



CASE STUDY

Process Analysis Cuts QA Release Time in Half, Saving an At-Risk Biopharmaceutical Alliance

PROJECT BACKGROUND

The Alliance Management organization of a top-tier contract manufacturer responsible for the interface between their manufacturing facility and a client biotechnology company recognized a chronic problem in the inability to consistently release drug product within normal industry timeframes. Through exploration of the issue, all parties reached the following conclusion:

- Once physical production was complete, the timeline required to test and secure the necessary approvals to release supplies was unacceptably long.
- The complete release process was not well understood, lacked predictability, and, therefore, often required management intervention.
- Delays in the release process and the lack of predictability would continue to escalate, due to a significant increase in market demand for the drug.
- Despite a lengthy and time-consuming release process, mistakes continued, further exacerbating delays by

generating unnecessary re-work.

While both parties agreed that the release process must be optimized, the collaborative relationship was severely strained and there was a lack of agreement on the root causes of the observed delays. Many causes had been hypothesized, including a lack of sufficient staff, unnecessary testing and reviews, and disagreements related to the significance of variations. However, neither party had developed a comprehensive and mutual understanding of the entire process, analyzed it objectively to identify root causes, nor developed a plan to eliminate non-value added steps, minimize constraints, and streamline the sequence of release activities.

IPM'S SOLUTION

Integrated Project Management Company, Inc. (IPM) worked independently with both parties (the manufacturing facility and Quality Assurance organization within the biotech company) to map the current release process from initiation of drug product manufacture through final product disposition and shipment to the market. In addition to including the flow of the drug product, Quality

Control/Analytical data, and batch record information, the resulting process map included the function(s) responsible for completing each activity, estimated activity durations, interfaces between the manufacturer and biotech, and key decision points as well as a process for reconciling deviations. In order to have a better understanding of how the current process actually performed in an operational environment, IPM also collected metrics at predetermined process checkpoints.

After analyzing the newly constructed process map, historical metric data, and supporting information collected during discovery, IPM concluded that significant enhancements in the actual release process could be achieved through a mutual understanding and rigorous application of the "as is" mapped process. Based upon industry knowledge, IPM also identified tertiary opportunities to further optimize the process. As an objective third-party, IPM was able to bring all parties together in a constructive environment to review the composite recommendations and ultimately drive consensus on a collaborative approach for implementation.

IPM led implementation of the recommendations by developing and managing an implementation plan, training practitioners, establishing and facilitating communication channels, and establishing metrics to track the real-time flow of process information as well as ensure the realization of the benefits of identified process improvements. At the conclusion of the implementation phase, IPM successfully transitioned program management responsibilities to internal resources for ongoing operational execution.

the process and quickly address any issues that threaten to deviate the lot from release targets.



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PROJECT RESULTS

IPM successfully managed the process characterization and analysis and subsequently drove the implementation of the release process optimization recommendations during a period of significant change within both organizations. The third-party manufacture was in the midst of being spun out from their parent company, and the biotech firm was undergoing reorganization resulting from a buy-out by a fully integrated pharmaceutical company.

Upon final implementation, the duration from drug product manufacture through release to market was reduced by an average exceeding 50% per manufactured lot, and the process became highly predictable without an increase in resources. In addition, the team now has the tools in place to track the progression of each lot through a series of predetermined checkpoints extrapolated from the lot's date of manufacture providing the ability to proactively manage