

# Pharmaceutical Company Meets New Drug Production Targets with the Help of Simulation

Pharmaceutical Company

Success Story

Pharmaceutical Manufacturing

ProModel



## CHALLENGES

A Philadelphia-area based developer of new drug products based on existing NSAIDs was beginning production of a new non-steroidal anti-inflammatory, at a vendor location. This product involves a proprietary sub-micron milling process that requires extensive cleaning between milling passes. Due to the logistics of this cleaning process, it is challenging to accurately predict system performance.

There was also a downstream process unit operations challenge to meeting the committed production targets. ProModel and the pharmaceutical organization partnered to develop a simulation-based solution to evaluate the equipment and resources necessary to achieve production targets for this new product launch. The same vendor was approved to produce another similar formulation. ProModel was able to quickly add it to the model.

## OBJECTIVES

The objectives of this simulation solution were:

- Accurate projections of the monthly, quarterly, and annual throughput for this facility.
- Identify the correct number of tanks and bins necessary to support the Milling Process with an emphasis on the turnaround time necessary for wash, inspection, and chilling.
- Experiment with varying delay times for various process steps in order to understand the impact on system performance.
- Determine the number of FTE's required for milling and tank wash, roller compaction and encapsulation processes.
- Determine bottleneck areas.
- Identify non value-added or redundant processes.
- Identify a cost-effective deployment strategy.
- Test an unlimited number of schedule demand scenarios.
- Determine and or increase throughput capabilities across scenarios.
- Enable the client team to change model inputs for rapid "what-if" scenarios.
- Analyze resource use and requirements (Equipment, WFI, etc.) over time and across any demand scenario.

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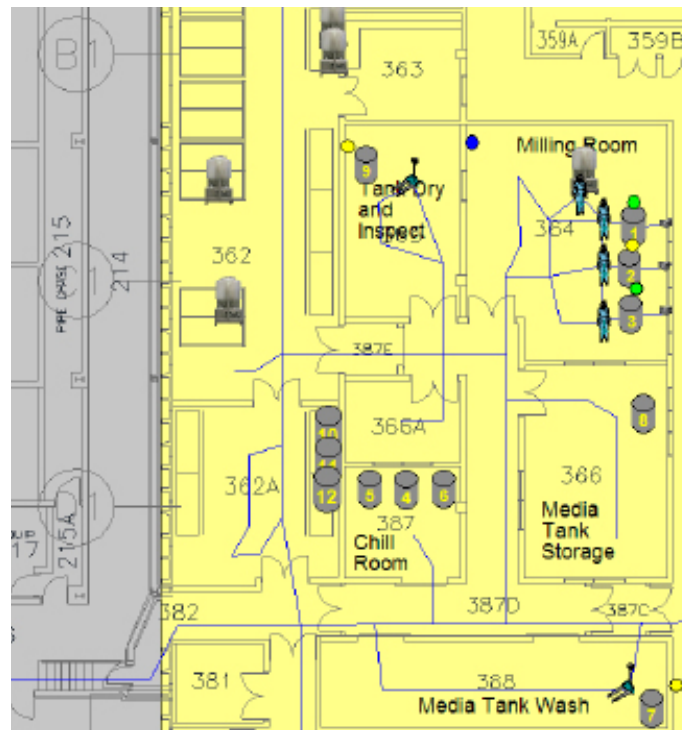


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## SOLUTION

As seen below, ProModel built the model on top of a CAD diagram of the vendor facility. The four key elements of the milling process, milling, media tank storage, tank dry and inspect, and tank chill, were in rooms adjacent to one another; while the roller compaction and encapsulation activities took place elsewhere. Critical to optimizing production was understanding the stringent requirements for the cleaning processes. Along with tank cleaning, a two shift long area cleaning was required at FDA specified intervals. The solution provided flexible inputs to allow necessary personnel to provide detailed controls for the duration of each process activity and resources needed for each process step. There are also separate levels of cleaning inputs for batch and campaign transitions. These inputs generate an FTE profile for each scenario tested. FTE types are defined by the area they are assigned to.

Critical to understanding the process is the ability to run the solution with constrained or unconstrained FTE resources.



## VALUE PROVIDED

The model was able to determine exactly how much of each drug and formulation could be made. The solution also allowed them to develop campaign strategies around the FDA cleaning requirements to optimize production. ProModel consultants were able to quickly add the additional product to the model so production capacity for it could also be understood.