, (5) price changes result in researching other materials that might not have been available during product development, etc.

The Lifecycle Management matrix provided in Appendix 4 will guide the cross-functional team through the processes to repeat when a change to a material is needed, as well as the information that should be captured by the team in the supply chain intelligence repository (Section 3C). The information in the matrix is not meant to be all-inclusive, but rather, provides examples of what could be captured by the team. The team will be able to refer back to the associated Good Supply Practice to ensure the processes are repeated properly and in a way that is commensurate with the need. The Lifecycle Management matrix delineates activities for team consideration that might not need to be repeated.

Supplier Change

A supplier change may be identified throughout the product lifecycle from a number of sources, such as (1) the company recognizes supplier performance concerns, (2) the company has new product demands that exceed the capabilities of the current supplier, (3) the company identifies economies of scale by consolidating work under a different supplier, (4) mergers and acquisitions have led to unnecessary supply chain redundancy, (5) market strategy requires location of the supplier in specific geographical locations that the current supplier cannot support, etc.

The Lifecycle Management matrix provided in Appendix 4 will guide the cross-functional team through the processes to repeat when a change to a supplier is needed, as well as the information that should be captured by the team in the supply chain intelligence repository (Section 3C). The information in the matrix is not meant to be all-inclusive, but rather, provides examples of what could be captured by the team. The team will be able to refer back to the associated Good Supply Practice to ensure the processes are repeated properly and in a way that is commensurate with the need. The Lifecycle Management matrix delineates activities for team consideration that might not need to be repeated.

Lifecycle Supply Chain Management

During the development of the initial supply chain, the cross-functional team should determine the frequency for ongoing monitoring of the supply chain based on the complexity of the supply chain, risk of the supply chain, and criticality of the product to the patient and business.

The Lifecycle Management matrix provided in Appendix 4 will guide the cross-functional team through the processes to repeat when monitoring the performance of the supply chain, as well as the information that should be captured by the team in the supply chain intelligence repository (Section 3C). The information in the matrix is not meant to be all-inclusive, but rather, provides examples of what could be captured by the team. The team will be able to refer back to the associated Good Supply Practice to ensure the processes are repeated properly and in a way that is commensurate with the need. The Lifecycle Management matrix delineates activities for team consideration that might not need to be repeated.

All information, decisions, results and assumptions should be documented in the supply chain intelligence repository (Section 3C) to support future decisions regarding the supplier and/or material. This Lifecycle Management process provides the foundation for the company to ensure there is an effective mechanism in place to support the ongoing monitoring of supply chain performance.

Appendix 1: Team Members

The following FDA and industry representatives participated on the Good Supply Practices Team at various times throughout the 2012 – 2018 timeframe. Please note that titles and companies for each person may have changed since the time they were involved in the work.

First	Last	Title	Company
Helge	Batz	Director Materials Management	Boston Scientific
Peter	Beckerman	Deputy Associate General Counsel for Program Review	FDA, Office of the Commissioner
M.	Bhupathy	Senior Director, Global Pharmaceutical Technology	Shire
Rebecca	Bishop	Procurement Manager	Eli Lilly
Dale	Carter	Head of Quality, Business Line Silica, Region Americas	Evonik Industries
Christopher	Claeboe	Director, Contract Manufacturing & Product Management	Codexis
Matthew	Deacon	Director - TS/MS-E.coli Platform API Manufacturing	Eli Lilly
Anthony	Durand	Senior Manager, Quality Assurance	Johnson & Johnson
Hanna	Edstrom-Valsinger	Sourcing Program Leader	GE Healthcare Life Sciences
Troy	Fugate*	Vice President	Compliance Insight
Dave	Gault	Senior Manager Risk, Compliance & Security	CPKelco
Sarah	Geisert	Sr. Director - Head of Global Product Safety and Regulatory	General Mills
Harry	Gill	Vice President	Patheon
Tedd	Green	President	Cook Pharmica LLC
Steve	Greer	Corporate Quality Assurance External Liaison	P&G
Patrick	Henry	Director of Business Development	Puritan Products
Warren	Horton	VP Quality	Patheon
Dale	Huff	Executive Director, Merck Supplier Development & Performance Management	Merck
Cynthia	Ipach	President and CEO	Compliance Insight
Kevyn	Irving	Vice President of Quality	Spineform
Tamima	Itani	Vice President, Global Regulatory Affairs & Regulatory Compliance	Boston Scientific
Todd	Jackson	VP, Supply Chain	Boston Scientific
Elaine	Jai	Supply Chain and Procurement Manager	Eli Lilly

Timothy	Johnson	Senior Director of Quality Janssen Supply Chain	Noramco
Al	Kentrup	Head, Global Quality Compliance and Systems	Takeda
Siek Meng	Khor	QA Director	Teleflex
Mike	King	Director, Supplier Quality - Medical Device & Diagnostics Sector	J&J - Ethicon Endo Surgery
John	Kolenski	Director, Food Safety & Regulatory Compliance	Kroger
Viliam	Kovac	Head of Global Supply Quality	Roche
Michael	Landberg	Strategic Global Sourcing	Boston Scientific
Stephanie	Leonardos	President & CEO	Amerikam
Diana	Lewis	Senior Specialist – Quality	Merck
Neil	Lewis	Global Technical Leader Microbiology Delivery	P&G
Hank	Llamas	VP of Supplier Quality for J&J MD&D	Johnson & Johnson
David	Lowndes	Head of Small Molecule Operations	Shire
Kristen	Lyons	Quality Engineer	Cook
Bei	Ma	Vice President, Global Healthcare Business Development	BSI
Todd	McCandless	Director of Business Development, Central Region	Puritan Products
Will	Mitchell	Corporate Quality Assurance External Liaison	P&G
Glenn	Muldoon	Associate Director, Procurement	Shire
Gwyn	Murdoch	Director, QA-Procurement, Global Quality Auditing and Compliance	Eli Lilly
Paul	Nelson	Vice President, Supply Chain and Project Management	Amring Pharmaceuticals
Mike	Oleksa	Senior Director	Steris
Jonathan	Patroni	Senior Director Quality Compliance Quality Assurance	Shire
Mark	Paviglianiti	Director, Supplier Development & Performance Management	Merck
Shonte	Pettiford	Quality Program Manager	Abbott
Marla	Phillips*	Director, Xavier Health	Xavier University
Gregory	Pierce	CEO	EngiLifeSciences
Payton	Pruett	Vice President, Corporate Food Technology	Kroger
Tom	Roberts	VP Quality Assurance, Corporate Compliance Officer Cook Inc.	Cook Medical
Susan	Rolih	Executive Vice President, Regulatory Affairs and Quality Assurance	Meridian Bioscience
David	Rothenberger	Consultant - QA Procurement	Eli Lilly

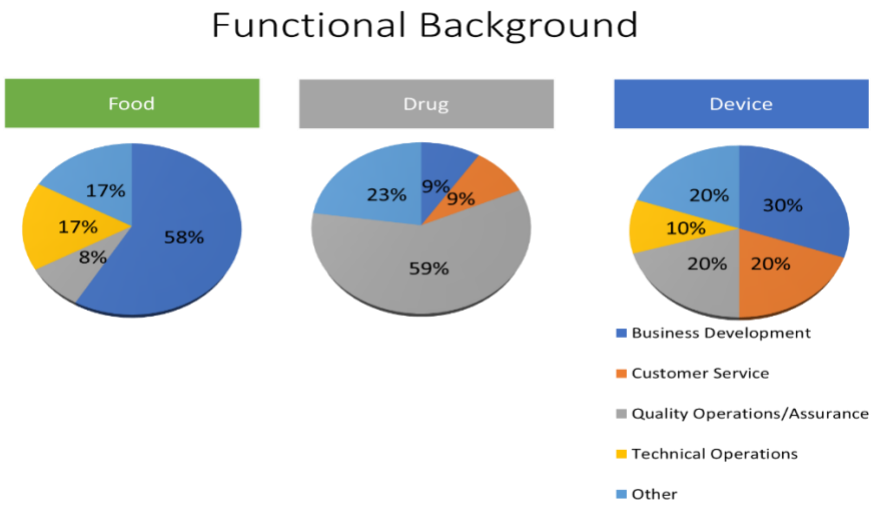
Elaine	Shannon	Senior Director, Global Quality Compliance and Systems – Knowledge Management	Takeda
Michelle	Smith	Senior Director, Regulatory Affairs and Design Assurance	Meridian Bioscience
Jack	Solomon*	Practice Leader, Supply Chain	Core Risks
Steve	Solomon	Associate Commissioner of Regulatory Affairs	FDA, Office of the Commissioner
Ken	Stopar	Director, Supplier Quality - Medical Device & Diagnostics Sector	Baxter
Mani	Sundararaja	VP Global Pharmaceutical Technology	Shire
Kelly	Taylor	Director - QA - Procurement	Eli Lilly
Dirk	Tormans	VP of Supplier Quality for J&J MD&D	Johnson & Johnson
Stelios	Tsinontides	Senior Director, Drug Product Manufacturing Sciences & Technology	Shire
Geert	Van Acker	VP of Purchasing	Baxter
Andre	Warren	Vice President	WLS Enterprises
Sherry	Warren	President	WLS Enterprises
Bonnie	Welshons	Director, Quality and Regulatory Operations	General Mills
Tony	Wiederhold	Consultant - Mfg. Procurement R&D/Manufacturing API procurement	Eli Lilly
Rafiqah	Williams	Vice President Global Quality Auditing and Compliance	Eli Lilly
Steve	Wolfgang	Consumer Safety Officer	FDA, CDER
Don	Zgoda	CQA Supplier Quality Management	P&G

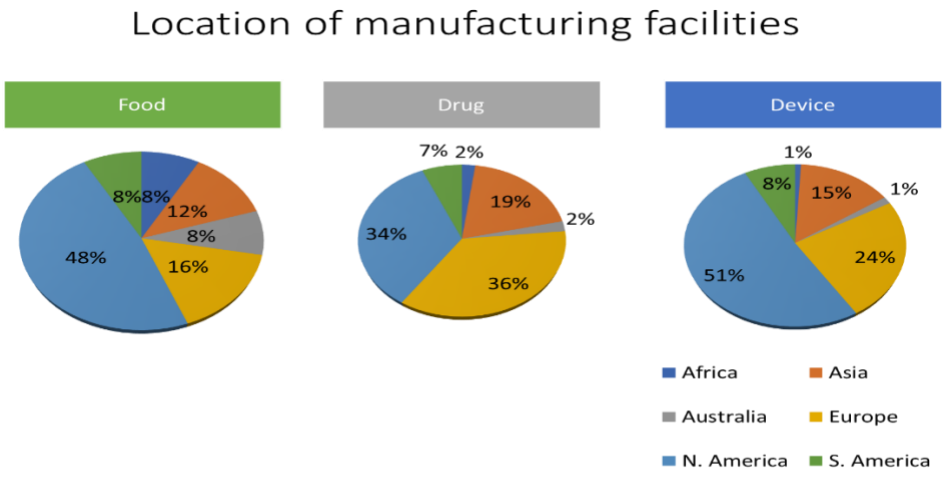
* Denotes Co-Leaders for the Good Supply Practices work

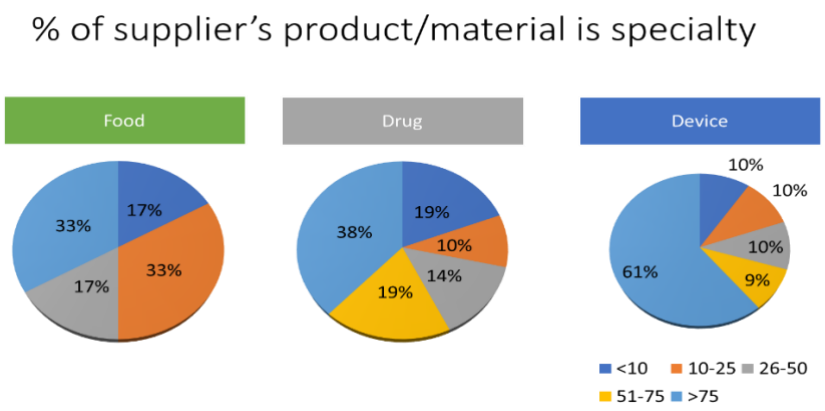
Appendix 2: Voice of the Customer Survey Results

Suppliers were engaged by the team through a Voice of the Customer Survey. Select examples from that survey are provided herein to demonstrate the corroboration of supplier feedback on the gap analysis conducted by the manufacturers themselves.

Demographics of Participating Suppliers (Total Respondents = 162):







Responses to Gaps in Supply Chain Development and Management:

Figure A: The Suppliers indicated that they are willing to share their process capability data with their customers as follows for the drug industry as an example: 45 percent of the drug suppliers indicated they are willing to share their process capability data greater than 75 percent of the time.

