Project Profile

Confidential Client

H1N1 Vaccine Manufacturer

Logistics Resource Planning and Scheduling Program



Objective

To assist H1N1 vaccine manufacturer with readiness for production lots with a set date based upon funding award for manufacturing by the US Government. IPS implemented a fast track approach to maximize efficiency while meeting the aggressive schedule going from new facility turnover to first production lots. The development of detailed logistics, staffing and materials resource planning minimized delays and enabled the client to get through engineering runs, facility PQs, media runs, consistency lots and first run lots in the desired timeline.

ips

Our program met the following objectives:

- Develop a detailed schedule and coordinated critical activities to minimize disruption to engineering and process simulations
- Used capacity modeling to effectively identify constraints and bottlenecks in order to develop shift and sequencing of events to meet schedule.
- Reviewed all activities (ops, QC, engineering, project) utilizing a riskand science-based approach to ensure product and patient safety (and meet compliance requirements)
- Provided resources for schedule and plan development, day to day updates, weekly reviews, assessments and compliance reviews
- Developed manufacturing readiness strategy including standards and key performance indicators

Project Description

Our combined expertise met all objectives and developed the detailed logistics, staffing, materials resource plans within two weeks of the start of the project. Services included:

- Development of initial standards for all production related activities in bulk blending and filling
- Development of equivalent standards for QC related to monitoring and testing hands on time (HOT)
- Leveraged standards, including models to determine required resources to meet aggressive schedule
- Developed an hourly schedule for each team (i.e., Bulk, Fill, QC and Maintenance) to highlight bottlenecks, conflicts, issues and provide potential resolutions
- Provided a weekly schedule with daily details for each function used for daily review which became the communication mechanism to ensure full coordination and alignment are achieved.



Project Profile



Confidential Client (cont'd.)

H1N1 Vaccine Manufacturer

IPS Value Added

- Employed a fast track approach to meet aggressive timeline
- Utilized a risk- and science-based approach as basis for sequencing of events and tests
- Identified bottleneck and resources issues and provided potential alternative for resolutions
- Provided a communication tool for schedule changes and resource needs
- Developed and implemented a proactive schedule and expedited solutions for identified issues
- Highlighted spatial conflicts between functions (i.e., QC for sampling and Bulk for PQ) and managed schedule to ensure functional needs of all teams was met
- Enhanced visibility and managerial span of control in terms of resource management and constraints



A sampling of output from the scheduling tools used throughout the project. (Confidential information was removed)

