



Confidential Pharmaceutical Client

Vaccine Facility and Equipment Design

Location

Maryland

Client

Confidential
Pharmaceutical

Market Sector

Science & Technology

Size

30,000 sf

The Opportunity

A start-up Biotech company had several new successful recombinant BCG vaccine candidates which were developed in a small research lab. They were looking to take these candidates to the next level and needed to expand to clinical manufacturing. PS&S provided a phased approach for the design of the equipment and facility. The first phase housed a scale up fermentation train along with centrifugation. The facility also included a process development lab, CIP systems, frozen storage, research labs and related office support space.

The Challenge

The clinical facility, along with the lab and office space, was to be located in a commercial building shell. Appropriate separation of manufacturing space and lab space needed to be incorporated with the ability for each to expand in the future. Cost for equipment was a concern in Phase 1 and it was decided to send the downstream process and aseptic filling off site in 2004. By 2008, the company had grown so fast it was now feasible to bring the downstream process and filling steps back into the building.

The PS&S Solution

Upgrades to the utilities were required to create the separation between the R&D and the clinical manufacturing. Several small dedicated air handlers were added to the roof to allow for flexibility of room use. Small batch sizes were also a problem. PS&S selected small-scale, validatable equipment for formulation, filling and lyophilization steps. Equipment was all bid to several vendors to ensure best cost.