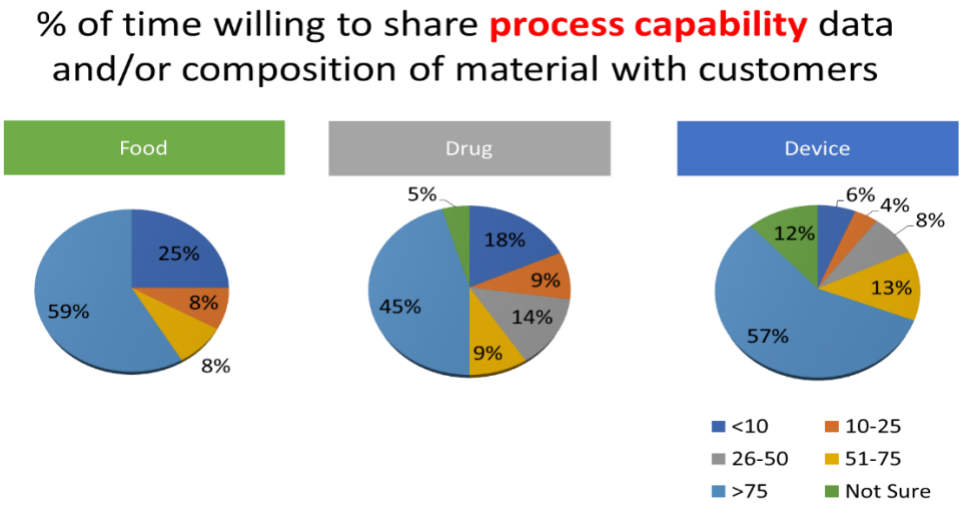


Figure B: The Suppliers indicated that they are largely not asked for their process capability data by their customers. For example, the drug industry only 27 percent of the drug and device suppliers indicated they are asked for their process capability data greater than 75 percent of the time.

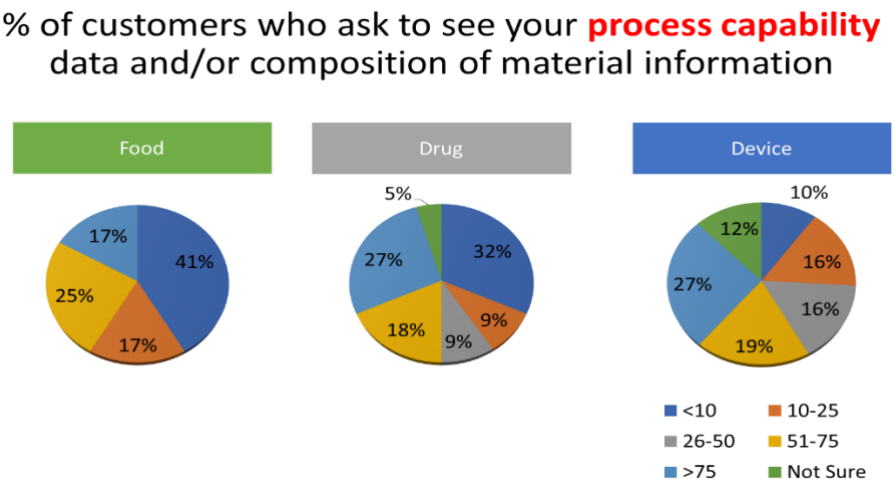


Figure C: The Suppliers indicated that they are largely not asked for input on specifications for their own products/materials, even though they are producing specialty materials (reference the demographic responses) for which they are the subject matter experts. For example, only 30 percent of the device suppliers indicated they are asked for input on specifications greater than 75 percent of the time.

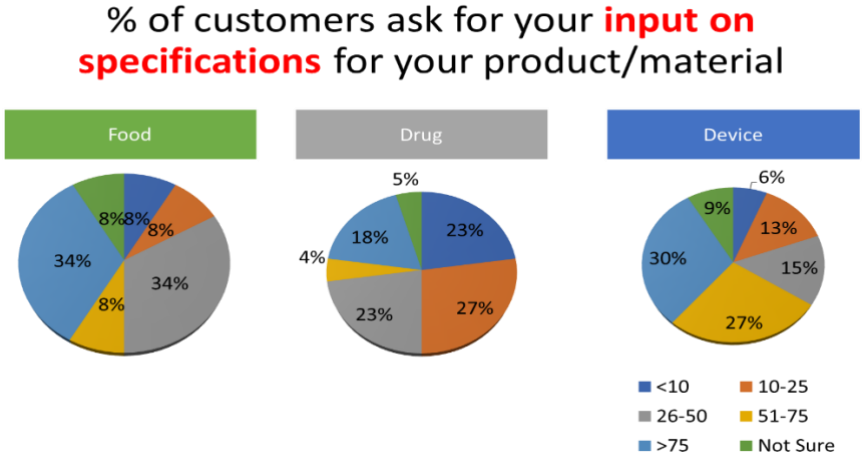


Figure D: Only 25 percent of the food suppliers indicated they are provided enough information about their customer's needs and process to know when it is important to report changes greater than 75 percent of the time. Across the three industries, this seems to be correlated to the amount of leverage the customers have with their suppliers, such that industries with more leverage appear to communicate less with their suppliers.

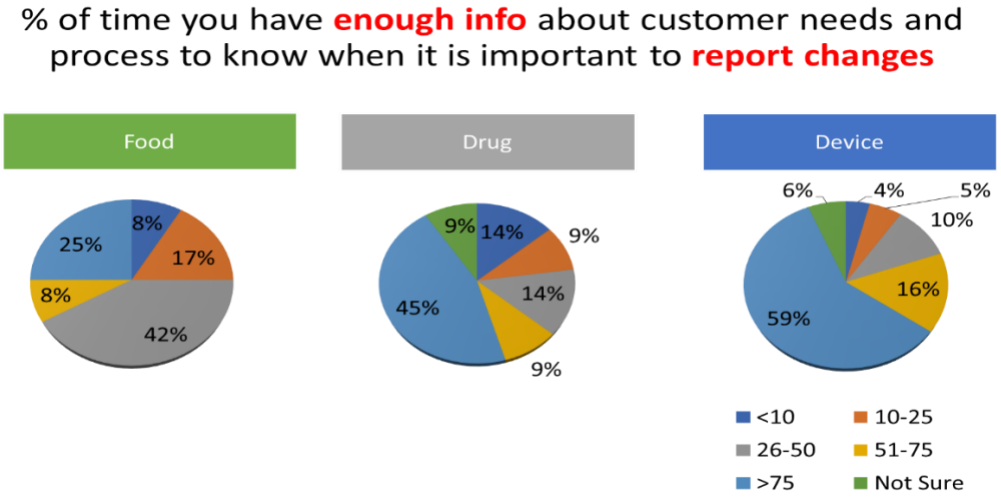


Figure E: The Suppliers largely indicated that they are not given access to the employees within their clients' organizations who have the responsibility, competency, and authority to make decisions. For example, only 23 percent of the drug suppliers indicated they are given this access greater than 75 percent of the time.

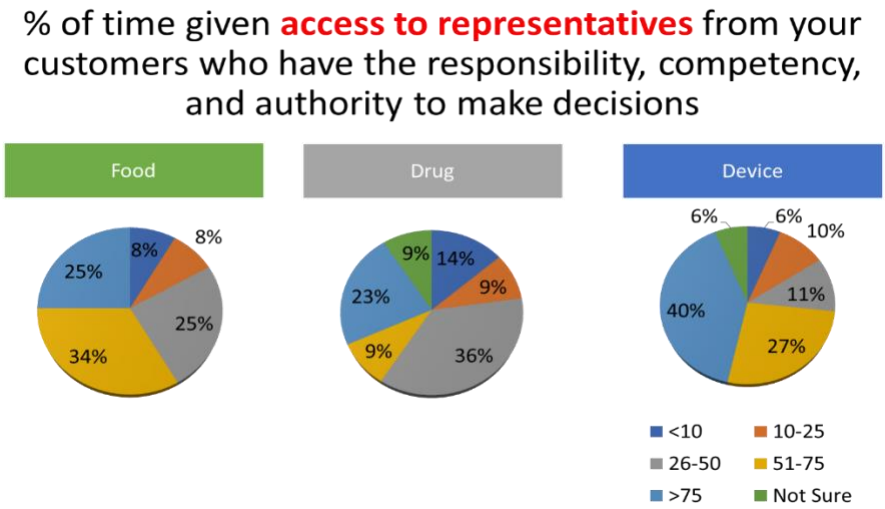


Figure F: A large percentage of suppliers indicated that they do not have Quality Agreements in place with their customers. For example, only 38% of the device suppliers indicated that they have Quality Agreements in place with greater than 75 percent of their customers.

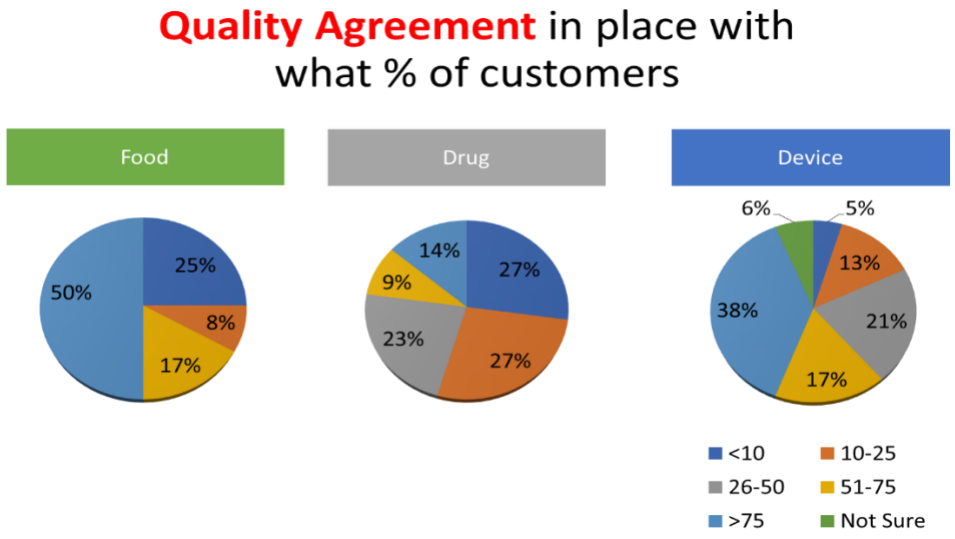


Figure G: Suppliers across all three industries indicated that they do not see that their customers are involving cross-functional team members in their due diligence process. For example, on 9 percent of the drug suppliers indicated they have witnessed their customers involving cross-functional peers greater than 75 percent of the time.

