Implementing Risk Strategies for the Pharmaceutical Supply Chain

Risk-based management strategies can be implemented to streamline one’s supply chain and improve efficiency via increased communication, transparency, and traceability.

Overview
Business dynamics in the pharmaceutical industry today are increasingly complex. Companies are being pulled in many directions between globalization, product competition, and increasingly rigorous regulatory requirements. Therefore, it is critical to be able to trace a product through its entire supply chain life cycle, all while navigating complexities, maintaining transparency, and remaining compliant throughout the process. Supply chain traceability is important for building more risk-based quality and compliance management programs, but companies are often challenged with where to begin. This webcast summary describes tools available for identifying and managing risks as well as techniques to incorporate risk mitigation into existing processes.

Supply Chain Visibility
Pharmaceutical businesses are becoming increasingly multifaceted; companies are establishing locations around the globe, and mergers and acquisitions also add complexities in terms of blending business practices for quality and compliance. Drug makers also must abide by regulations that should be addressed at both local and national levels and that vary by country and region.

Supply chains have numerous complexities and risks as they expand with the need for more outsourcing. It is imperative that suppliers adhere to the same level of quality and regulatory compliance that is expected from the parent organization. The more pharmaceutical companies expand, and the more outside entities they partner with, the more murky supply chain visibility becomes.

Unfortunately, just 25% of pharmaceutical companies are assessing their end-to-end supply chains for risk, and only 17% have any visibility of their suppliers’ operations (1). But, there’s good news: a recent Gartner study says that 53% of companies are planning to invest in additional tools to improve this supply-chain visibility by 2018 (2). This finding suggests that as companies rely on outsourcing materials, goods, and services—and are recognizing the risks inherent in their supply chains—they are budgeting to build better visibility and risk management into their supply chains.

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Five Threats to Supply Chain Visibility and Integrity

1. **Visibility (end-to-end traceability).** A 2016 poll reported that approximately 73% of enterprises do not have full visibility of changes with their own supply chains. This is a major risk (3). The entire supply chain needs to be managed well, including frequent inspections of processes and operations to ensure quality and regulatory standards are maintained. If not, companies can only react when problems arise, which leads to increased costs, a breakdown of best practices, an increased threat of counterfeiting, or possible public health issues.

2. **Cost.** Material costs are fairly easy to track, but what’s often overlooked are expenses related to administration and quality department/inspection overheads. If something fails at the supplier end, the drug company may be liable for material and non-material costs. In addition, public perception of the brand may still suffer if there is a serious quality failure.

3. **Supplier communications.** Poor communication between the brand owner and the supplier is a major problem. The contract and quality agreements detail the processes and results that are required, but how are these agreements tracked throughout the long-term relationship? In addition, communication is frequently a disorganized conglomeration of phone calls, faxes, emails (often unsecured), and expedited deliveries with no formal tracking of who is communicating with whom and when. Lack of communication can have downstream effects. Operations involving different time zones or languages only compound the problem.

4. **Siloed systems.** If the enterprise systems are not integrated with those of the suppliers, traceability can be affected. Using outdated or mismatched technology can leave gaps if managers cannot monitor a supplier’s quality processes efficiently and in real time. Solutions are available to help managers monitor a supplier’s quality processes efficiently and in real time, but managers often don’t make such a financial commitment to add the integrations, thereby creating information silos that are hard to break.

5. **Security.** While some data-sharing is necessary, it is not surprising that brand owners may be hesitant to allow suppliers direct access to their information technology (IT) infrastructure, leaving them feeling vulnerable. The right balance needs to be achieved in order to protect the company and also allow for appropriate traceability mechanisms such as auditing. These five threats can present a very real danger to an enterprise and introduce harmful variations in quality levels and practice across the entire supply chain. To combat these threats and bring about positive change in the relationship between enterprise and suppliers, quality management systems (QMS) now offer supply chain capabilities with processes that enhance quality, improve productivity and, most importantly, incorporate traceability at the center of any supply chain management strategy.

**Top Benefits of Cloud-Based Solutions**

Cloud-based supply chain solutions can provide visibility of even the most complex global supply chains. Tools and modules can be used to trace the movement of materials and supplies, and report summarized or detailed data levels.

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**Figure 1:** How quality management systems support the supply chain.
depending on the quality manager’s requirements, offering a range of benefits. The first step, however, is to figure out how to extend quality throughout the supply chain effectively (see Figure 1). The current gaps with manual procedures need to be identified and replaced with automation. Specifications for how deviations are tracked, investigations are completed, and complaints are classified, for instance, need to be evaluated. Any corrective actions must be created utilizing the same seamless process from any of the quality processes.

