REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Design and Build Out of Biologics Facility

Client

Mid-size

Industry

Biologics

Business Challenge

Planning to build out a new facility intended for entire biologics production.

Project Timeline

N/A

Client Challenge

A European based company engaged in biological drug development was involved in an enormous undertaking when they contacted RCA. They were in the planning stage to build out a new facility intended for their entire biologics production.

RCA Approach

RCA supported the design and assisted in the build out of both their microbiology and physical chemistry laboratories to support its up- and down-stream fermentation process. RCA was contacted to provide the subject matter experts to review the conceptual designs for the following areas and supporting utilities; Facility; HVAC and cleanrooms; Compressed Air; Purified Water System; Extension of existing clean gases (N2, CO2 and O2); Extension of existing Water for Injection System; Environmental Monitoring System; Building Management System; Extension of Clean Media Automation System.

RCA completed the design review and documented their findings in the form of a report. Items reviewed were listed as was the compliance status and risks. Noteworthy results of this engagement included:

- Recommendations for segregation of manufacturing activities, including pre- and post-viral inactivation sections analyzed with regard to air-handling systems, as well as movement of materials and personnel.
- Recommendations and findings for the GMP Water systems supporting each stage of the manufacturing process.
- Recommendations and findings for the GMP Clean Steam systems supporting each stage of the manufacturing and sanitization processes.
- Review and recommendations regarding the Site Validation Master Plan.

Results

The outcome was a GMP compliant facility ready to undergo an FDA inspection. Jump forward to the present and the facility is now producing engineering batches.

In a subsequent engagement, the client asked RCA to provide interim temporary staff for a 3-month period. The positions RCA assisted the client with in terms of staff augmentation included, an Acting Director of Quality Assurance whose responsibilities were to review and approve the QMS policy and procedures, handle validation and qualification efforts and inspectional readiness. Next was a Project Manager to report to the Quality Director. Key responsibilities included: development and maintenance of project schedules, tracking and reporting progress, roadblocks, etc. Additionally, we placed a Quality Control Scientist tol report to the Quality Director. Their role was to develop methods and operational practices for QC labs, training QC staff as required and assist in the design and implementation of qualification studies, including environmental monitoring programs for all technical systems.