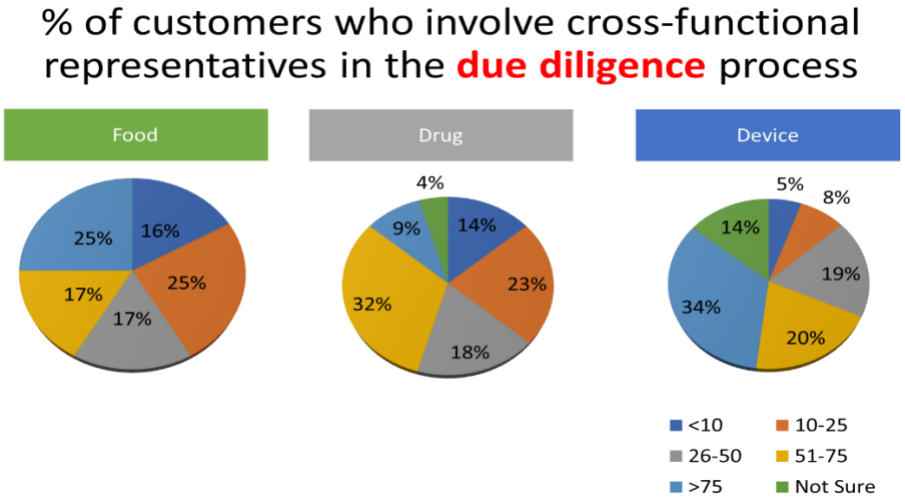
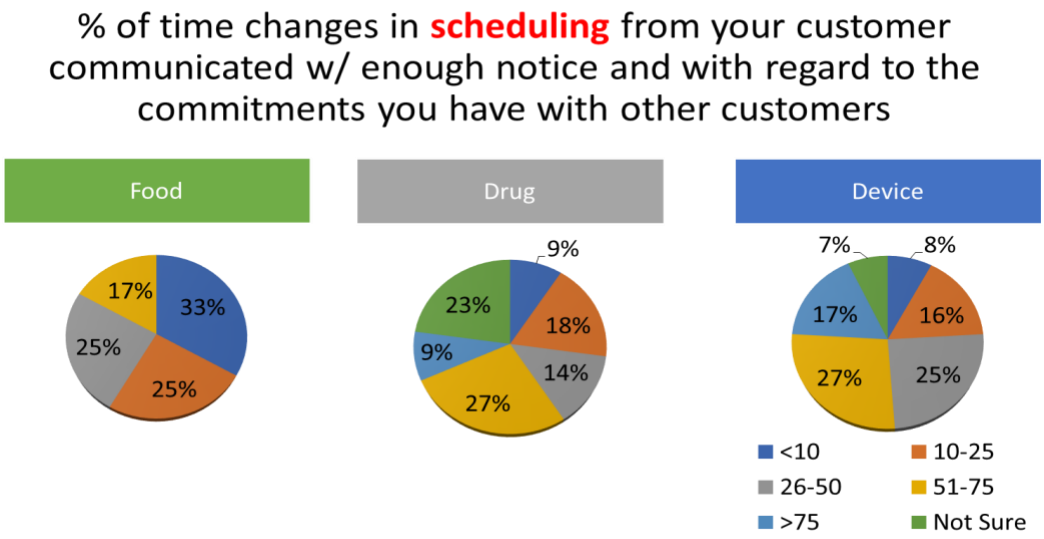
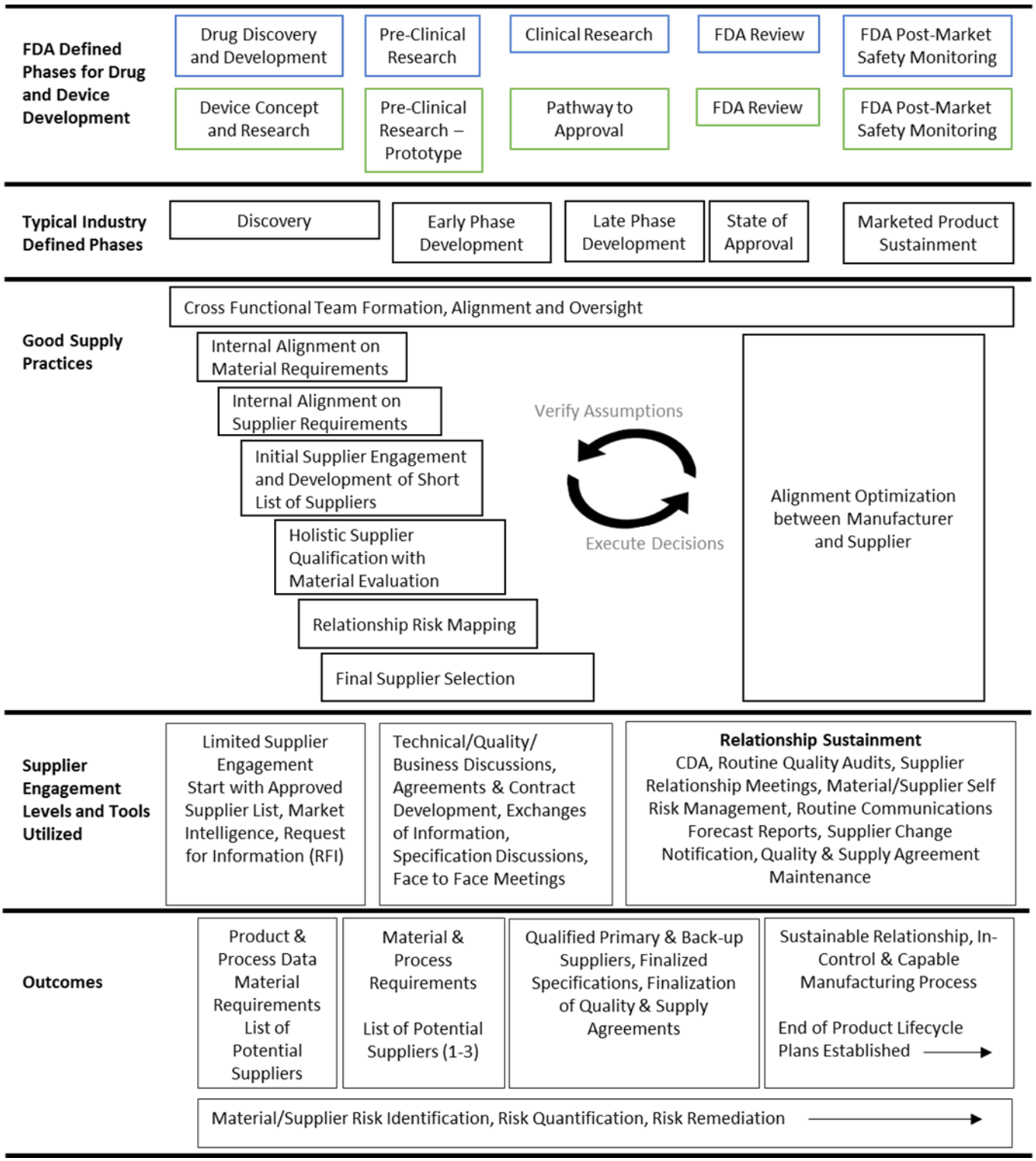


Figure H: Very few suppliers across all three industries indicated their customers communicate changes in scheduling with enough notice and with regard to the commitments they have with other customers. For example, none of the food suppliers expressed that their companies provide this information greater than 75 percent of the time. Only 9 percent of the drug suppliers and 17 percent of the device suppliers responded that their customers provide this information greater than 75 percent of the time.



Appendix 3: The GSP Swim Lanes



Appendix 4: Lifecycle Matrix

GSP Solution	GSP Section	Initial Assessment	Change of Material	Change of Supplier	Lifecycle at Frequency X
Cross-Functional Team Formation for alignment on material requirements	Section 3B	Document functional areas to include	No need to repeat (use same team)	No need to repeat (use same team)	No need to repeat (use same team for the review)
Cross-Functional Team Formation for alignment on supplier requirements	Section 3B	Document functional areas to include	No need to repeat (use same team)	No need to repeat (use same team)	No need to repeat (use same team for the review)
Supply Chain Risk Management Triage	Section 3D	Document risk and impact of the material and supplier	Document risk and impact of the material	Document risk and impact of the supplier	Assess the assumptions and decisions of initial risk categorization
Self-Qualification Risk	Section 3E	Document the risk score per category and overall	May need to repeat depending on the nature of the change	May need to repeat depending on the nature of the change	Risk Score (repeat Self-Qualification at specified intervals)
Internal Alignment on Material Requirements	Section 4A	Document critical material requirements per material	Document critical material requirements for new material	No need to repeat	Conduct review of material performance acceptability per material versus specifications - gain supplier input

GSP Solution	GSP Section	Initial Assessment	Change of Material	Change of Supplier	Lifecycle at Frequency X
Internal Alignment on Supplier Requirements	Section 4B	Document importance rating for each supplier selection criterion per material to source	The cross-functional team should ensure that the current supplier still meets the criteria needed to supply the new material.	The cross-functional team should ensure that criteria initially established is still accurate for the current needs before assessing possible suppliers.	The cross-functional team needs to ensure that the criteria initially established is still accurate for the current needs. This is an opportunity to re-assess the original assumptions.
Outcome of Multi-Sourcing Strategy decision	Vignette	Document number of suppliers needed for each material	Ensure new material is available in quantities to meet sourcing needs.	Ensure new supplier can meet sourcing needs.	Conduct a review of the acceptability of the chosen strategy
Communication Strategy from Manufacturer to Supplier	Section 4C	Documentation of what information is critical to share with each supplier, who shares it and when.	May need to repeat if the new material has special requirements.	May need to repeat depending on the nature of the change, and familiarity/relationship experience with the supplier	No need to repeat, but adjust based on supplier feedback on manufacturer performance.
Communication Strategy from Supplier to Manufacturer	Section 4C	Documentation of what information is critical to receive from each supplier, who needs to receive it, and when it is needed.	May need to repeat if the new material has special requirements.	May need to repeat depending on the nature of the change, and familiarity/relationship experience with the supplier	Conduct a review against acceptability of type and timing of communication from supplier to manufacturer.

GSP Solution	GSP Section	Initial Assessment	Change of Material	Change of Supplier	Lifecycle at Frequency X
Engaging the Supplier	Section 5A	The suppliers are engaged as SMEs to provide input on specifications and material performance for intended use.	The suppliers are engaged as SMEs to provide input on specifications and material performance for intended use.	The suppliers are engaged as SMEs to provide input on specifications and material performance for intended use.	The suppliers are engaged as SMEs to discuss the acceptability of the specifications, process capability and performance of the material. Partnership effectiveness is assessed
Holistic Supplier Qualification - Proof of Capabilities for Material and Supplier	Section 5B	Conduct a material and supplier evaluation based on stated capabilities versus demonstrated capabilities	Conduct a material and supplier evaluation based on stated capabilities versus demonstrated capabilities	Conduct a material and supplier evaluation based on stated capabilities versus demonstrated capabilities	Conduct a review of performance versus the selection criteria
Relationship Risk Mapping of Self and Supplier strengths and weaknesses	Section 5C	Document risk score of each manufacturer/ supplier relationship	Document risk score of each manufacturer/supplier relationship	Document risk score of each manufacturer/ supplier relationship	Conduct a reassessment of the relationship risk based on re-evaluation scores and performance
Final Supplier Selection Decision	Section 5C	Document the supplier selection decision and rationale	Document any supplier selection changes and rationale	Document the supplier selection decision and rationale	Not Needed

Appendix 5: Cross-Functional Team – Contributions and Needs

Functional Areas	Examples of Functional Area's goals affecting Supplier and/or material requirements decisions	Examples of what is needed from Supplier by this cross-functional group	Examples of what this cross-functional group can contribute to the Supplier and material requirements decision process
Technology-development e.g., Research, Development, Concept, Design, Engineering	• Demonstrate feasibility, proof of concept • Hand off to next stage with adequate documentation, stage gate approval • Provide composition of product and ID sources of materials used in development • Time deadlines – therefore availability/speed, robust formulation, efficiency • Establish consistent process goals; cpk's where required.	• Speed • CoA and/or other documentation to support that it meets acceptance criteria and is free of defects • Meets suitable grade of material • Possibly, some level of technical support • Key attributes for the material • Historical lot to lot variation • Input on specifications and potential products which could meet needs.	• Technical expertise • Knowledge of material and product requirements • Timing and impact of delays from conducting more extensive search for unproven supplier and/or material • Historical experience with suppliers of research materials • Input on selection criteria • Provide input on the criticality of the materials and their impact on CQAs. • Input on specifications and whether they need to be tightened based on experimentation. • Information on whether materials are complex to produce and require special supplier capabilities • Whether the material is derived from animal origins

Functional Areas	Examples of Functional Area's goals affecting Supplier and/or material requirements decisions	Examples of what is needed from Supplier by this cross-functional group	Examples of what this cross-functional group can contribute to the Supplier and material requirements decision process
			• Provide input for the sampling regimen if they are trying to monitor impurities, etc…
Technology - launch & commercial support, e.g., Pharm Tech, Engineering, Industrial Engineering, Technical Services, Tech Ops, Process technology	• Batches for demonstration of ability to make product at commercial scale • Time deadlines – therefore availability/speed, robust formulation, efficiency • Spare parts and supplies needed for commercial support	• Speed • CoA and/or other documentation to support that it meets acceptance criteria and is free of defects • Possibly, some level of technical support • Low variability • Control charts or inspection reports demonstrating process capability • Input on specifications and potential products which could meet needs.	• Historical experience with material and suppliers of that material, strictly from processing standpoint, e.g., manufacturability, flow • Identify and evaluate technical capabilities • Packaging as it affects material handling • Historical experience of lot-to-lot variation in critical materials impacting the engineering/validation lots. • Specific training required for consistency • Intellectual Property assessment along with Legal • Requirements for quantities of materials at Launch or post launch.
Quality, e.g., Quality Compliance, Quality Assurance, Lab	• Lab's ability to expediently release material • Department efficiency, not being bottleneck, e.g., zero	• All documentation arrives complete with product delivery; data integrity assured	• Quality terms and conditions to share with supplier early in the process • Negotiate changes to Quality Agreement if necessary

Functional Areas	Examples of Functional Area's goals affecting Supplier and/or material requirements decisions	Examples of what is needed from Supplier by this cross-functional group	Examples of what this cross-functional group can contribute to the Supplier and material requirements decision process
	deviations, no investigations, documentation is good Minimum problems, e.g., recall, adverse event	• Supplier's ability to meet specifications • Supplier's willingness to accept Quality terms & condition, and to sign Quality Agreement, keep Quality Agreement current • Supplier's willingness to support non-conformance investigations and make acceptable corrective actions • Responsiveness to complaints • Communication of change • Participate in 3rd party shared audit program • Supplier's management of their suppliers • Willing to invest in capital to maintain and improve facilities and performance • Ability to protect the product, e.g., warehousing and transportation (including serialization)	• Historical experience with suppliers, e.g., scorecards, previous audit results, CAPA implementation, material receipt history • Confirm specifications provided by technical people meet regulatory requirements • Auditor (or 3rd party) with quality, and possibly technical, expertise to assess suppliers • QA Engineering or Mfg. Engineering to support interface to supplier. May be type specific; plastics, electronics, or may even be language specific to facilitate technical or problem resolution. • Information on any non-standard test methods created for a specific material. • Understanding the supply chain for materials and any inherent risks (including compliance with serialization requirements)

