

SUPPLY CHAIN VISIBILITY IN PHARMACEUTICAL OUTSOURCING



**WHY DO MANUFACTURERS LACK
VISIBILITY IN THEIR SUPPLY CHAIN**



**HOW DOES THIS LACK OF VISIBILITY
AFFECT OPERATIONS**



**WHAT CAN BE DONE TO IMPROVE
SUPPLY CHAIN VISIBILITY**

WHY DO MANUFACTURERS LACK COMPLETE VISIBILITY IN THEIR SUPPLY CHAIN?



While pharmaceutical companies are ultimately responsible to assure the control and review of outsourced activities and the quality of purchased materials, many struggle with this due to the complexity of multi-tiered supply chains, the lack of or inadequacy of IT systems, limited experience, and resource constraints.

The supply chain has gotten increasingly complicated over the past decade. The complexity arises from the entrance of vendors from many countries into the marketplace; vendors that previously played a small or limited role. This is most evident in countries such as India and China, where there are numerous excipient, chemical, API, and CMO suppliers.

Mergers and acquisitions complicate the supply chain, particularly around quality. When mergers and acquisitions occur, the aim is to complete the deal as quickly as possible. In many cases, the acquiring companies run lean manufacturing operations, which constrains personnel to perform supply chain gap analyses, supplier assessments, and to manage any quality issues that may arise, via deviations, OOS issues, non-conformances, and poor/incomplete investigations in supplier corrective action reports (SCAR).

HOW DOES THIS LACK OF VISIBILITY AFFECT OPERATIONS?



Lack of visibility into the supply chain introduces risks due to the inability to ensure compliance and fully understand demand and capacity, as well as assess and react to any disruptions, which ultimately affects quality and performance.

Operations experience unplanned delays when materials received do not conform to specifications or arrive without the certificate of analysis and/or other required certifications. In addition, a company may receive material with an acceptable Certificate of Analysis, but the material simply does not perform when used in the manufacturing process. This can be due to an error at the supplier, poor shipping temperature controls, or data integrity issues at the supplier that internal auditors were not trained to detect. Lastly, the issue may arise out of a poorly constructed Quality Agreement with the supplier, whereby they did not have any legal requirement to notify their client of quality issues encountered during the manufacture of the API, etc.

HOW CAN MANUFACTURERS IMPROVE VISIBILITY IN THEIR SUPPLY CHAIN?



Manufacturers can improve visibility into their supply chain by implementing processes to control and review the outsourced activities and quality of purchased materials that incorporate quality risk management, regular monitoring and review of suppliers, leveraging technology and increasing the use of real-time data.

Manufacturers need to keep detailed records of the quality of the lots received, in addition to on-time receipt of materials. This quality information should be at equal footing with delivery metrics in evaluation of the supplier relationship. There are no acceptable replacements for on-site audit, especially the qualification and re-qualifications audit, as well as for-cause investigations. Suppliers need to be viewed as a partner, as long as they share and act accordingly.

Lastly, geographic and geopolitical environments must be constantly monitored to head off potential supply chain interruptions.

HOW DOES FOLLOWING THE SQ OUTSOURCING MODEL ENABLE UP TO 48% COST SAVINGS ANNUALLY?



The SQ Outsourcing Model enables cost savings by managing costs per audit versus full-time equivalent (FTE) resources. This model maintains a higher level of compliance and inspection readiness while allowing internal resources to focus on other business needs.

WHAT STEPS DO YOU RECOMMEND ORGANIZATIONS TAKE TO BEGIN TO IMPROVE VISIBILITY?

We recommend that pharmaceutical companies ensure they have processes in place to control and review outsourced activities and quality of purchased materials, and that they regularly monitor and review their suppliers, leveraging technology where possible, to provide real-time data.

Well-planned, well-written, and successfully executed supplier and quality agreements are essential to control the process and quality of the final product. Periodic scorecard assessments, along with interim re-audits, SCAR issuance, and investigative reviews should be implemented to maintain supply chain quality.



HOW CAN MAETRICS HELP COMPANIES IN THE PHARMACEUTICAL INDUSTRY IMPROVE SUPPLY CHAIN VISIBILITY?



In crucial areas of business operations such as supply chain visibility, experience and objective advice matters.

Maetrics can provide a dedicated team to analyze the supply chain and offer strategic advice. Having seen numerous supply chain failures, we bring deep insight into where things can go wrong and real results to improve business operations. With a team of consultants on hand, we then ensure that your tailored plan is implemented effectively, keeping you updated throughout.



ABOUT MAETRICS

Maetrics is dedicated to guiding life sciences companies through the challenges related to quality, regulatory, and compliance. Our comprehensive services allow clients to reach new efficiencies as well as business goals.

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Compliance Agility + Global Acumen

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