Global Pharmaceutical Company

One of the largest healthcare companies in the world and a global leader in consumer products and animal care has a large facility in the Mid-Atlantic Region. This is their only domestic manufacturing facility and accommodates five major technologies: fermentation, organic synthesis, sterile, pharmaceutical, and vaccine with over 680 dedicated employees.

The site also houses research capabilities and experimental vaccines. The recent addition of a new production facility for vaccines further enhances their biotechnical capabilities. In addition, the facility was working to install a new diabetic treatment production line and they wanted to confirm that the design and installation plan was capable of meeting target production volumes without interfering with other product manufacturing.

Objectives

• A tool designed to evaluate whether all facility assets can keep up with product demands
• A flexible solution into which any input changes can be made from a spreadsheet template architecture
• A model to evaluate WFI (Water for Injection) and ERW (Endotoxin Reduced Water) utilities supply and demand to assure production needs are met

Results

The model output shows that the Harvest portion of the facility can handle two batches at a time and complete the process in 3.48 days which makes it capable of achieving production targets of four batches per week. However, the Purification portion requires a much longer cycle time and is the focus of the model testing process.

<table>
<thead>
<tr>
<th>Sector</th>
<th>WIP</th>
<th>Completed</th>
<th>Mean Process Time (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvest</td>
<td>2</td>
<td>8</td>
<td>3.48</td>
</tr>
<tr>
<td>Purification</td>
<td>3</td>
<td>5</td>
<td>6.07</td>
</tr>
<tr>
<td>Total System</td>
<td>5</td>
<td>5</td>
<td>9.50</td>
</tr>
</tbody>
</table>

Purification Area Results:

• Not enough mix tanks created a bottleneck at Unit Op (Trypsin Digest). This bottleneck was resolved by changing the preparation of concentrated buffers that are diluted when utilized in the process flow. The prep tanks were able to maintain an adequate buffer supply for the process operations.

• Identified the constraining purification process step and evaluated prospective changes that removed constraints. Experimented with several design changes to the process via the model.

• Confirmed that the utilities would be sufficient for required production. These values will be affected if additional buffer prep capacity is brought on line.

• The system with changes would be able to meet the four batches per week requirement.
ProModel consultants worked with a Pharma Company team of experts to develop a “Software Development Toolkit” (SDK) architecture. This SDK was created so they could vary the inputs via flexible spreadsheet input templates. ProModel created an adaptable format appropriate for broad application. All of the manufacturing processes were represented as tank icons in the customized model which helped illustrate and determine future bottlenecks, optimal batch sizes, and proper lead times for MRP.

The model construction made it possible to add new features as process development continued for the products and facility. New equipment and process changes could be evaluated to confirm that plans for boosting output were achievable.

Custom output reports can be created on any key performance indicators as desired, see examples below.