Functional Areas	Examples of Functional Area's goals affecting Supplier and/or material requirements decisions	Examples of what is needed from Supplier by this cross-functional group	Examples of what this cross-functional group can contribute to the Supplier and material requirements decision process
		• Willing to use 'our' tests & methods	
Regulatory – Regulatory Affairs, Regulatory Compliance, Regulatory Operations, Commercial Regulatory Affairs or Compliance	• File by target date • Approval	• Supplier regulatory compliance history and capability • Supplier's Risk Profile • Supplier's willingness to share compliance information, e.g., 483's • Transparency to internal mfg. defects if required.	• Regulatory requirements based on material and finished product • Historical experience with suppliers • Historical experience with SCAR resolution with supplier • Supplier audit performance and management plans
EH&S	• Stay in compliance with Regulatory agencies • No incidents • Key metrics, e.g., Days without accident	• Supplier's capabilities • Supplier's compliance • Impact of material and supplier • Supplier's Risk Profile • Carbon footprint • Safety Data Sheets where applicable	• Identify regulatory requirements • Assurance of supplier's compliance • Audit and/or evaluate supplier • Supplier/material impact on company, e.g., Waste disposal, hazards, Risk class • Environmental impact • Historical experience with suppliers
Sales/Mktg/Business Development/ Customer Svc	• Speed to market • Cost (sometimes) • Continuity of supply • Competitive advantage	• Understand timing in order to create commercialization plans • Supplier's Risk Profile and potential impact on Finished Product	• Timing and impact of Finished Product delays • Forecast of short and long term demand for Finished Product

Functional Areas	Examples of Functional Area's goals affecting Supplier and/or material requirements decisions	Examples of what is needed from Supplier by this cross-functional group	Examples of what this cross-functional group can contribute to the Supplier and material requirements decision process
		• Innovation - differentiation	• Provide market research for Finished Product
Commercial Manufacturing, Production, Operations, Packaging	• Timely deliveries • Efficiency Production cycle times and lead times	• Supplier's capacity & flexibility • Quality • Supplier's Risk Profile • Supplier's Enterprise Risk Management maturity • Supplier capable of supporting development needs, e.g., technical expertise, timing, documentation • Lot size capacity	• Historical experience with suppliers • Packaging requirements • Inspection, Dock to Stock Programs • Requirements for quantities of materials at Launch or post launch.
Purchasing, Procurement, Supply Management, Strategic Sourcing, Commodity Management, Category Management	• Savings on alternate sources – Total Cost of Ownership • Reliability, secure supply able to meet requirements • Support production schedule • Support customers • Support Strategic Supplier commitments	• Proven and successful relationship • Strategically aligned, cultural fit • Economically sound and financially stable • Flexible, ability to meet future demand • Willing to invest in capital • Long term cost structure • Transparency • Supplier's Risk Profile	• Historical experience with suppliers • Keep the focus on Total Cost of Ownership • Negotiate changes to templates, e.g., Supply Agreement, Quality Agreement • Determine type of supplier relationship, e.g., strategic, commodity, etc. • Supplier Risk Profile, Disaster recovery • Supplier Relationship Management • Storage requirements • Potential incoming shipping risks

Functional Areas	Examples of Functional Area's goals affecting Supplier and/or material requirements decisions	Examples of what is needed from Supplier by this cross-functional group	Examples of what this cross-functional group can contribute to the Supplier and material requirements decision process
	• Supplier's capability of acquiring the raw materials An effective MRP system to keep track of the orders and the planning process	• Supplier ethics & social responsibility • Supplier willing to sign Supply Agreement • On time delivery • Ability to protect the product, e.g., warehousing and transportation • Low risk profile • Product security • Willingness to communicate historical or current changes to prints or specifications • Input on container requirements	• Specific container requirements (size, MOC, etc..)
Management of Third Parties, CMO's, CRO's: Supply Chain, Supplier management, Vendor Relationship Mgmt., Strategic Sourcing Mgmt.	• Continuity of supply	• Supplier's Risk Profile • Supplier willing to sign Supply Agreement • Systems/tools required • System capabilities & compatibility • Transparency of the supply chain	• Understanding the supply chain for the materials and any inherent risks.
IT	• No problems • Transaction efficiency	• Systems/tools required	• Cyber security of information • Product cyber security for devices

Functional Areas	Examples of Functional Area's goals affecting Supplier and/or material requirements decisions	Examples of what is needed from Supplier by this cross-functional group	Examples of what this cross-functional group can contribute to the Supplier and material requirements decision process
	• Data accuracy	• System capabilities & compatibility, including serialization • Supplier's Risk Profile	• Serialization compliance and capability
Finance	• Profit: revenue, cost • Cash flow, including inventory, receivables	• Focus on Total Cost of Ownership • Supplier's Risk Profile	• Financial evaluation of supplier • Keep the focus on Total Cost of Ownership
Logistics, incl. warehouse	• Security of shipments, e.g., diversion, weather • Cost • On-time •	• Understand shipping & handling requirements, including serialization • Import/export impact • Supplier's Risk Profile	• Logistics impact of different suppliers and/or regions • Historical experience with suppliers • Total landed costs • Geographic and logistical risks • Assessment of serialization compliance • Space requirements for materials
Legal	• Protection, e.g., Indemnification • Enforceable Terms and Conditions • Unambiguous terminology	• Understand critical requirements	• Determine impact of changes to templates, e.g., Supply or Commercial Agreement, CDA, Quality Agreement • Negotiate changes with supplier
Technical Field Service	• Ability to meet/deliver international requirements	• Supplier's int'l sourcing capability • Technical certification • Packaging for spare parts • Spare parts availability and cost	• Knowledge of support required after sale

Appendix 6: Cross-Functional Team – Team Formation and Scoring

The following instructions are intended to guide companies through the development and implementation of Cross Functional Teams to support the success of the business in a way that is commensurate with the need.

Process:
The Team Leader(s) should involve the cross-functional representatives directly in order to ensure each functional role is accurately represented, instead of relying on assumptions. The tool provided within this appendix and the previous appendix (Appendix 5) should be revised to reflect the actual functional groups within the company using the tool, and to include input from each functional group on their goals, information needed, and information each can provide. Following this process, the tool within this appendix provided below can be used to score the appropriateness of cross-functional involvement and to develop a successful team going forward.

Scoring Process.
Please have each functional area answer the following questions in the tool below:

1. Does this functional group feel their involvement has been missed, or has not been included at the right time during the supplier selection process?
2. Does a representative from this functional group feel they are included in the process at the right time?
3. Score the likelihood of involving each functional group going forward.

Scoring System:
- 10 highly likely
- 7 slightly likely
- 3 slightly unlikely
- 0 highly unlikely

Cross-Functional Team Formation Tool:

Typical Functional Areas	Does the functional group feel their involvement has been missed? (Yes or No per group)	Does the functional group feel they are included at the right time? (Yes of No per group)	Score likelihood of involving each cross-functional group in the Supplier selection going forward (0, 3, 7, 10)
Technology- development e.g., Research, Development, Concept, Design, Engineering			
Technology - launch & commercial support, e.g., Pharm Tech, Engineering, Industrial Engineering, Technical Services, Tech Ops, Process technology			
Quality, e.g., Quality Compliance, Quality Assurance, Lab			
Regulatory – Regulatory Affairs, Regulatory Compliance, Regulatory Operations, Commercial Regulatory Affairs or Compliance			
EH&S			
Sales/Mktg/Business Development/ Customer Svc			

Commercial Manufacturing, Production, Operations, Packaging			
Purchasing, Procurement, Supply Management, Strategic Sourcing, Commodity Management, Category Management			
Management of Third Parties, CMO's, CRO's: Supply Chain, supplier management, Vendor Relationship Mgmt., Strategic Sourcing Mgmt.			
IT			
Finance			
Logistics, incl. warehouse			
Legal			
Technical Field Service			

Appendix 7: Knowledge Management – Supply Chain Intelligence Repository Examples

The supply chain intelligence repository should include information from the Approved Sourcing List (ASL).[2] Importantly, however, the repository should include information that goes beyond minimum cGMP requirements for acceptable suppliers, contractors, and consultants. Examples of information that could be included in the Supply Chain Intelligence Repository through good Knowledge Management practices are as follows (not intended to be an inclusive list):

- Documentation of cross-functional team members to include for alignment on determination of material impact on product and process development
- Determination of attributes deemed critical or non-critical
- Development history reports
- Design of Experiment studies on alternate vendor batches
- Campaign summaries from clinical supply
- Risk assessments related to the criticality of materials/components to the product
- Documentation of cross-functional team members to include for alignment on initial supplier selection criteria requirements
- Determination of overall product risk category and supply chain risk management decisions
- Results from Self-Qualification risk assessment
- Internal alignment on material requirements
    - Document a summary of critical raw material or component attributes and how they were selected during process development.
        - Document different suppliers used during development, any specifications that changed, or key observations from manufacturing during development campaigns
        - Documentation or charting of critical attributes
        - Any changes to the specifications from the vendor or internally
    - Inherent material risk
- Internal alignment on the relative importance of risk-based supplier selection criteria
- Outcome of alignment on multi-sourcing strategy decision
- Rationale and assumptions related to final supplier selection

[2] **Approved Supplier List (ASL):** 21 CFR 820.50(a)(3) states that each manufacturer must "*Establish and maintain records of acceptable Suppliers, contractors, and consultants."* In this GSP, ASL refers to the document containing these records. An ASL identifies all Suppliers that are approved for use by the manufacturer, and the goods/services/locations for which they are approved. This can be utilized within a system to document various stages of Supplier quality management activities throughout the relationship between the manufacturer and the Supplier. The Approved Supplier List is a GMP controlled document.

- Supplier prices
- Communication strategy from manufacturer to supplier
- Communication strategy needed from supplier to manufacturer
- Decisions made through supplier engagement, such as input on specifications of the material to be supplied, intended use, testing methods, etc.
- Results of material evaluation
- Target product profiles
- Control strategies related to material/component criticality
- Results from the holistic supplier qualification and proof of capabilities
- Results from the relationship risk mapping, and decisions made from the map
- Results from Lifecycle review of supplier and supply chain performance
- Complaint history
- Rejection rates
- Specifications
- Analytical specification tests for raw materials
- Changes related to material, supplier, product, process, etc.
- Results from Lifecycle review of material performance, and decisions with suppliers related to suitability of material specifications
- Results from Lifecycle review of product performance
- Master supplier data: key contacts, locations, contracts in place with key notification and renewal dates
- Supplier classification
- Indication that vendor is under evaluation
- Receipt of a quality questionnaire
- Audit/assessment date and frequency of audit/assessment (alternatively, may use evaluation instead of audit/assessment)
- Quality agreement and frequency of Quality Agreement review
- Designation that a supplier is certified or preferred
- Rejection of a supplier from approved list
- Product list
- Capacity
- Capabilities list
- Key Performance Indicators
- Feedback from Manufacturing regarding ease of use, quality, etc.

Information which may be shared with suppliers, created by suppliers, or created along with suppliers:

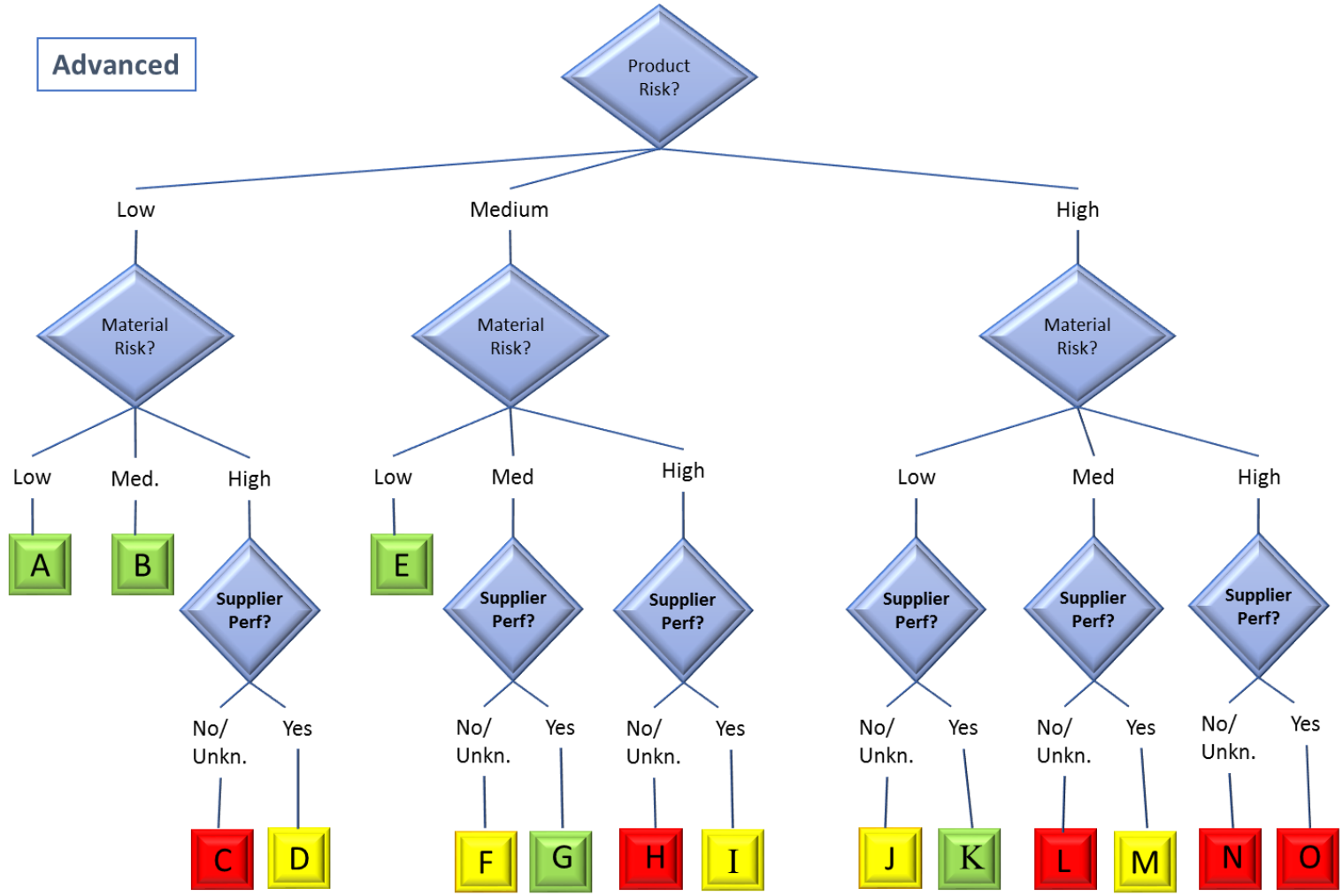
- Supply Chain for the material or component
- Capacity and forecast projections
- Flowchart or diagram of the manufacturer's process
- Control points within the manufacturer's process
- Supplier Risk Assessment