From a broader perspective, the company must evaluate its commitment to quality, identify areas where compliance is needed, and examine the company culture. In addition, procedures and processes should be communicated to suppliers, which will ensure efficiency and adherence to the company’s level of quality.

Finally, risk is applied to these factors via a systematic review, assessment, treatment, and control. This can occur internally, but ultimately needs to extend to the supply chain suppliers.

Visibility/traceability. Cloud-based software systems can offer solutions to quality concerns associated with both material and non-material costs, while avoiding the financial penalties associated with traditional system integration solutions. Reputable Cloud-based tools can be seamlessly integrated into existing systems so as not to disrupt work flow. This integration allows for information sharing, transparency, and collaboration along the entire supply chain.

Removing silos. Because all parties have access to Cloud-based data in real-time, suppliers can view live metrics such as corrective action or design changes while the enterprise owners can monitor the suppliers and their performance. All parties can receive notifications or acknowledgments on their mobile phones.

Integration and automation. The importance of integration and automation is key to supporting visibility, compliance, and operational excellence. The enhanced features of some QMS may leave managers concerned that they will be high maintenance. However, by incorporating the appropriate platforms, large amounts of procedural and process-driven work can be automated with tools that can allow:

- Integration of communications, ordering and invoicing,
- Visibility of inventory levels,
- Real-Time Dispositioning of defective supplier materials,
- The streamlining and optimization of the receiving and inspection process,
- Access to real-time supplier risk and quality data, and
- Access to the supplier scorecards, aggregate risk reporting, and the approved supplier list.

These quality systems can also facilitate the management and tracking of supplier non-conformances, create work-flows and sign-offs for all supplier-related processes, reduce error and loss of critical information by ensuring quality workflows are followed, increase supplier selection efficiency using a centralized supplier evaluation process, create a single place to aggregate quality data, and strengthen security. Cloud-based systems offer secure methods for suppliers to log in, allowing access to data relevant to only them. Any data inputted on their end will sync automatically in real-time back to the owner. This system helps build relationships and trust, and dishonest suppliers are quickly weeded out.

The most successful companies will eliminate the manual systems of the past where information was recorded and shared on Excel worksheets or paper, and choose to digitize their supply chains. The easiest way to make that transition is through a comprehensive Cloud-based and/or on-site quality management system. A digitized, fully connected supply chain where everyone is on the same page is the best way to ensure stronger collaboration. It also empowers a business to maintain control over supply chain partners and vendors to retain quality standards. If there is a problem, users can identify it more quickly and correct it before the product reaches the market. Digitization also allows companies to respond better to customer demands, market changes, and the loads of data received through stronger visibility and transparency. The goal of the fully digital connected supply chain is to create one holistic network within and outside the company that mitigates risk, which enhances efficiency, brand value and ultimately patient safety.

Internet connectivity, browser standards, new user interfaces, and social technologies are far more mature than they were a few years ago and help enable Cloud-based technologies. Cloud-computing provides an ideal mechanism for collaboration about quality, with the same security guidelines as they relate to access and restrictions. Communications related to quality processes take place in the same Cloud environment so they can be appropriately routed and tracked.

Demonstrable business value combined with consumer safety, and the technology to make it happen, provide sufficient justification for the incorporation of a comprehensive digital QMS that encompasses the entire supply chain.

Reduced supplier issues. Automated processes make supply chain management much easier. Incoming goods can be tracked (receipt and inspection), a list of suppliers and materials can be easily maintained and updated to be always “inspection-ready,” compliance certificates can be store, maintained and accessed immediately, any deviation or complaint event can be acted on quickly, decisions and processes can be repeated to ensure consistency across all suppliers.

Traceability. By automating supply chain processes, quality managers can track goods from conception to completion, creating more accurate supplier ratings, all in real time. Scoring profiles can be generated for each supplier as well as detailed criteria scales. Profiles can be updated in real time.
to include activities such as inspections or corrective actions. In keeping with the transparency theme, these ratings are made available to the suppliers so they can act upon any performance issues.

Any updates made to the supplier list will sync in real time, and they can be continuously reviewed. Performance metrics such as ordering on time, correct documentation, and response to order changes can be monitored.

**Data analytics.** Big data is invaluable and can ultimately help managers monitor their supply chains on several levels, from data overviews of the entire supply chain down to granular details. This data can be used to identify which parts of the supply chain require improvement or highlight previously unseen opportunities that are vulnerable to exploitation. Ultimately, this all helps increase output and supply chain effectiveness.

