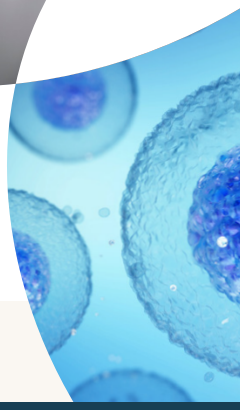
Syner·G

Case Study



The Critical Role of CQV Leadership in Achieving GMP-Ready Cell & Gene Therapy Production

Challenge

A leading biopharmaceutical organization specializing in biologics, including cell and gene therapies, sought to expand its manufacturing capacity for mRNA enzyme therapeutics. The initiative involved designing and constructing a highly technical, GMP-compliant facility capable of supporting multiple product lines within an aggressive 18-month timeline. The critical requirement was to ensure system integrity, compliance, and functional validation, particularly through a comprehensive CQV process that would confirm all equipment, utilities, and systems met regulatory standards for biomanufacturing.

Approach

The scope encompassed the design and build of an approximately 18,000 square foot facility, including Class C/D cleanrooms, QC laboratories, storage areas, and final packaging spaces. Syner-G served as the Owner's Representative, orchestrating multidisciplinary teams across project management, construction, engineering, quality, validation, metrology, and technical documentation.

A key focus was on the CQV lifecycle: systematic commissioning of each system, rigorous qualification of utilities, and comprehensive validation to ensure operational reliability, environmental control, and data integrity—all aligned with cGMP standards. This process involved developing detailed protocols, executing performance qualifications, and ensuring systems seamlessly integrated within the validated cleanroom environment.

Throughout the project, we proactively managed risk mitigation strategies and coordinated third-party suppliers to ensure timely installation, commissioning, and full qualification of process equipment and support systems.

Results

End-to-end CQV execution: Led all aspects of installation, operational qualification (OQ), and performance qualification (PQ) for critical process and utility systems, ensuring they met strict regulatory and safety standards.

Validated infrastructure: Delivered a GMP AOF-compliant manufacturing environment, including complex cleanroom classifications, QC labs, and packaging operations capable of supporting three distinct product lines.

Seamless tech transfer: Facilitated GMP readiness planning from initial site assessment to final SOP development, translating engineering and process documentation into compliant, validated procedures optimized for scale-up and commercialization.

Timely delivery: Achieved completion and validation of the facility within 18 months, enabling the client to initiate GMP manufacturing and meet critical development milestones.

Conclusion

In biopharma, success hinges on validated systems that delivery consistency, safety, and compliance. With our deep expertise in CQV, Syner-G's Technical Operations team ensures every component operates seamlessly and up to standards. We are passionate about empowering our partners to turn scientific innovation into safe, realiable therapies for patients.