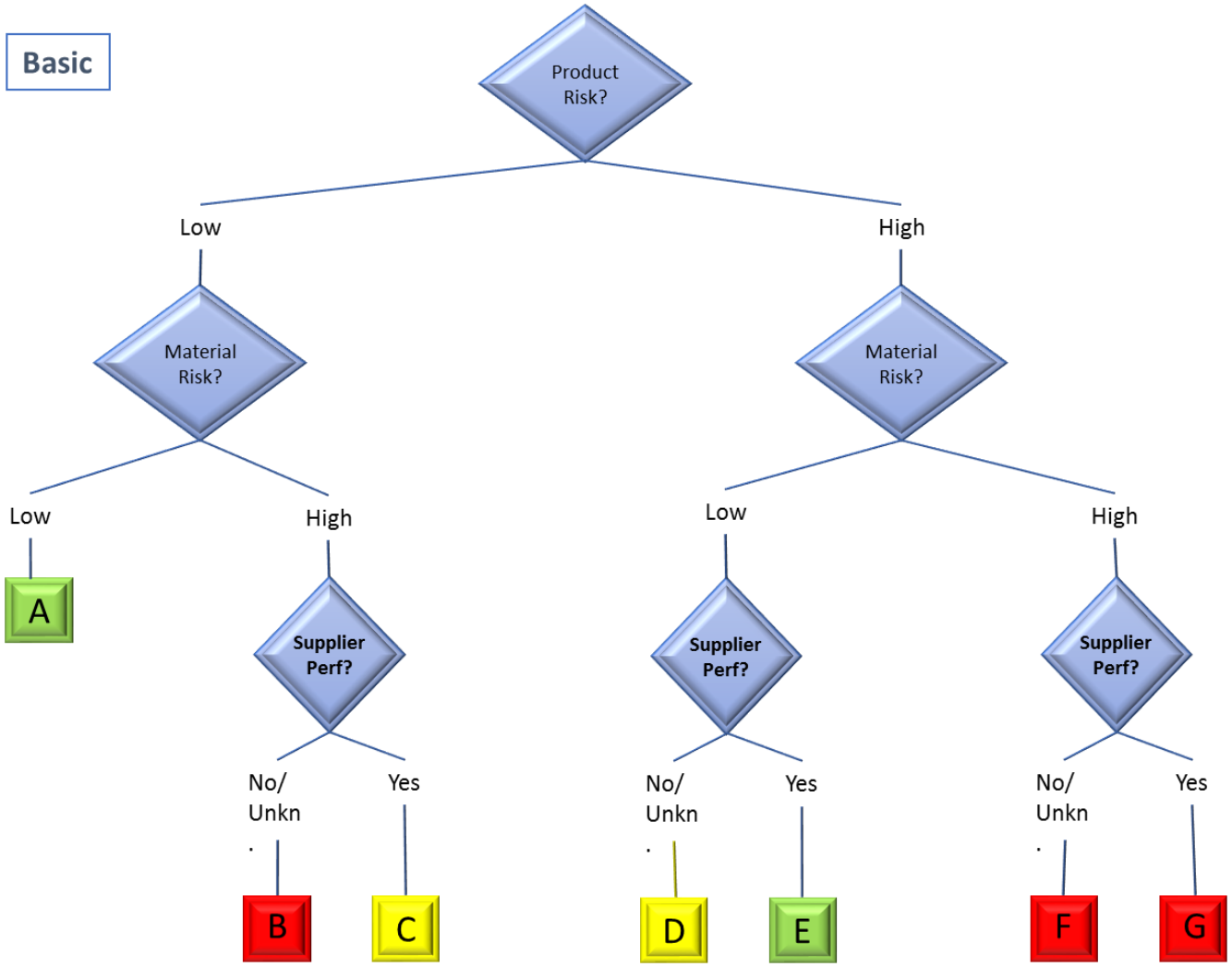
- Risk mitigation commitments
- Supplier relationship management documents
- Supplier agreements
- Changes made to Supply or Quality Agreement Template and explanation
- Communications, meeting minutes, commitments
- Forecasts of demand
- Quality agreements
- Audit reports

External Intelligence to capture:

- Financial performance of various commodities that impact supply of materials
- Supplier company financial performance
- Regulation changes in global regions that impact suppliers
- Natural disasters that could impact supply chain
- Labor laws and violations of those laws by suppliers
- Environmental laws and violations of those laws by suppliers
- Safety laws and violations of those laws by suppliers

Appendix 8: Risk Management Triage Flowchart




Basic
Product Risk?
Low
High
Material Risk?
Material Risk?
Low
High
Low
High
A
Supplier Perf?
Supplier Perf?
Supplier Perf?
No/ Unkn.
Yes
No/ Unkn.
Yes
No/ Unkn.
Yes
B
C
D
E
F
G

Appendix 9: Cybersecurity Risk Awareness

As with any aspect of the supply chain, cyber security is only as strong as its weakest link. Cyber security should be taken into consideration during the supply chain risk assessment process. Therefore, there should be a process in place to assess the risks associated with digital information and electronic equipment as noted below, as well as appropriate mitigation steps taken pursuant to the identified issues. It is important to involve the appropriate subject matter experts (e.g., IT department, software engineers, etc.) in the assessment of these risk factors throughout the supplier engagement process.

Two main considerations for cyber security to be addressed during the supplier engagement process are:

I. **Digital Information**: Cyber security of information that is transferred or stored.
II. **Electronic equipment**: Cyber security controls for electronic equipment and medical devices.

Digital Information Security

Electronic data (including, but not limited to, pricing, processes, formulas, projected dates of product launch, product design, patient data, etc.) is often sent from one site to another site within an organization, as well as between organizations such as with suppliers, customers, and providers. All stakeholders should discuss the appropriate control mechanisms necessary to meet applicable cyber security regulations to prevent illegal access or manipulation of data – including storage of information such as patient names, testing results, etc.. Cyber Security risk assessment considerations should include:

- Manufacturer and user site controls
- Data transfer security
- Supplier controls
- Data storage

All parties involved with assessing supply chain risks must take into consideration the sensitivity of e-data and security controls. Prior to sending data, all stakeholders must be aware of the requirements of cyber security as indicated by the applicable regulatory requirements and company standards.

Electronic Equipment Access Control

In addition to digital information security, further risk assessment evaluations must be taken into consideration when working with electronic equipment/devices (including medical device products used by patients and customers). It should be understood that a medical device can

consist of multiple parts and components which may have an undetected indirect impact on the overall cyber security of the product. Therefore, all stakeholders in the supply chain should identify and assess risks associated with the mechanisms involving, but not limited to, the following:

- Code or functionality manipulation
- Access to the medical device
- Access to other electronic equipment or information/data that could be gained through any part of the medical device

All parties involved with applicable parts/components of the medical device or device interface should understand the importance of secure e-data and access controls.

Post Market Risk

Post market management of cyber security issues (e.g. – software patches) should be in place to involve all applicable segments of the supply chain. Any identified risks must be communicated and mitigated to all impacted stakeholders such that the risk can be minimized and properly mitigated. It is important that suppliers, contract manufacturing organizations, sub-assembly manufacturers, third party software developers and final product manufacturers should have open communication to inform applicable stakeholders of identified or potential cyber security risks. All parties should be aware that vulnerabilities are constantly evolving and the risk assessments and/or testing of the system should be performed at a predefined frequency and for-cause.

Appendix 10: Self-Qualification - Scoring Mechanism

Data has shown that companies contribute to the overall risk in the supply chain by:

- Not understanding their own product and process well enough to be able to scientifically demonstrate what is needed for incoming and final product specifications
- Not having or not following comprehensive supply chain identification and management practices
- Not engaging the right internal and external stakeholders in the discussions at the right time.

As a result, a process has been developed to assess the performance of the companies in a way that will demonstrate overall risk that is drilled down to individual finished products and suppliers.

Scoring System:

- 10 Yes, this is true
- 7 This is often true
- 3 This is infrequently true
- 0 No, this is not true

Note: if there are questions in any of the sections that do not apply to your operations, do not score the question.

Definition of Key Supplier: the term Key Supplier is used in some of the self-qualification questions in order to recognize activities that are to be conducted commensurate with the need. Each company can define what is meant by Key Supplier for its operations, but is intended to include suppliers of critical materials, high and medium risk materials, and functional materials. A raw material that is viewed as a commodity may or may not be identified as a Key Supplier by some companies (for example, it may be a commodity, but might be sole sourced, or sourced from an under-regulated region of the world, or supplier capacity is low, etc.).

Self-Qualification Assessment:

Section 1: Operating Systems and Business Capability		
A	We maintain the Quality Agreement with our Key Suppliers as a living document that we have agreed upon with the supplier, reference throughout the year, discuss during meetings, and assess for needed changes.	
B	The type of relationship needed with this supplier has been agreed upon by a cross-functional team, and this relationship can be achieved.	
C	We respect the frozen period of our suppliers related to scheduling changes.	
D	We communicate a steady, realistic order forecast with our suppliers.	
E	We pay our suppliers on-time and in accordance with agreements made with the supplier in order to support their business needs.	
	Total Raw Score for Section 1 (out of 50)	**0**

Scoring System:	
10	90 – 100% of the time
7	51 – 89% of the time
3	11 – 50% of the time
0	0 – 10% of the time

Section 1 Formula: A + B + C + D + E ≤ 50

Mitigation Plan:

- 40 - 50: No action required, assuming all responses are 7 or higher.
- 21 - 39: Cross-functional awareness escalation and development of mitigation strategies.
- 0 – 20: Immediate Cross-functional action plan development, implementation and mitigation.

Section 2: Relationship Alignment		
F	We have active discussions with our Key Suppliers regarding "intended use" and have documented their feedback regarding the appropriateness of our use of their material.	
G	We have periodic performance meetings with our Key Suppliers to assess the potential for improved results and efficiencies to be gained by both parties (i.e. the performance review includes a measure of our performance and our supplier's performance with metrics that trigger action for improvement). These results trigger action to support supplier development and investment in our supplier when appropriate.	
H	We ensure our suppliers have direct access to the appropriate cross-functional representatives from our business.	
I	We are a trustworthy partner for our suppliers in how we communicate, follow through, and our commitment to the relationship success.	
J	Our communication with our suppliers is sufficient and acceptable to our suppliers in order to support their ability to supply us consistently and effectively with the material needed to ensure the success of our final product.	
K	We respect the business of our Key Suppliers by understanding the profit margin they need in order to maintain their business (e.g., through should-cost analyses* or similar methodologies), and are able to articulate the benefit(s) of our business to them.	
L	We have a process of gaining evaluations of our own performance from our Key Suppliers, and have a documented response process (CAPA) back to those Key Suppliers.	
	Total Raw Score for Section 1 (out of 70)	**0**

Scoring System:	
10	90 – 100% of the time
7	51 – 89% of the time
3	11 – 50% of the time
0	0 – 10% of the time

Section 2 Formula: F + G + H + I + J + K + L ≤ 70

Mitigation Plan:

- 60 - 70: No action required, assuming all responses are 7 or higher.
- 26 - 59: Cross-functional awareness escalation and development of mitigation strategies.
- 0 – 25: Immediate Cross-functional action plan development, implementation and mitigation.

