Confidential Pharmaceutical Client

PDP-6 GMP Upgrades

Location

West Coast, USA

Client

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Market Sector

Science & Technology

PS&S California, Inc. provided architectural, structural, mechanical and electrical engineering services for GMP upgrades of a pharmaceutical facility that produces PDP-6 product. Prior to design efforts, PS&S performed an analysis and created a Basis of Design (BOD) report which focused on options for architectural layouts of the manufacturing area and the mechanical and electrical upgrades required to support the proposals.

The BOD consisted of three distinct projects intended to help the client meet the demand due to changing market requirements. The projects consisted of renovations to the existing production space: New Longitudinally Compressed Tablet Laser (LCT-4) Room, Vision Inspection System for Finished Tablets and Microbiology and Finished Products Laboratories.

PS&S' expertise in pharmaceutical processes stood out during development of the BOD report. The client wanted a Cleaning Hot Water Skid to be installed which would provide central cleaning water for use by various manufacturing areas. The Biopharma group was required to determine the capacity of the hot water skid and the facility infrastructure required to support its installation. A User Requirements Specification was established and proposed piping layouts and flow diagrams were created to help establish proposed system design parameters. As a result of our investigation, it was determined that the project should be re-evaluated because of potential harm to employees if put into operation. The client decided not to pursue the project.

For each of the renovation projects, architectural work included space programming to determine the optimal locations for the major production equipment. New finishes for the spaces were also developed. Mechanical engineering work included schematic design of three new air handling units and four new exhaust fans, all capable of serving GMP spaces. Existing site utility requirements were also verified during the design process. Structural engineering included the design of a new bridge providing access between building roofs and support of rooftop mechanical equipment.

Manufacturing is a 24/7 operation. Therefore, PS&S had to design the project in such a way that construction could be completed without the need to shut down any of the existing manufacturing suites. Design implications included routing of ductwork and piping on the roof to avoid indoor construction and architectural construction phases along the perimeter of the GMP areas.

This project proved to be extremely challenging. Various manufacturing departments at the facility compete for the limited space needed to meet their production requirements. Further complicating the issue was the amount of personnel and number of different departments who had a stake in the success of the project. As a result, PS&S took control from the start by interviewing key decision makers and identifying production and regulatory issues early on to help the client visualize a path to successful project completion.