According to Accenture’s study *Big Data Analytics in Supply Chain: Hype or Here to Stay?*, embedding big data analytics in enterprise operations has led to:

- 4.25x improvement in order-to-cycle delivery times.
- 2.6x improvement in supply chain efficiency of 10% or greater.
- 64% “of supply chain executives consider big data analytics a disruptive and important technology, setting the foundation for long-term change management in their organizations.”

**Gaps in the Supply Chain that Create Risk and Concern**

Onboarding is one of the biggest challenges in supply chain management (*Figure 2*). Engaging with new partners can be beneficial, but working with a new supplier can have risks. Therefore, companies must ensure that there is alignment before starting to work together. An easy way is the supplier audit; take a good look at the supplier’s operations to build an audit plan. However, the approval process still needs to be vetted, but the setup of a supplier and approved vendors is still manual. This can be streamlined, however, through a supplier quality network.

A supplier quality network is an automated way to interact with suppliers in an environment that allows them to access only the portions of the system that they need (see *Figure 3*). Suppliers need access to parts that will allow automation, but not to gain access to the company’s system. A Cloud-based system can help by only displaying relevant information to the supplier. The goal, however, is to create more than just an approved supplier list. Suppliers should be empowered to create profiles, designate people within their organization to handle certain tasks, and own their supplier profile.

From a risk-based perspective, these profiles can be continuously reviewed, and a risk management plan will already be in place, assessing various levels of operations and their associated risks, all in providing real-time information back to the supplier.

**Supplier Network Solutions (SNS)**

Another area for improvement is getting information about specifications through the supply chain quickly. One of the biggest risks is response time when building approval on specifications per the quality agreement. This process must be streamlined, but ideally in a way that incorporates the supplier. The current way usually includes a lot of back and forth via email, which is not traceable or linked to the system, and turnaround time is slow. SNS automate the process through notifications, risk assessments, and integration. Essentially, a specification change is submitted through the system. The receiving individual is notified and can instantly go into the system to review, assess risk, or make updates. This person can instantly approve the change, automatically notifying the sender. This creates a seamless, traceable way to transfer information with a quick turnaround time.

Supplier network components also help out with the initial audit to approve a supplier. Companies often use self-audits to help accelerate the process whereby the supplier provides
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Information related to operations and policies, for example. The time required to return an assessment and complete a supplier corrective action report (SCAR) slows down the process, especially with a lack of automatic communication. The supplier network component will help eliminate this lag time, and also provides traceable information and improved response times.

In addition, SNS can help with daily operations such as shipments. There is a huge gap between the time when an issue is discovered to when it is resolved by the supplier, and a timeframe to resolve the issue is usually not provided to the company. Production is put on hold and, therefore, the company is unable to respond to demand or a management request is created to prepare the submission a planned deviation for review and approval. The vendor then needs to issue a SCAR to ensure corrective actions are being taken. Severe lack of visibility and unclear timelines create big risks.

An SNS can help by providing the ability to report the issue with a click of a button, notifying the supplier in real time of potential problems. They can get into the system to see all the relevant information to help them address the problem. The supplier investigates and makes recommendations, while the vendor can take action and issue the SCAR. The SCAR also benefits from an automated, real-time process, allowing instant completion of documentation and distribution through the system without delay or back-and-forth emails. Suppliers can also play a more active role in ensuring quality by following the process set up in the system, again in a visible and traceable manner.

**Conclusion**

Communication, transparency, and traceability in supply chains can be achieved via Cloud-based technologies. Such systems are helping to break down silos, and the end result is improved efficiency in the supply chain, and elimination of wasted time and resources. Big data and analytics help drive output and also boost supply chain effectiveness. This is especially important to pharmaceutical companies that are looking to make their supply chains more efficient. This efficiency will help them stay competitive, improve relationships with partners around the world, and ultimately get therapies to market faster.

SNS doesn’t just help the downstream process, but also the upstream process. Suppliers may have information as well that needs to be communicated. They can upload the information to the system, which gets reviewed in real time by the company that can be instantly send back with their approval. So, the SNS that connects the supply chain to the QMS can go both ways and is helping to break down information silos, creating one centralized and standardized process. In the event something does go wrong, all of the information relevant to the affected product is available on the Cloud, eliminating time wasted sifting through paperwork. The problem can be identified much quicker and therefore rectified sooner.

**References**

3. Data derived from a 2016 webcast audience poll.