Section 3: Quality and Regulatory Compliance Systems		
M	Our supplier selections are approved through an established process that involves cross-functional team alignment.	
N	We have systems in place to ensure our Supplier's technological capability is acceptable and sufficient to support our business based on the supplier selection requirements we established. [Compare against the criteria outlined in the internal alignment on supplier requirements section]	
O	We have systems in place to ensure our Supplier's quality and regulatory compliance is acceptable and sufficient to support our business based on the supplier selection requirements we established. [Compare against the criteria outlined in the internal alignment on supplier requirements section]	
P	We have systems in place to ensure our Supplier's business capability is acceptable and sufficient to support our business based on the supplier selection requirements we established. [Compare against the criteria outlined in the internal alignment on supplier requirements section]	
Q	We have systems in place to ensure our Supplier's operational capability is acceptable and sufficient to support our business based on the supplier selection requirements we established. [Compare against the criteria outlined in the internal alignment on supplier requirements section]	
R	We have systems in place to ensure our Supplier's social responsibility is acceptable and in alignment with our expectations based on the supplier selection requirements we established. [Compare against the criteria outlined in the internal alignment on supplier requirements section]	
S	We have the resources necessary to execute our supplier audit schedule as planned.	
T	We have the resources necessary to close supplier investigations on-time with scientifically sound investigations and corrective action plans.	
U	We have the resources necessary to close supplier audit findings on-time.	
V	We implement knowledge management practices in a way that provides access to employees across our organization to historical and real-time decisions made, rationale used, studies conducted, and failures that occurred.	
W	We have shared objectives across functional groups that enables our organization to work together collaboratively for the common good of the patients/customers we serve, and for our business.	
	Total Raw Score for Section 1 (out of 110)	**0**

Scoring System:	
10	90 – 100% of the time
7	51 – 89% of the time
3	11 – 50% of the time
0	0 – 10% of the time

Section 3 Formula: M + N + O + P + Q + R + S + T + U + V + W ≤ 110

Mitigation Plan:

- 90 - 110: No action required, assuming all responses are 7 or higher.
- 31 - 89: Cross-functional awareness escalation and development of mitigation strategies.
- 0 – 30: Immediate Cross-functional action plan development, implementation and mitigation.

Section 4: Product and Process Technical Capability		
X	Our process control ranges and product specification ranges are supported by data and/or have scientifically sound justification.	
Y	Our technical transfer for process and/or analytical/test methods meet predetermined protocol requirements first time.	
Z	Our product is manufactured during commercial production without failures related to product and/or process development inadequacies.	
AA	Our products have no complaints in the field related to product and/or process development inadequacies.	
BB	We understand the process capability of our key suppliers for their manufacturing process, and have action limits around that process capability.	
CC	We discuss with our Key Suppliers the appropriate specifications to have in place for their material, and have documentation to demonstrate the suppliers' agreement with those specifications.	
	Total Raw Score for Section 1 (out of 60)	**0**

Scoring System:	
10	90 – 100% of the time
7	51 – 89% of the time
3	11 – 50% of the time
0	0 – 10% of the time

Section 4 Formula: X + Y + Z + AA + BB + CC ≤ 60

Mitigation Plan:

- 50 - 60: No action required, assuming all responses are 7 or higher.
- 26 - 49: Cross-functional awareness escalation and development of mitigation strategies.
- 0 – 25: Immediate Cross-functional action plan development, implementation and mitigation.

Appendix 11: Material Risk - Scoring Mechanism

The following instructions are intended to guide companies on how to identify meaningful material requirements. This process should be conducted by a cross-functional team working together to align on the holistic requirements that are important to the product, patient and company.

Section A: The process.

1. Form a cross-functional team through which to conduct this assessment following the process developed in Section 3B.
2. The tool provided within this appendix will guide a company through assessing the readiness of processes in place to identify, manage and control material requirements.
3. The team should review the questions related to each process, then identify if the company has that process in place.
4. If a process is not in place at a company, then the team should score the likelihood of implementing that process as suggested, using the scoring definitions outlined below.
5. The team should work to identify any barriers that might exist to implementing the processes as suggested, so as to ensure the process is adequately supported.

Scoring Process: As a team, rate the likelihood of implementing the processes as suggested.

Scoring System:

10	Already implemented
7	Willing to implement, but there are barriers
3	Maybe, but there are barriers
0	Not at all

Output

- The team can use the output of this tool to identify which processes need to be established to support the ongoing success of material identification, management and control.

Material Assessment Process Category	Questions	Background	Response	What is the likelihood of Implementing as suggested (0, 3, 7, 10)?	What barriers exist to implementing as suggested?
Existing Tools/ Historical Knowledge	Are historical documents being reviewed by a cross-functional team prior to selecting materials and specifications? If so, which historical documents are being reviewed prior to selecting potential vendors? For example, is there an Approved Sourcing List?	Information/Guidance on the materials is available. For example, lessons learned or positives/negatives for the materials and associated specifications is detailed in a way that is easily searchable/retrievable. An Approved Sourcing List details which suppliers have been used in the past and what materials they have supplied.	Yes or No? If Yes, which documents?	0, 3, 7 or 10	
Risk Assessment	Is a risk assessment performed on each material prior to early phase development?	A risk assessment to look at various risks with Procurement, Technical Services, Quality, and others will help to determine what risks exist and may help shape which suppliers are evaluated. It is important to conduct this as early as possible.	Yes or No?	0, 3, 7 or 10	

	Is a Cross-Functional Team involved in the Risk Assessment of materials?	A cross-functional team can help evaluate risks from multiple angles. For example, Technical Operations may have previous experience with a supplier which demonstrated a lack of process controls and oversight of key specifications.	Yes or No?	0, 3, 7 or 10	
	As part of the risk assessment, does the team look at how EACH material may contribute to the critical quality attributes of the product?	Understanding the end in mind helps the team begin the process of setting specifications for their materials.	Yes or No?	0, 3, 7 or 10	
	Prior to early phase development, does the cross-functional team align on whether special characteristics or requirements are needed, such as a special grade of material that might be required?	Understanding the specific requirements desired helps the team begin the process of setting specifications for their materials. The team could be looking at specific product/process requirements such as: tolerance, grade, micronization, and bacterial load.	Yes or No?	0, 3, 7 or 10	
	Does the team assess whether the material requires unique or special supplier capabilities?	Are there suppliers who can supply the specialized material? Additionally, does the material even exist; it might require investment into suppliers to develop the material, etc.	Yes or No?	0, 3, 7 or 10	
Documentation	Is historical information from the supplier reviewed to determine if the supplier can consistently maintain the specification?	Data analysis, if available, can help determine which suppliers can meet specifications.	Yes or No?	0, 3, 7 or 10	

	Is a list of materials documented which the team feels need to be controlled to ensure CQAs are met?	As a deliverable of the risk assessment, a final list of materials should be available. These materials will need further discussion to determine the specifications.	Yes or No?	0, 3, 7 or 10	
	Are mitigation and contingency plans documented based on the identified risks?	In some cases, tighter/custom specifications may not be warranted. There may be other ways to handle the risks listed (more safety stock, strategic suppliers, etc.…)	Yes or No?	0, 3, 7 or 10	
	Are the risk assessment, historical information, and material requirements captured and documented? If so, describe how the information is stored and retrieved.	The rationale behind why specific vendors were considered, materials which need greater oversight, or the risks inherent to the materials, should be easily retrievable for future discussions/registrations.	Yes or No? If Yes, Where?	0, 3, 7 or 10	
Testing Criteria/Specifications	Is alignment on the testing criteria for every material achieved with the technical team prior to early phase development? Why or why not?	Technical resources understand the process and why specific tests may need more oversight/specifications.	Yes or No?	0, 3, 7 or 10	
	Are sampling regimens determined with a cross-functional team prior to the material evaluation and suitability studies?	Depending on the risks of the material, different sampling regimens may be required.	Yes or No?	0, 3, 7 or 10	

	Are the specifications for the materials determined through a technical assessment and risk evaluation with a cross-functional team prior to material evaluation and suitability studies?	Specifications should not be copy and paste exercises from the CoA. There should be thoughtful discussions around which ones are chosen and why.	Yes or No?	0, 3, 7 or 10	
	Is the grade of the materials determined through a technical assessment and risk evaluation with a cross-functional team prior to material evaluation and suitability studies?	There may be some grades of material that are more readily available than others.	Yes or No?	0, 3, 7 or 10	
	Are the specifications determined/established along with the supplier prior to the material evaluation and suitability studies?	The supplier may not be able to commit to reliably and consistently providing materials with the specifications under consideration.	Yes or No?	0, 3, 7 or 10	
	Once the material specification is determined, are changes to the specification (prior and/or post launch) discussed with the supplier for input on suitability and capability, etc.	As more information is gained during process development, some risks may be reduced, added, or increased. This should have a direct bearing on the materials and their specifications.	Yes or No?	0, 3, 7 or 10	
	Can the specifications be adjusted to make it easier for supplier(s) meet the requirements without affecting	Sometimes specifications are like wish lists that have room to be adjusted, making it easier for more suppliers to consistently deliver on spec materials.	Yes or No?	0, 3, 7 or 10	

	the performance of the material?				
	Are the material specifications supported by lab/pilot experimentation data and information (for ex: Design of Experiment studies)?	Studies can reveal process parameters that impact the output quality of an intermediate or product	Yes or No?	0, 3, 7 or 10	

Appendix 12: Internal Alignment on Supplier Requirements - Relative Importance Rating

The following instructions are intended to guide companies on how to identify meaningful supplier selection requirements for use in building and maintaining a successful supply chain. This process should be conducted by a cross-functional team working together to align on the holistic requirements that are important to the product, patient and company.

Section A: The process.

1. Form a cross-functional team through which to conduct this assessment following the process developed in Section 3B.
2. Internal Alignment on Supplier Requirements (Section 4B):
    a. Review the supplier requirements provided within this Appendix to determine any deletions, revisions and additions necessary to ensure the requirements are relevant to the company.
    b. Identify for which material you want to identify a supplier using the supply chain risk management triage methodology provided in Section 3D.
    c. For every selection criteria example provided in the tool, determine as a cross-functional team what the relative importance is of that criteria in the selection process for the material used in the finished product. Use the scoring definitions outlined in "Step 1" below to add the score to the "Relative Importance" column in the tool.
3. Holistic Supplier Qualification (Section 5B):
    a. Evaluate a supplier for your finished product to determine how well that supplier fits your identified needs based on what you indicated is important.
    b. Use the scoring definitions outlined in "Step 2" below to add the score to the "Does Supplier Fit Your Need" column in the tool.

Step 1: As a team, rate the relative importance of each selection criteria in the selection table. Rate each risk element in each section using the following scoring system.

Scoring System:

10 Critical
7 Important
3 Slightly Important
0 Low Importance/Not Relevant

Step 2: As a team, rate how well the supplier performs against the importance ratings you identified in Step 1. [Note: the orange boxes in the tool represent the scores that are carried over to the relationship map explained in Section 5C]. Again, rate each example in each section using the following scoring system.

Scoring System:

10 Very well aligned
7 Mostly aligned
3 Slightly aligned
0 Poorly aligned

Output

- This assessment can be conducted when developing a new supply chain, making a change to a supplier, making a change to a material to ensure the supplier selection is still adequate, and when conducting a lifecycle review of supplier and supply chain performance.
- A comparison of the relative importance score versus the supplier performance will enable each company to identify possible supplier candidates that are viable.
- Supplier decisions should only be made after comparing the supplier strengths and weaknesses to those of your company. Through the Relationship Risk mapping process provided in Section 5C, your company can identify the supplier that best meets the needs of your product, supply chain and business.

Selection Criteria Category	Examples of Criteria to Include	Relative Importance? 10 Critical 7 Important 3 Slightly Important 0 Low Importance / Not Relevant	Does Supplier fit your need? 10 Very well aligned 7 Mostly aligned 3 Slightly aligned 0 Poorly aligned
Supplier Operating Systems & Business Capability	Able to support speed to market		
	Lead-time for development work meets our needs		
	Flexibility: Ability to respond to changes in demand and/or specifications, e.g., facility, labor		
	Breadth of product line to supply different materials – potential for partnership alliance and supply chain efficiency		
	Importance of Total Cost of Ownership (unit price, plus indirect costs, such as shipping, potential failure and mitigation costs based on risks, testing, importation fees, etc.) compared to other criteria		
	Long term operational and financial viability – low debt, profitability, diversity of clientele, multi-year business plan, investment in operations, etc.		
	Not a competitor		
	Demonstrated successful history/familiarity with the supplier		
	Location (environmental scan end-to-end, time/conditions in transit, detainment in import, etc.)		
	Inventory strategy aligned with the need, e.g., Vendor Managed Inventories, Maintain Inventory, Postponement strategies		
	Supplier demonstrates application of cross-functional processes		
	Vertically integrated (versus outsourced operations)		
	Supplier is capable of protecting confidential information		

	Transaction efficiency: Manual vs. automated business systems, single point of contact, E-commerce		
	Current capacity is acceptable		
	Future capacity is acceptable		
	On-time delivery		
	Lead-time for commercial product meets forecasting demands and accuracy		
	Supplier has acceptable systems and practices to manage operations, e.g., purchasing, manufacturing, inventory.		
	Scale of supplier's business is aligned with our needs/requirements, e.g., not too big that supplier does not care about our requirements		
	Supplier has acceptable systems and practices to manage Enterprise Risk Management (ERM), including Business Continuity, Disaster Recovery, Cyber Security and supplier risk management.		
Relationship Alignment	Social responsibility practices are acceptable, e.g., Sustainability, diversity		
	Willing to participate in periodic technical and business reviews		
	Direct access to technical staff is given to us		
	Need to have involvement in, or understanding of, selection of tier 2 suppliers		
	The supplier is willing to share information we need regarding quality and compliance. NOTE: it is important to list the specific information needed, e.g., Quality Policy, Regulatory filings, stability protocol and results.		
	Meets the Strategic need for: Company Culture, Commitment, Trust, Confidentiality/values, Transparency		
	Effective, timely and relevant communications		
	Willing to agree to terms of Supply Agreement		
	Shares intelligence: market, technical (improvements and new products), regulatory		
	Willing to sign Code of Conduct/ Integrity statement		

	Willing to share metrics/KPI's		
Quality and Regulatory Compliance Systems	Quality System Compliance Information meets our requirements. NOTE: it is important to list the specific information needed, e.g., Quality Policy, Regulatory filings, stability protocol and results, change control.		
	Material traceability is possible for root cause analysis and recall capability, etc.		
	Quality Agreement: The supplier is willing to enter into a Quality Agreement		
	Non-FDA System Compliance Information The supplier has systems to control and is compliant with requirements for: - REACH - RoHS - GHS - Controlled Substances - Transportation - Environmental, Health and Safety - Ethics and Labor requirements - Anti-terrorism procedures are acceptable - Other:_____		
	Supply and Purchasing Quality & Compliance Controls. The supplier has acceptable Quality & Compliance systems to control their supplier selection practices: - Supplier Selection Program - Supplier Qualification Program		
	Validation. The supplier has acceptable systems to ensure validation of methods, process and facility		
	Possesses specific technical expertise, process capabilities and experience		

Supplier Product & Process Technical Capability	The supplier has demonstrated process improvements to afford future economies of scale to support price negotiation opportunities for ongoing win-win		
	Packaging type meets the business needs (amount of material needed, type of package needed)		
	Ability to handle hazardous material		
	The supplier has demonstrated sustained expertise with the processes and equipment needed to manufacture the desired material.		
	Overall Total Scores (Total Possible = 430):	0	0
	% Total Score out of Possible:	0	0

Appendix 13: Communication Strategy for Customers

The following instructions are intended to guide companies through the development and implementation of a Communication Strategy that is suitable for each supplier relationship.

