SYNER-G BioPharma Group

CASE STUDY

THE RIGHT PARTNERSHIP CAN MAKE ALL THE DIFFERENCE:

Syner-G Partners with Leading Supplier in Life Sciences to Build Out New cGMP Compliant Facilities

Syner-G BioPharma Group is a functional and strategic partner for life sciences and biotechnology companies that assembles fit-for-purpose teams comprised of the right industry professionals and subject matter experts to deliver timely, cost-effective, and successful outcomes for their clients.

CHALLENGE

As production for COVID-19 vaccines ramped up, a world leading supplier was presented with a significant challenge: they needed to rapidly scale up the production capacity of animal-origin free enzymes. This initiative would require the construction and validation of two new US-based manufacturing facilities. Given the time constraints and the magnitude of the project, this leading supplier partnered with Syner-G's local San Diego team of reputable consultants to successfully scope, staff, and execute the two bioprocessing facility design and construction projects.

Projects of this size and scope typically require a minimum of 3 months for planning and preparation, however, the team at Syner-G hit the ground running and leveraged their deep industry expertise in quality, technical operations, scientific operations, and program management to accelerate the thorough planning phase of this project to a duration of only 3 weeks.

HEAR FROM THE CLIENT

"We looked at other consulting firms, but none had resources like Syner-G...They quickly responded to our needs, understood our concerns, and addressed them directly. They were very collaborative from the beginning and could bear the demand we needed immediately to kick off our bioprocessing facility design."

Director of Technical Operations,
Leading Supplier in Life Sciences

< 12 MONTHS

250K SQUARE FT

2 cGMP FACILITIES

HEAR FROM THE TEAM

"Syner-G partnered with this client to provide subject matter expertise on GMP facility design and construction, QMS, and CQV. These are all very detail-oriented processes that require the right mix of knowledge, experience, and diligence to correctly place equipment and systems into use."

Liza Lamb
Sr. Director of Technical Operations

SOLUTION

Despite timeline challenges, due to supply chain shortages and delays, Syner-G successfully coordinated the design and construction of the two new cGMP biomanufacturing facilities in under 12 months – a combined total of more than 250,000 ft2. The newly designed facilities included multiple modular cleanrooms, dual-site QC laboratories, warehouses, and final packaging areas to support three unique product lines.

In tandem with completing the facility buildouts, Syner-G also facilitated the complex international technology transfer from the client's site in Lithuania to the newly constructed US bioprocessing sites. To support this project, Syner-G provided specialized quality expertise to translate and update quality documentation to fit North American standards and assembled a team of subject matter experts to conduct proactive risk assessments, develop a quality management system (QMS), author standard operating procedures (SOPs), and execute on commissioning, qualification, and validation (CQV) activities.

HEAR FROM THE TEAM

"Thanks to our historical familiarity with this client's resources and tools, Syner-G provided experienced contributors to act as delegates on behalf of their leadership in order to directly overcome challenges as they arose."

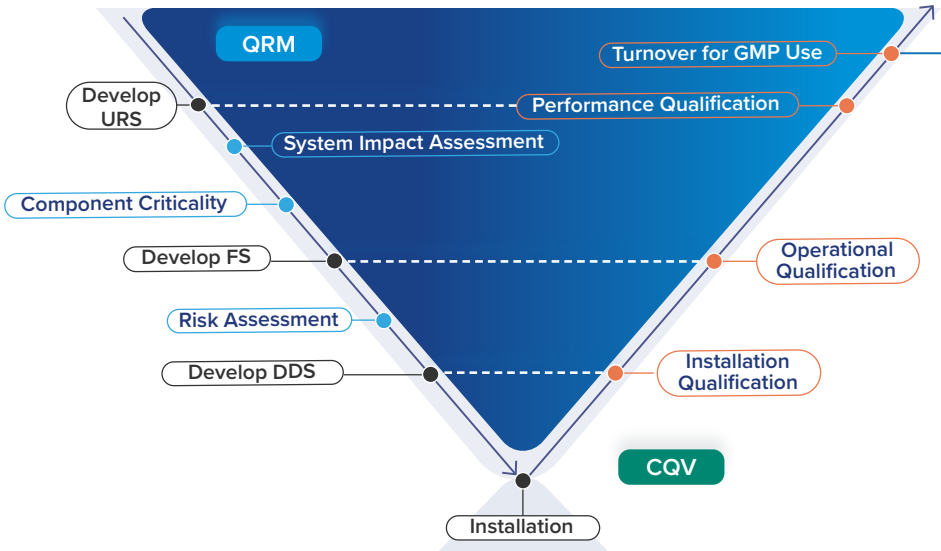
Rich Sordello
Program Manager

Syner-G worked closely with their client's team to develop phase-appropriate strategies based on operational readiness needs. Leveraging best practices and decades of experience supporting manufacturing scale-up efforts for pharma and biotechnology companies, Syner-G utilized the Engineering V-Model for Equipment and System Implementation (See Figure 1) to provide guidance for the planning and scope of this project.

TECHNICAL PROJECT MANAGEMENT

Planning
Management

ENGINEERING



OPERATIONS

Maintain / Operate

- Document Control
- Change Control
- Periodic Review
- Data Integrity
- Facility Management
- Calibrations

Retire

- Decomissioning Systems
- Data Retention
- Decomissioning Facilities
- Data Migration

Terms:

- **URS-** User Requirements Specification
- **FS-** Functional Specification
- **DDS-** Detailed Design Specification
- **QRM-** Quality Risk Management
- **CQV-** Commissioning, Qualification, and Validation

QUALITY

Technical Writing
Document Control
QMS Implementation

THE OUTCOME

Syner-G's specialized and flexible approach was instrumental in securing the overall project timeline for simultaneously completing the technology transfer and facility build-out efforts. Syner-G was honored to partner on this project and rise to the challenge of scaling this leading supplier's cGMP manufacturing operations to support the ramp-up of COVID-19 vaccine production.

HEAR FROM THE CLIENT

"Working with Syner-G's experienced, dedicated team who showed care for us as clients was a refreshing aspect of the project... Their leadership was very responsive and thorough. They were always willing to make changes and adapt as the project progressed, which helped keep the schedule on track. Their process-oriented approach to problem-solving proved invaluable to the project's success."

Director of Technical Operations,
Leading Supplier in Life Sciences

HEAR FROM THE CLIENT

"A large part of what drives us as industry leaders is our steadfast dedication and commitment to collaboration and transparency. The immense scope of this project meant working closely and honestly with our client to correctly place Syner-G team members with the right expertise to support all aspects of the project while managing timelines and budget."

Chan Lam
Vice President of Commercial Operations

Syner-G BioPharma Group is a life sciences consulting firm that provides professional services to early-stage, mid-market, and large enterprise organizations in the pharmaceutical, diagnostics, and medical device industry sectors.

At Syner-G, our success is directly tied to the success of our clients. We're dedicated industry professionals who roll up our sleeves and work side-by-side with our partners to guide tomorrow's big breakthroughs. We believe in the power of collaboration and are honored to partner with clients who are working to make a positive impact on human health.

Learn more at www.synergbiopharma.com