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White Paper

Quality as an Enterprise Value Creator: Digital Strategies for Supplier Quality Risk Management

Quality compliance is often relegated to the cost of doing business; a reactive approach, reliant on overly complicated processes, focused on checking boxes, satisfying regulators, and flagging non-conformance. While digital solutions have emerged to enable paperless workflows and automated data pulls and visualization to streamline quality-related processes, a substantial opportunity remains to truly modernize quality and evolve the function from a cost center to an enterprise value creator.

This transformation will be powered by technological advances that create more timely access to data, combined with new analytics capabilities, positioning bio/pharmaceutical companies to extract new insights, achieve greater speed and effectiveness, and support more agile risk-based decision making. In a recent report from McKinsey entitled "Smart Quality: Reimagining the Way Quality Works"[1] the authors envision far-reaching benefits of this digital evolution, including improved product quality, process reliability, and ultimately, efficacy and patient safety.

This whitepaper explores how current market trends and drivers are coalescing to accelerate the development and adoption of digital strategies in the area of supplier quality risk management. These new approaches are an essential part of the roadmap for the data-driven enterprise and set the stage for next-generation quality.

Market Trends and Drivers

The bio/pharmaceutical industry has experienced a remarkable revolution in recent years with both groundbreaking modalites such as gene and cell therapy, and technologies which have come-of-age as a result of the pandemic, such as mRNA vaccines. In parallel, leading edge approaches to manufacturing, such as single-use and continuous processing, are rapidly gaining traction. Combine these industry dynamics with unabated growth in demand for new therapeutic options and an increasingly competitive landscape, and priorities for drug developers and manufacturers come into sharp focus:

- Reduce process development timelines and accelerate time to market
- Accelerate approvals of technology transfers and capacity increases
- Mitigate risks related to sources of raw materals and components for biopharmaceutical production
- Ensure adherence to ICH Q10 (Pharmaceutical Quality System) as the regulatory environment evolves

Undoubtedly, the COVID-19 pandemic and associated supply requirements and constraints were key drivers of these trends. The pandemic and all its ramifications, however, only served to amplify long-standing imperatives to streamline workflows and accelerate timelines, ensure supply chain resilience, and maintain an unabiding commitment to patient safety.

Digital technologies will play an increasingly important role in positioning biopharmaceutical companies to not only respond to, but take advantage of these market trends. Among the operations where these technologies can have a significant impact is in supplier quality, a function that, as noted above, should be recognized for its potential to become a value-creator for the enterprise.

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Sources of Supplier Quality Risk

As part of their supplier quality risk management program, each biopharmaceutical company is responsible for establishing processes to assure the control of outsourced activities and the quality of purchased materials. There are many and varied sources of risk that must be managed including, for example, supplier reliability, product availability, supplier quality performance and product quality performance (Table 1).

Supplier reliability, performance, and product availability risks are typically managed via supply agreements which define requirements and metrics such as on-time in-full (OTIF) and lead time compliance and adherence that will be used to track performance. To help customers reduce supply risk, nearly a decade ago, we introduced the industry's first electronic tool for tracking the original manufacturer (eOMT) of thousands of materials for bio/pharmaceutical raw materials including process chemicals, cell culture media, chromatographic materials, excipients, and APIs. Additional resources for managing supplier performance and product availability include business continuity, disaster recovery, and crisis management plans which outline how we, as a supplier, mitigate our own supply chain risks.

Risks associated with supplier quality can be mitigated during the supplier selection process with use of quality agreements, change notification commitments, and audits. Once a supplier is selected, metrics and data on the response to inquiries, complaints, and changes, including the number, the time provided to qualify the change, and the quality of the data package, are closely monitored. From a product quality perspective, extensive information is needed for the material qualification process including certificates of analysis, regulatory statements, extractables and stability data. Once the product arrives on site, batch specific data are reviewed, and additional testing may be required. Any defects are identified, and the first pass yield is determined.

Having complete and accurate supplier quality information is essential for risk management and business continuity and helps ensure the supplier is compliant with regulatory expectations and well-prepared for inspections. Furthermore, timely access to data and analytics about those raw materials and products offers the bio/pharmaceutical company actionable insights about suppliers, processes, and workflows, which translates into better risk-based decisions.

Given the sheer number of components and raw materials used in manufacturing, however, supplier selection, material qualification, and quality risk management have become increasingly time- and resource-intensive. These vital processes are further complicated by the fact that regulatory requirements continually evolve and there is always a need for more information and greater transparency from suppliers to effectively mitigate risk and ensure supply chain reliability.