Data has shown that the manufacturers contribute to the overall risk in the supply chain by:

- Not adequately communicating product or process needs
- Not having, or not following, comprehensive supply chain identification and management practices
- Not engaging the right internal and external stakeholders in the discussions at the right time

As a result, the process described herein is designed to assist in the development of an effective communication strategy that will demonstrate overall benefit and risk that is drilled down to individual finished products and suppliers. Additionally, this process can be used to assess existing relationships to determine the appropriateness and effectiveness of information already being communicated.

If you are looking for a place to start, consider the following approach.

Choose Raw Material Suppliers, Component Suppliers, or Contract Service Providers. Consider choosing at least two and preferably 3-5 raw material or component suppliers to assess and one or more Contract Service Providers (such as CMO, contract lab, or other contract service). The ideal evaluation would allow the company to explore the dynamics around some of the following supplier aspects:

a. One that is a current satisfactory supplier for at least one material or component.
b. Single source supplier of a raw material or component
c. One that is a currently considered to be an unsatisfactory supplier for at least one material one component.
d. One supplier with which you have a trusting relationship
e. One supplier that you do not trust
f. A foreign supplier
g. A domestic supplier
h. One supplier that is also a competitor if this case exists
i. CMO, contract lab, or other contract service

Scoring Process. With your Cross-Functional Team, consider the following:

1. Assess the information provided in the tool below.
    a. Are there other risks you can identify or have experienced?
    b. Are there other benefits you can identify or have experienced?

c. Are there other types of information that you need to consider for your operations? If so, determine the benefits and risks of each as a team.

2. Determine what you are already sharing.
Indicate with a Yes or No if your company is sharing the examples listed in the tool below. If you are establishing a relationship for the first time, this column should be left blank. Skip to #3.

3. Evaluate Probability of Sharing Information.

a. For a new relationship: Use the benefit/risk information to determine what information your organization should share for the particular supplier relationship at hand. Align on a score for the probability of sharing the information in the tool on a scale from 0 - 10 as defined below.

b. For existing relationships: Determine if it is appropriate to share what is being shared, or if there are benefits to sharing what is not currently being shared based on the benefits and risks related to that particular relationship. Align on a score for the probability of sharing the information in the tool on a scale from 0 - 10 as defined below.

Scoring System:

- 10 Yes, we will share the information
- 7 We are highly likely to share the information
- 3 We slightly likely to share the information
- 0 We will not share the information

Note: if there are questions in any of the sections that do not apply to your operations, do not score the question.

Importantly, document why the decisions were made to communicate or not communicate the various examples of information. This will ensure future team members understand the rationale and assumptions that were made so the effectiveness of the strategy can be adequately assessed

#	Information Companies are concerned about sharing with their Suppliers	Potential Risk of sharing this information	Potential benefit of sharing this information	We currently share this information (Yes or No)	Probability of Sharing going forward (0, 3, 7, 10)	Comments on why the decision was made to share or not share
1	Market Forecast (Finished Product). Long-term Supply Demand (e.g., 12 - 36 months). Amount of supply needed from the supplier. Include potential upside and downside.	Supplier could ask for a price increase if they feel that the customer forecast is strong and market price is increasing. Hold the customers to this long-term commitment. This can happen even if the customer indicates that there is only a 4 month fix.	Critical for supplier to know as well as the upside and downside. Supplier has confidence in the business offered to them. Transparency into real due dates will allow flexibility on supplier side. The supplier invests in their systems. Supplier plans better for their capacity to meet customer's needs.			
2	Inventory Strategy	If the customer is building inventory, then the supplier might shift customer's work product to another customer if they run into capacity issues.	Important if customer is running JIT so the supplier is best prepared to fill customer requirements (and recognizes the importance of communicating any risk to supply). The supplier could allocate supply to customer.			

3	Intended use	Confidentiality concerns.	Could suggest alternatives. To ensure supplier material meets the requirements for how the customer wants to use the material. Ensure customer has the right grade of material. Allows customer to engage supplier subject matter experts.			
4	Further processing/packaging steps. General examples of what you will do to/with their material after you receive it.	IP concerns. If in a country without IP protection or if supplier has a history of not managing IP properly or if the supplier is a competitor, then probably not the right selection. Lack of proper change notification (change will not impact additional manufacturing).	To streamline operations (if the customer allows the supplier to know that it will clean and sterilize the material or component then the supplier might be able to perform that instead). Supplier can improve controls to mitigate risk. May be able to advise that further processing will not work with component. May be able to offer different product that is better or customize product. May be able to conduct the next steps for you.			

5	Adverse events and failure investigations of the finished product when you aren't sure of root cause (might not be related to the supply, but you need the input of the supplier)	Supplier may hide their contribution. May not continue to supply (if supplier is not normally in a regulated environment and customer may not have leverage - and are sole source). Supplier may use manufacturer's knowledge to supply to the competition	Leveraging suppliers knowledge in investigation and root cause determination			
6	Regulatory filings (CMC, process changes, PMA, 510(k) etc.)	IP concerns. Regulatory filing may reveal that the supplier is the sole source and supplier may take advantage of that information. May want to tack on changes that the supplier wants to make if they see that customer is making a change.	This level of documentation and IP sharing is necessary and an FDA expectation for CMO's, but not for suppliers. Refer to row for Intended Use and Further Processing. If customer is sole sourced, it would be important for strategic suppliers to invest in and support the product. Supplier can help ensure compliance. Supplier can add changes without additional filings			

7	SOPs, Work Instructions and Test Methods	IP concerns for specific work instructions (only a concern if the supplier would take advantage of the information, but beneficial so they can better support customer).	To align the two companies to a common practice (examples: change control, OOS investigation, test method). This alignment on common practice will potentially eliminate issues with: change notification, misalignment of test methods, and misalignment of investigation. To ensure supplier has a mature and robust system.			
8	Inspection results of the customer related to the product that includes the supplier material or component	May be related to systems for which the supplier has no direct or indirect involvement. Could supply redacted findings if information is needed.	Keeps supplier informed of failures and a possible misalignment of test or inspection methods. Could be needed if the material or component was not determined suitable by agency (particulates, etc.). Solicits suppliers help in finding root cause. Align on solution and CAPA. Identification of possible transportation issues.			

9	Master Batch records/Device History Record	IP concerns	CMO needs this information, otherwise, redact non- relevant information. Streamlining technology transfer process. Can compare suppliers without assumptions (accurate quotes on exact process).			
10	Cost/profit margin (as needed to be shared)	Supplier may increase their price	Transparency engenders trust and collaboration on pricing model. Long term benefit of relationship building. "Should-cost" analysis			
11	Other Suppliers (potential or current)	Integrity issue. Contract concerns regarding disclosure if a confidentiality clause is in place. Supplying this information may result in a sensitive relationship between the parties.	Names are generally not shared, unless customer is trying to negotiate a lower cost with current supplier (share a should-cost analysis). Helps supplier understand the market verses their capability. Mitigates risk of issues in supply chain. Potential negotiating leverage for customer; adds competition to discussion. Engenders trust and a healthier relationship.			

Appendix 14: Communication Strategy for Suppliers

The following instructions are intended to guide suppliers through the development and implementation of a Communication Strategy that is suitable for each customer relationship.

The process described herein is designed to assist in the development of an effective communication strategy that will demonstrate overall benefit and risk that is drilled down to individual finished products and customers. Additionally, this process can be used to assess existing relationships to determine the appropriateness and effectiveness of information already being communicated.

If you are looking for a place to start, consider the following approach.

Consider choosing at least two and preferably 3-5 customers to assess. The ideal evaluation would allow the supplier to explore the dynamics around some of the following customer aspects:

a. One that is a current satisfactory customer relationship.
b. One in which you are a single source supplier of a raw material or component for that customer.
c. One that is a currently considered to be an unsatisfactory customer for at least one material one component.
d. One customer with which you have a trusting relationship
e. One customer that you do not trust
f. A foreign customer
g. A domestic customer
h. One customer that is also a competitor if this case exists

Scoring Process. With your Cross-Functional Team, consider the following:

4. Assess the information provided in the tool below.
    a. Are there other risks you can identify or have experienced?
    b. Are there other benefits you can identify or have experienced?
    c. Are there other types of information that you need to consider for your operations? If so, determine the benefits and risks of each as a team.

5. Determine what you are already sharing.

Indicate with a Yes or No if your company is sharing the examples listed in the tool below. If you are establishing a relationship for the first time, this column should be left blank. Skip to #3.

6. Evaluate Probability of Sharing Information.

    a. For a new relationship: Use the benefit/risk information to determine what information your organization should share for the particular supplier relationship at hand. Align on a score for the probability of sharing the information in the tool on a scale from 0 - 10 as defined below.

    b. For existing relationships: Determine if it is appropriate to share what is being shared, or if there are benefits to sharing what is not currently being shared based on the benefits and risks related to that particular relationship. Align on a score for the probability of sharing the information in the tool on a scale from 0 - 10 as defined below.

Scoring System:

- 10 Yes, we will share the information
- 7 We are highly likely to share the information
- 3 We slightly likely to share the information
- 0 We will not share the information

Note: if there are questions in any of the sections that do not apply to your operations, do not score the question.

Importantly, document why the decisions were made to communicate or not communicate the various examples of information. This will ensure future team members understand the rationale and assumptions that were made so the effectiveness of the strategy can be adequately assessed.

#	Information Suppliers are concerned about sharing with their Customers	Potential Risk of sharing this information	Potential benefit of sharing this information	We currently share this information (Yes or No)	Probability of Sharing going forward (0, 3, 7, 10)	Comments on why the decision was made to share or not share
1	Changes proposed	For situations which do not need additional evaluation, Customer could delay timely implementation of improvements. Know what to communicate.	To ensure product performance and regulatory compliance. Critical to ensure changes do not affect safety or efficacy of finished product. Regulatory compliance. Prevents unintended consequences such as OOS, adverse events.			
2	Actual capacity	Customer may move to a supplier who has additional capacity. If information is not shared then the customer could find out through failure to deliver.	To assess capacity of supplier and to be able to plan for scale up of production. Improve availability of supply from synergies of treating supply chain as a single system.			

3	Actual schedule flexibility	Customer and supplier may not be aligned on priorities. Customer could be slower to commit to forecast.	To optimize supply and have a common understanding of schedule flexibility. Customer and supplier can work together to determine schedule. Improve availability of supply from synergies of treating supply chain as a single system.			
4	Conducting on-site audits	Customer may move to a Supplier who will allow on-site audits.	To ensure the supplier has an adequate QMS and process controls in place. Ensures compliance. Allows suppliers to learn and improve from customer audits. Inconsistency between customer and supplier's interpretation of regulations and standards allows inconsistencies to be identified and resolved.			
5	Batch records	Customer may insource process or find another supplier. IP concerns.	To assist in investigations and understand risk and/or material variability. Help customer assess and mitigate risk.			

6	Regulatory inspection results	Customer may want to control how responses are handled. Customer may overreact and/or ask for unnecessary information.	To ensure regulatory compliance and understanding of current state of supplier's QMS. Possible delay (for desk assessment) rather than an on-site audit if reports from an independent third body are available. Customer may be able to provide advice based on prior experience.			
7	SOPs/Technical Specifications	Customer may insource process. IP concerns.	To help customer understand the characteristics of the finished product. Product performs better in the customer's application. Align SOPs between customer and supplier (ie OOS). Especially important to align on test methods being utilized.			
8	DMF or other regulatory filings	Customer may insource process or find another supplier. IP concerns.	To assist in customer's filings and requests for additional information from regulatory bodies. Transparency of supply chain (sub tier).			

