



Pharmaceuticals & Biotechnology

Client
Bayer

Location
Berkeley, CA, USA

Sterile Bulking, Filling, and Freeze Drying Facility

Project Description

CH2M HILL Lockwood Greene provided engineering services and validation master planning for Bayer's greenfield sterile bulking, filling, and freeze drying facility (SFF B).

The facility formulates recombinant protein bulk products and fills those products into vials for freeze drying and final capping. CH2M HILL Lockwood Greene's scope included the following:

- Documentation for project design including process block, flow, and piping and instrumentation diagrams
- Layout to provide movement of materials and equipment during the formulation process to prevent contact of clean and soiled equipment
- Logical flow path and staging of autoclaved and non-autoclaved production materials and equipment
- Detail purchase specifications for all equipment inclusive of validation requirements
- Design of washing and CIP/SIP systems for change parts and equipment
- Vendor selection and bid evaluations
- Studies to identify best methods for handling hazardous and non-hazardous materials
- Equipment and facilities general arrangements
- Software design specifications, functional requirements, and unit operational requirement services

Features of the project included:

- Relocating the core team to a satellite office near the client's site facilitated the design process.
- Designing flexibility via layout segregation allowed multiple products to be processed without loss of product integrity.
- Integrating an automatic load/unload system allowed vials to be transported from the filler to the lyophilizers and then the capping line without personnel intervention
- Leveraging prior experience with the required equipment allowed specification and bid of the freeze dryers, which were critical to many other aspects of the design, within only three months of the design onset.

- Preparing preliminary studies ensured the best possible design for HVAC systems; segregation of products; production activities; and personnel, material, and waste handling.
- Working closely with several consultants ensured that unique project requirements were met
- Incorporating validation services into the earliest phases of the project ensured the integration of validation requirements in the process, design, and specifications as they were developed, not after the fact.

The scheme consists of a three-level facility with a total 73,000 sf building area. The first floor is comprised of the main facility access, locker-gowning rooms, the primary process areas (Bulking, Filling, Freeze Drying) and the process mechanical areas. The process area layout, consisting of Class A, B, C, and D areas, is based on product and personnel flows. Bulking and formulation are located on the same level as filling. The partial second floor houses production support, a breakroom, and offices. The third floor comprises production support areas and the building mechanical space (AHUs and electrical equipment).

The process is designed to enable the filling of multiple products in varying vial sizes with a recombinant product. The vials are transported to the lyophilizers and capping and labeling steps. Two capping streams are part of the process train.

The central control system selected is an ABB Advant Distributed Control System (DCS). The DCS provides direct sequential control, regulatory control, and data management for PLC provided with the processing equipment. All process data is collected onto a single database for electronic data management in compliance with 21 CFR, Part 11. Electronic Batch Record System allows immediate access to data and records through a system and site network.

The 233 ft. by 140 ft. building is stretched east to west at the south side of the site to allow northward expansion for future fill lines. The SFF B is connected to the new warehouse/packaging facility with a non-classified third level bridge.