As informational requirements change and expand, two options are available to handle the inundation of data. Additional resources can be employed to manually compile more data, put it into a meaningful format, and understand and interpret it; or the data can be cleaned, structured, and contextualized in a framework that enables more rapid derivation of meaningful insights and better decision-making.

Sources of Risk and Mitigation Activities

	Supplier Reliability	Supplier Quality	Product Quality
Metrics & Data	• Original Equipment Manufacturer • Lead Time/Lead Time Adherence • On-Time In Full (OTIF)	• Audit Observations • Complaint Trends • Changes (#, Quality of Communication/Data Package)	• Certificates • Regulatory Statements • Stability Data • Extractables Data • Elemental Impurities • Trace Elements • TUPP/Particulates • Defects • First Pass Yield
Risk Mitigation	• Supply Agreement • Business Continuity Plans • Disaster Recovery Plans • Crisis Management Plans	• Supplier Selection Process • Audit • Quality Agreement • Change Notification Commitment	• Material Qualification Process • Compare/Test to Specification • Process Analytics

Table 1.

Sources of supplier risk.

Evolving to a Proactive, Digital Approach

Automated supplier quality performance tracking, along with advanced analytics can provide insights leading to better, more agile risk-based decision-making. These technologies can also help facilitate knowledge management, the focus of which is to support the bio/pharmaceutical quality system goals of achieving drug product realization, establishing and maintaining a state of control, and facilitating continual improvement. Because supplier quality risk management qualifies suppliers and products for use in manufacturing, it is inextricably linked with knowledge managemement. Information related to yield and other process parameters must circle back to inform the types of products and suppliers with whom the bio/pharmaceutical company chooses to work.

Historically, the process to gather information required about suppliers and their products begins with a request for information (RFI) sent by the prospective customer to the supplier's quality services organization. Similarly, the bio/pharmaceutical manufacturer may request an audit of a supplier site. For suppliers with many locations around the world, it can be challenging for the customer to know where to send the RFI or request the audit, further complicating and lengthening the process when speed is at a premium.

The pandemic added a new twist to the audit process. With travel restrictions and the requirement for social distancing defining how customers and suppliers could interact, the industry needed to get comfortable with and enable distant assessments or virtual inspections. Biopharmaceutical manufacturers had to create risk-based plans that would guide decisions regarding what suppliers and locations needed to be inspected and audited, and for what purposes. As a supplier, we have responded by implementing digital tools to perform remote internal or customer audits as well as inspections by authorities at our global sites. RX-360 audit reports, summaries, EXCiPACT™ certificates and related data can perform a risk assessment and determine whether they have the necessary information allowing them to confidently forego an audit.

With supply chain requirements and constraints as drivers during the pandemic, the industry and its regulators had to cooperate on a global scale to make vaccines available to the world's population at unprecedented speed, while managing post-approval changes (PAC) that resulted from supply chain disruptions for established products. If the same file could have been submitted for PACs and novel vaccines throughout the world, the processes would have been significantly streamlined. This vision of harmonization and convergence relies on the development of data standards and descriptions.

As a result of supply constraints, the need for second sources has come into sharp focus. Every part of the vaccine manufacturing process, from lipids used to produce the nanoparticles to carry the mRNA, to glass vials in which the vaccines were stored and shipped, represented a supply chain risk. Prior to the pandemic, the BioPhorum Operations Group (BPOG) had already initiated workstreams focused on creating the foundation for greater flexibility when manufacturing. As examples like this one demonstrates, there is a general need for innovative approaches that help biopharmaceutical manufacturers with their PAC submissions.

The pandemic also revealed the need for the creation, convergence, and harmonization of data standards and descriptions. In response to this global public health emergency, vaccines and therapeutics needed to be produced in many locations and distributed around the world; to facilitate this, regulators had to approve technology transfers and production capacity increases in their respective countries. These requirements, which apply to all therapeutics and vaccines, not just those related to the pandemic, have many differences and nuances which slow the process. There are substantial costs to file, including the additional labor required to ensure each filing is an exact match to the respective requirements in each country. As a result, we have recognized the need for harmonized data standards to increase the speed and efficiency in communication amongst suppliers and bio/pharmaceutical manufacturers.

As a supplier, we are taking an active role in helping the industry advance towards data harmonization and standards (Figure 1); one example is our partnership with BASF Pharma Solutions through which we recently launched a new standard for the electronic transfer of quality and regulatory information from suppliers to users in the bio/pharmaceutical industry. The electronic data standard, entitled Standard Quality and Regulatory Documentation (StaQRD), expands and improves upon the electronic data standard published by the American Society for Testing and Materials (ASTM) by including quality and regulatory compliance data beyond the information contained within certificates of analysis (CoA).

