SYNER-G BioPharma Group

CASE STUDY

From Collaboration to Compliance: A Strategic Initiative for a Safer Workplace

With decades of expertise in safety and compliance, Syner-G BioPharma Group is a strategic partner for life science organizations, helping them develop compliant facility controls and disinfection programs that promote safer working environments.

CHALLENGE

A leading provider of R&D and manufacturing services for the pharmaceutical and biotech sectors faced a significant challenge: expanding its commercial client base while adapting to new regulations for manufacturing sterile drug products (EU Annex 1).

Their existing cleaning and disinfection processes relied on a single disinfectant, leading to residue buildup and increased risk of damage to facilities and equipment. This resulted in significant remediation costs and considerable operational downtime. Recognizing this as an opportunity for improvement, the company's leadership team partnered with Syner-G's team of technical experts and seasoned program managers to implement a fully compliant disinfection program across three facilities, prioritizing the health and safety of hundreds of employees. This initiative encompassed several key areas, including manufacturing processes, material disinfection and transfer, facility disinfection, sterility assurance, compliance, training, facility management, environmental health and safety (EH&S), quality assurance, and environmental monitoring. The goal of this collaboration was not only to ensure a safe working environment but also to set a new standard for operational excellence within the industry.

SOLUTION

Syner-G took a holistic approach in evaluating the client's facility controls, encompassing disinfection, gowning protocols, personnel procedures, material ingress, equipment disinfection, and waste management. This thorough assessment was focused on strengthening the overall Contamination Control Strategy (CCS), creating a robust and integrated framework to enhance safety, compliance, and operational excellence. As part of the evaluation, Syner-G conducted detailed risk assessments and identified gaps in existing procedures to develop a comprehensive remediation plan. During implementation, they introduced new cleaning agents with supporting documentation, incorporated industry best practices, onboarded new tools and equipment, and updated all relevant procedures, accompanied by custom training modules.

OUTCOME

The facility disinfection program was successfully implemented across all three of the client's sites, benefiting hundreds of employees in under 7 months.

< 7 MONTHS OVERALL TIMELINE

The results of the program demonstrated superior environmental control alongside a significant reduction in chemical residues and microbial contamination. A key factor in the project's success was Syner-G's close collaboration with the client's working teams, gaining a deep understanding of their unique culture, needs, and challenges. This collaborative approach enabled seamless engagement with key stakeholders, ensuring an effective sitewide rollout of the program.

This case study demonstrates the critical role collaboration plays in navigating challenges within the manufacturing of sterile drug products under new regulations. Syner-G's unwavering commitment to safety, compliance, and operational excellence empowers clients to overcome obstacles and implement solutions that drive lasting change and organization-wide success.