

## Supply Chain Risk Mitigation

### An Evolving Approach

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**S**AFC Biosciences views supply chain management as a structured process that seeks to evaluate, monitor and control supply chain risk, safeguarding continuity while maximizing profitability for its supply chain partners. Successful supply chain management in the biopharmaceutical industry is no longer simply a case of having the right material in the right place at the right time to guard against production delays. Today, the basis of our supply chain offering includes risk mitigation, robust supplier relationship management and critical raw material management, combined with a deep understanding of our customers' unique and changing needs.

The traditional cost-focused supply chain has evolved into a center for value creation. Although there will always be a drive to increase shareholder value by reducing cost, we recognize the increasing importance of creating relationships with many specialized partners, drawing on their core competencies to improve overall customer service and facilitate entry into new markets. Through ongoing supplier consultation and collaboration on materials and specifications, SAFC Biosciences works to closely align supply and demand, increasing service efficiency and visibility while reducing cost and improving product quality.

#### COMPLIANCE FOR RAW MATERIAL SUPPLY

In the past, many raw materials were sourced from commercial, non-GMP manufacturers who did not always notify clients of product changes. This problem was exacerbated when lot-to-lot differences were not examined until well into product development or manufacturing. Increasingly, industrial biopharmaceutical manufacturers are demanding that their strategic suppliers must comply with the same stringent regulatory standards as their own, often to meet applicable parts of FDA or EMEA regulations.

Our customers choose to mitigate these risks by using more compliant materials, secure in the knowledge that the processes and materials used will not be arbitrarily changed without prior determination of the impact of each change. Understanding that controllable, repeatable, reliable processes are key to compliance, we can further reduce the risk of manufacturing errors through improved process documentation, taking appropriate actions when deviations occur and establishing critical process parameters.

#### SUPPLY CHAIN QUALITY MANAGEMENT

SAFC Biosciences' supplier manual and supplier quality standard operating procedures (SOPs) detail evaluations of all supplier quality systems and manufacturing processes, even how the



manufacturer manages its own "next-tier" suppliers. On-site audits and regulatory questionnaires form a key part of this process, along with sample testing and certificate of analysis (COA) validation. Raw material specifications are communicated to suppliers with each purchase order while strategic suppliers use customized specifications and test methods when providing critical components.

Using supplier quality agreements to document the understanding of critical quality parameters, SAFC Biosciences' quality performance measures form an important part of our "supplier scorecards." These criteria include all non-conformances, specification non-compliance, incomplete documentation, improper packaging or labeling, and quality and technical support during investigations and corrective and preventative actions (CAPA).

Supplier performance data are reviewed regularly and formally with suppliers based on parameters established at the beginning of the relationship. SAFC's vendor management system incorporates processes for management of consequences, rewarding high-performing suppliers and either improving poorer performers or finding superior alternative suppliers. This rigorous system also includes regular market and category assessments as well as a formal risk management process.

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