StaQRD uses the widely adopted Extensible Markup Language (XML) to define required and optional information and proposes exact names for these attributes to ensure consistency, harmonize descriptions, and reduce the risk for introduction of errors. By streamlining the transfer of relevant information from suppliers to users in the bio/pharmaceutical industry, this standard offers the potential to facilitate the various activities related to better managing a manufacturers' inbound value chain.

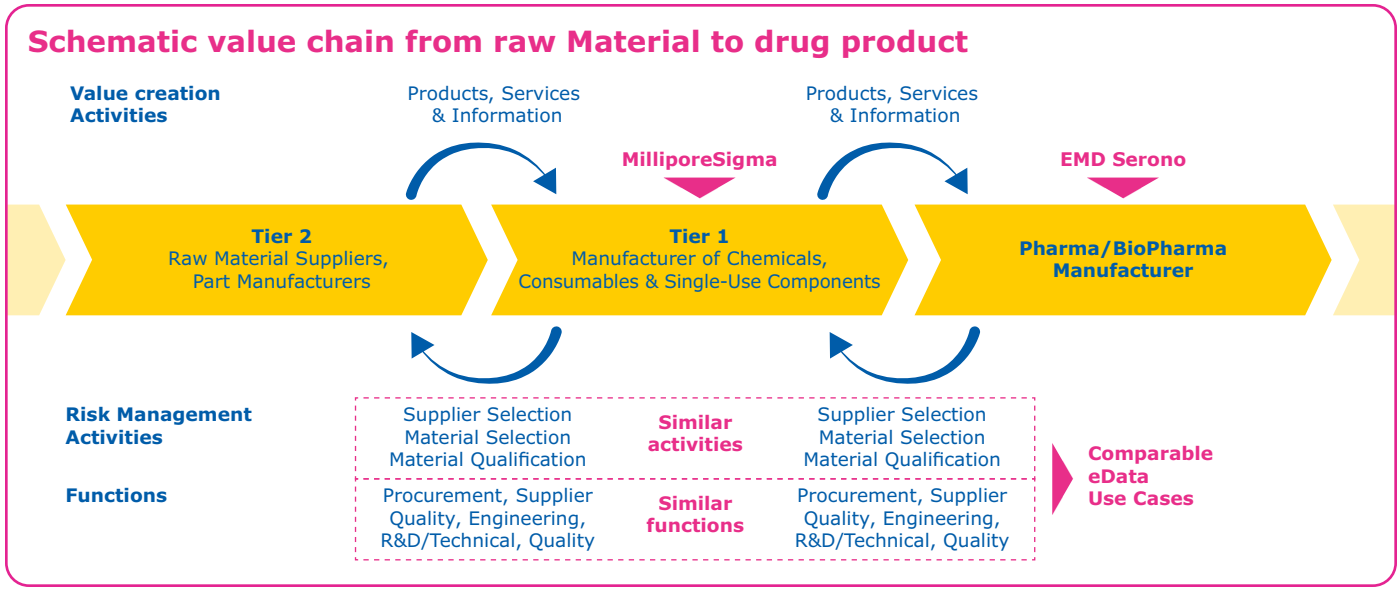

Figure 1.

An eData standard could streamline information transfer across multiple steps in the value chain.

Quality Takes Center Stage

The ability to conduct faster and more agile risk assessments, qualification processes, and decision-making will be a critical contributor to ensuring the quality function evolves from a cost center to an enterprise value creator. One critical success factor will be digitalization of supplier risk quality management. As a major supplier to the bio/pharmaceutical industry, we recognize our role in achieving this goal and are committed to providing our customers with the necessary data, information, and oversight to make it a reality.

Remote audits, virtual audits, eData standards supporting the transfer of detailed quality and regulatory information, and other digital advances, will increase speed to market and reduce supply chain risks, while maintaining quality and compliance. These digital tools will facilitate access to data, real-time oversight of suppliers, reduce or eliminate expensive, time-consuming material testing, and streamline supplier/customer quality-related business processes. In doing so, they will create more capacity in the organization to perform analysis and derive insights from the automated data collection, thus enabling more agile risk-based decision making.

Reference

1. Smart Quality: Reimagining the way quality works, McKinsey & Company, Pharmaceuticals & Medicinal Products Practice by Alvaro Carpintero, Tacy Foster, Evgeniya Makarova and Vanya Telpis.

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