Recovery and Purification Capacity Analysis

Client

Major Biotech Manufacturer

Situation

The firm’s Clinical Trials Program was faced with very large production capacity shortfalls at one of its key U.S. manufacturing facilities, which led to delays in scheduling clinical trials.

The facility produces four separate products using very limited, shared resources in a constrained space. The process involves the preparation, running, and cleaning of equipment, for which the client was having difficulty controlling and keeping track of the effect of numerous production delays. These delays led to the expiration of three batches in 2004 valued at $1 million dollars each, as well as costly delays in the clinical trials.

Their production team has never needed to undertake Process Improvement efforts before, so at this point they had many questions but few answers. They engaged ProModel Corporation to help them based on prior success with ProModel at their other facilities.

Objectives

• Determine why the manufacturing plant was unable to meet the demand required for clinical trials.
• Provide the client with a solution that allows them to test, in a risk free environment, potential solutions once the root cause(s) were identified.

Solution

ProModel’s team utilized its VAO (Visualize, Analyze, Optimize) technology in collaboration with the client team to create a customized integrated production simulation and scheduling solution.

• This solution consists of a detailed production simulation model integrated with a scheduling system in order to combine the ease of a scheduling system with the ability of simulation to help develop robust plans.
• Microsoft® Visio was used to map out the process flow and used as the foundation for the model. If the analysts want to change or add a new process they simply change the flow chart and it automatically updates the model and the Microsoft® Excel input templates.
• The Excel input templates make it easy to change production tasks process times and the resources requirements.
• Scheduling software is integrated with the model and is used to evaluate the proposed schedules with Gantt chart output reports.
• An unlimited number of “What-If” scenarios of different improvement options can be run, and then the systems Key Performance Metrics can be compared to evaluate the best course of action.

The application can provide accurate answers to the following types of questions:
• What are the best shift patterns to use?
• How can more batches be produced per year?
• How can delayed batches be saved before expiration?
• What is the correct combination of resources?
• How should investments be made to quickly realize ROI?

The solution was verified to be accurate within 2% of the current 10-day purification process cycle time.

Results

• Identified ways to reduce the Cycle Time of the products by more than 7%.
• Helped increase the service level of on-time deliveries from 80% to over 93% within 6 months.
• Helped determine ways to increase the capacity of the production system by more than 5% with no additional capital expenditures.
• Helped show how to minimize the incidence of batch expiration, resulting in a cost avoidance of over $3 million per year.
• The client now has a highly flexible model that represents and predicts the performance of their production process, which can be used to continually improve the process over time.
• A user friendly interface enables the client team to quickly create scenarios itself as part of its continuous improvement efforts.
Results

Batch production per year doubled (figure 1) that paid for itself within 100 days (figure 2).