9	Profit margins & actual cost	Customer requests lower price and takes away profits.	To ensure a fair price for both parties. Customer ensures margins are high enough to maintain supplier's business. Customer may be able to assist with purchase of materials to save costs. Customer may be willing to invest in supplier operations.			

Appendix 15: Key Tools for Supplier Engagement

Request for Proposal

The company will typically issue an RFP (request for proposal) when the company is seeking a supplier for a new material or service. The following examples of information could be included in the RFP from the company to the supplier:

a. Background information on the project
b. Expected objectives from the project
c. Expected deliverable(s) from the supplier and/or item
d. Approximate timing of project
e. Projected type of relationship necessary. Whether the company will need technology assistance from the supplier or if the company is looking for a strategic partner, such as investing in the project, etc.

Companies should host a question and answer period intended to provide the supplier with information to support the best proposal from the supplier. Each of the suppliers should be informed of the pre-determined supplier acceptance criteria. The criteria for supplier selection should be developed by the company's cross-functional team based on several critical inputs, and may include quality and regulatory requirements, technical specifications, technology needs, operational requirements, potential risks to safety, efficacy, continuity of supply, business/financial performance, and company specific requirements. This information is best communicated during a meeting with the appropriate cross-functional representatives from both the company and suppliers. The company should discuss all relevant details of the selection process, including the specific criteria against which the supplier will be evaluated, criticality and/or weighting of the criteria, the manner in which performance will be measured, and timing of selection.

Supplier Selection Lists

A list of potential suppliers may be needed by the company throughout the product lifecyle as various events result in supplier and/or material changes (e.g., supplier cannot meet forecasts, new material is needed, etc.). The list of potential suppliers should be maintained within the Supply Chain Intelligence Repository (Section 3C), and should start with the Approved Supply List (ASL). Supplier lists should be dynamic such that the company has the ability to update the list with ongoing Supplier performance monitoring. This will ensure the company is able to make future decisions with the most up-to-date and relevant information, such as identification of the supplier qualification state, when the next audit of the supplier should occur, and whether or not

the supplier is certified. Importantly, the company should have a process developed for de-qualification and documentation of this downgraded status (Section 5B).

Quality Agreement

A Quality Agreement is a document used to delineate expectations, roles and responsibilities between the company and supplier in order to ensure regulatory compliance and product quality, safety and efficacy. A Quality Agreement may be a regulatory requirement depending on the type of material and how the material will be utilized in the company's process.

The degree of Quality Agreement rigor between the company and supplier is based on the risk classification of the material as used in the manufacturing process of the finished product and other supply chain risks. Risk classification should be established by the cross-functional team, incorporating all necessary inputs into the risk analysis (Section 4A - Material Risk, and Section 4B -Supplier Risk).

The company may elect to utilize a Quality Agreement template specifically written for the type of material or service provided (e.g. API, excipient, calibration service provider, etc.) or may utilize a general terms agreement referencing separate documents such as specifications and other technical or quality specific requirements. There are many sources available for Quality Agreement templates[3].

Early discussions between the company and supplier regarding the Quality Agreement contents are key, as Companies generally require that a Quality Agreement be in place and approved before commercial use of the material. Also, if a supplier has concerns or will not sign the Quality Agreement, it is valuable to know this early in process in order to: 1) work through the issues, 2) find another supplier, or 3) develop a risk mitigation strategy. As soon as a supplier has been identified as a potential candidate to provide a service or material, the Quality Agreement should be provided to the supplier for review, to at least ensure a high level agreement on terms. Many relationship issues might be avoided if the company and supplier reach acceptance of the Quality Agreement terms as soon as possible.

The company and supplier should review the Quality Agreement to ensure alignment on expectations, responsibilities, deliverables and key terms and conditions. This review should be conducted by a cross-functional team to ensure the content thereof is appropriate and covers

[3] http://ipecamericas.org/ for excipients, and http://apic.cefic.com for active pharmaceutical ingredients

relevant regulatory, legal, technical and business-specific requirements. Any areas of misalignment or disagreement should be discussed to determine if a compromise or resolution can be reached. The company should ensure the key terms and conditions are well-understood by all internal and external parties and should confirm acceptance before proceeding with the relationship.

The company and supplier should be willing to discuss and align the terms of the Quality Agreement based on both the supplier's and company's quality system requirements, product regulatory requirements, and the risk of the supplied material. The following table provides examples of common disagreements between the company and supplier where Quality Agreement negotiation breakdowns have been observed to occur. The company can consider the mitigating action examples provided:

RISKS/PROBLEMS	MITIGATING ACTIONS
Supplier will not agree to specific terms	Confirm acceptance of the terms of the Quality Agreement early in the supplier selection process. If supplier does not agree with terms: • Discuss concerns and modify as acceptable • Eliminate supplier from selection process • Accept the risk of not having an agreement and mitigate the risk
Change Control: Difficulty agreeing on which changes should be communicated, because supplier does not know what changes affect your product	Agree on what is important • Change to physical or chemical characteristics • Change in DMF (too narrow) • Change in trend • Affect quality
Different lab equipment	Test methods and equipment must be aligned
Treat the Quality Agreement as a "check off the box"	All commitments stated in the Quality Agreement must be reviewed
Conflicting terms	Cross functional review of all terms and ensure consistency
Employees within the company and supplier are not aware of the terms	Distribute and explain the terms of the agreement to all those involved
Supplier not willing to sign an agreement due to insignificant amounts purchased	Eliminate from supplier selection process or apply appropriate risk mitigation strategy
Disagreement of time related requirements such as record retention, change notification timing, and audit observation response timing.	Company should be willing to negotiate terms of the Quality Agreement based on the supplier's quality systems and reach common ground

Supplier is not a commercial entity but a university or not-for-profit institution.	Must apply appropriate risk mitigation based on risk of material or service

Supply Agreement

The Supply Agreement, or Contract, is a legally binding document detailing the responsibilities and obligations of all parties from a financial/business perspective, and often contains the Quality Agreement (or makes reference to the Quality Agreement).

The Supply Agreement (1) establishes business guidelines and responsibilities, (2) helps build a stronger collaboration and relationship through mutual commitment, and (3) provides recourse for breach.

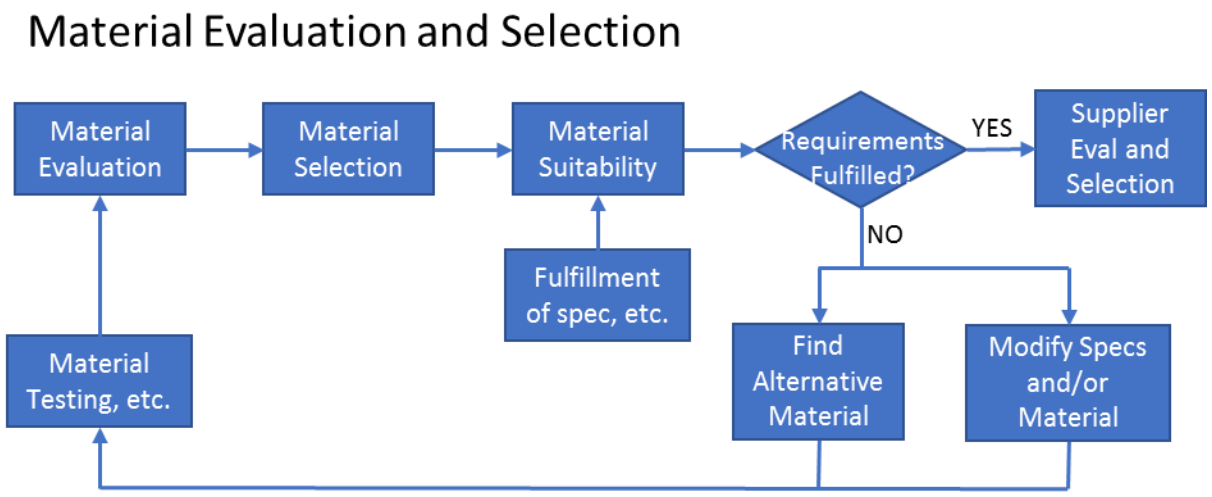
During the Initial Supplier Selection stage, the cross-functional team will determine whether or not a Supply Agreement is required for each good/service, and, if so, what critical terms to include. The company should plan and prepare for possible questions and concerns from supplier with terms and conditions of the Supply Agreement, and be prepared to negotiate mutually acceptable solutions. By discussing the Supply Agreement early in the process,the company has more time to find an alternate supplier if parties cannot agree to mutually acceptable terms. If mutual agreement cannot be reached on any terms, this should be documented by the company as a risk and considered in the final supplier selection process.

The following table provides examples of common disagreements between the company and supplier where Supply Agreement negotiation breakdowns have been observed to occur. The company can consider the mitigating action examples provided:

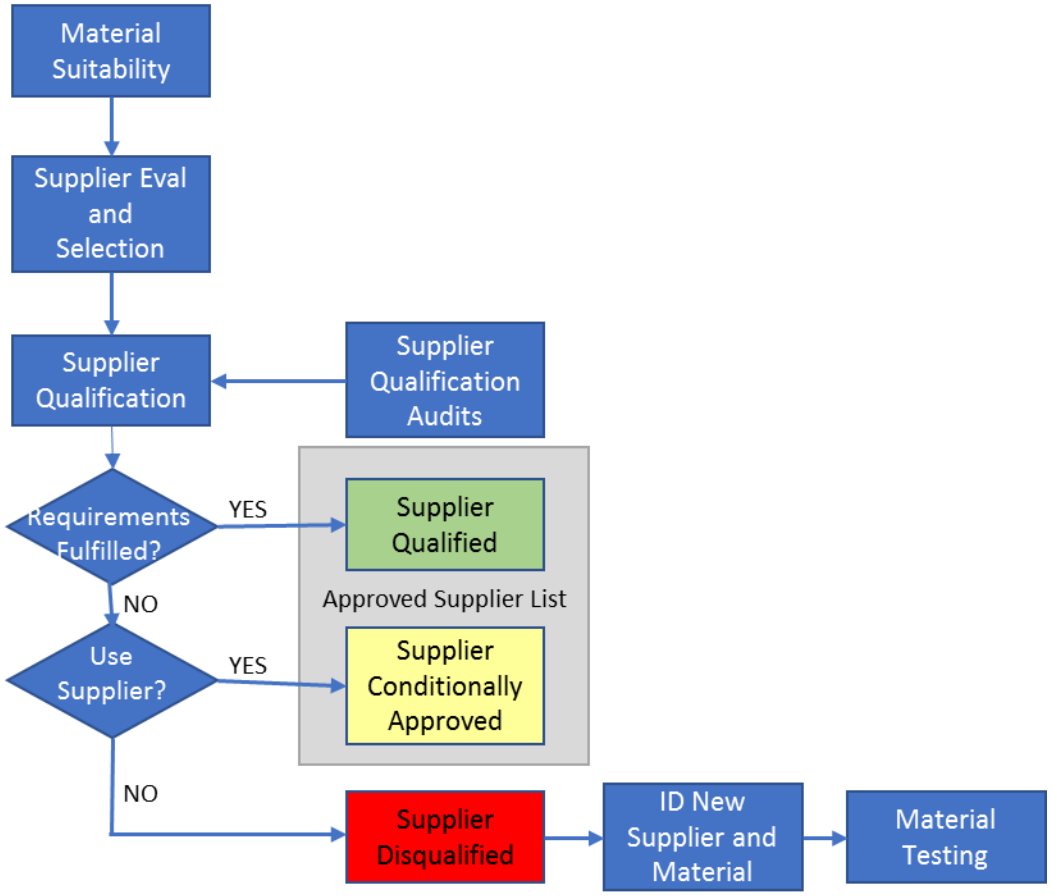
RISKS/PROBLEMS	MITIGATING ACTIONS
Firm period	Firm period should be based on lead-times and commitments the supplier must make to support the customer needs. There can be multiple commitment dates to cover expensive long lead-time items and labor, or other value added.
Volume commitments	Buyer should not be obligated to buy goods/services not required. However, supplier should receive fair compensation for incurred costs and lost profits.
Timely approval	Buyer should be staffed to approve receipts on a timely basis. However, in peak periods, more time may be needed. If problems arise, extra time may be required for CAPA.
Payment terms	Reasonable and on time.
Indemnification	The party at fault should protect the other party

Terms conflict with other documents, e.g., P.O., Quality Agreement	Cross-functional review of all terms and ensure consistency
Supplier does not agree to specific terms or conditions, or supplier is not willing to sign an Agreement	Confirm acceptance of the terms of the Agreement early in the supplier selection process. If supplier does not agree with terms: • Discuss concerns and modify if possible • Eliminate supplier from selection process • Accept and develop appropriate risk mitigation strategy
Company unable to commit to volume or specifications	Supplier cannot commit to price until volume and specifications are finalized. Supplier may be willing to agree to estimates and/or ranges based on early assumptions, and margin targets.

Appendix 16: Material Selection and Supplier Qualification Flowcharts



Supplier Qualification Process



Appendix 17: Relationship Risk Mapping