

Driving Operational Excellence: Optimizing a Quality Management System for a State-of-the-Art Biomanufacturing Facility

BACKGROUND

Syner-G Biotech Consulting recently partnered with a global leader in nucleic acid and mRNA production to implement an optimized Quality Management System (QMS) for their newly established commercial manufacturing facility. This state-of-the-art expansion featured three advanced manufacturing lines and a sterile fill-finish suite, requiring seamless cross-functional coordination to achieve operational readiness within a tight deadline. To ensure compliance with regulatory requirements while supporting efficient engineering operations, the client sought to refine and evolve their existing QMS. Leveraging deep expertise in quality management and regulatory compliance, Syner-G's team of experts delivered a custom solution, navigating tight timelines and operational intricacies to drive the project to success.

PROJECT SCOPE

Syner-G, recognized for its expertise and agility in addressing client needs, collaborated closely with the client to execute a dynamic, phased project plan. By employing an agile approach, the Syner-G team maximized project efficiency while delivering high-impact results. This strategy involved appropriately phasing the project and prioritizing critical elements to enable key operational readiness milestones.

The team conducted a comprehensive gap analysis to assess and address deficiencies in the client's processes and procedures, ensuring compliance with regulatory standards, including 21 CFR Parts 210 and 211. As part of this effort, Syner-G reviewed 142 documents, revising outdated procedures, creating new documentation, and retiring redundant materials. These improvements streamlined the QMS and optimized manufacturing operations.

Syner-G's team collaborated with the client's subject matter experts (SMEs) to ensure updates aligned with operational goals and fostered cross-functional alignment across critical functional areas, including Quality Assurance, Document Control, Engineering, Computer Systems Validation (CSV), GMP Operations, Logistics, and Procurement.

To maintain clarity and transparency, the Syner-G team utilized advanced project management tools and visual dashboards to track project status, risks, and successes. Regular cross-functional meetings were held to enhance communication and coordination, which were essential for managing concurrent workstreams.



OUTCOME

Syner-G successfully completed project deliverables on schedule and within budget, ensuring the client's facility was inspection-ready while supporting commercial manufacturing operations. The updated documentation mitigated risks of non-compliance, reinforced operational excellence, and established a solid foundation for sustained success at the new facility.

In this project, Syner-G's team of experts went beyond addressing the client's immediate challenges but also strengthened their operational and regulatory framework, demonstrating Syner-G's unique ability to deliver high-quality, customized solutions that drive long-term success and growth for its clients.