

Biotech & Pharma Manufacturing C Simulation



Manufacturing



Healthcare

Overview

A biotech startup, providing experimental personalized medical treatment, wanted to conduct data-driven pharmaceutical manufacturing simulation to optimize decision-making processes when delivering new products. These products were undergoing clinical trials, and the manufacturing processes remained unclear while US Food and Drug Administration (FDA)

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early stages. Saving on scale cannot be achieved because the products are so highly personalized for each patient. During clinical trials, the pharmaceutical products are produced in very small quantities, while the production process is constantly changing based on the responses of the patients. The company required a digital tool to test the future mass production manufacturing environment and identify bottlenecks. Its leaders retained [Princeton Consultants](#) to develop a pharmaceutical manufacturing simulation model of the future production process and optimize decision-making.

Problem

Princeton Consultants developed a model for the future manufacturing process and facility scheduling strategy based on simulated data, because no actual data was available. The consultants had to determine the maximum production capacity the facility could reach without loss in quality. The priority was to prevent production failures, so it was necessary to detect possible bottlenecks and evaluate options to remove them with the help of a pharmaceutical simulation model. If an error occurred during production, the time-consuming process had to be restarted from the beginning, resources were wasted and, most importantly, the patient might not have enough time to receive treatment.

A small number of machines, used at different phases, were involved in approximately 50% of the production. This equipment was expensive and bulky and could not be supplemented. Optimizing its use required

hours a day in the procedure room. Overtime was very costly and needed to be minimized.

When the pharmaceutical simulation project started, the Princeton Consultants team encountered unusual modeling problems associated with specific requirements.

- Developers did not have statistics and metrics to confirm that the pharmaceutical simulation model worked correctly because the pharmaceutical manufacturing process itself was not finalized.
- To prevent process interruptions, large buffer intervals were introduced. This policy successfully minimized failures, but also led to downtime of scarce equipment because the machines were not used for most of the buffer time. It was necessary to find a balance and determine the minimum buffer time necessary to reduce failures.
- The simulation run ranged from 80-120 days, which significantly slowed down the scheduling algorithm. In fact, 90% of the time was spent on planning, rather than on the actual simulation run.

In addition, scheduling was complex for several products manufactured simultaneously with the same scarce resources that needed to be preserved to prevent processing failures. The goals of the pharmaceutical manufacturing simulation were to prioritize procedures, minimize failures, increase the efficient use of resources, reduce the overall production duration, and minimize overtime for operators.

evaluating and comparing scenarios.



*Pharmaceutical simulation
model demo*

At the early stages of development, the model reflected the prototype process that existed at the clinical trials. The correctness of basic model behavior was verified on that prototype process. Process changes and new

functionality were then added. After each iteration, intensive tests were run. Detailed results and key metrics were tracked and reviewed by the project and client teams to determine if they were reasonable given the assumptions.

In order to determine the optimal buffer volume, a simulation was carried out with different parameters and scenarios, balancing risk and reward according to the number of failures. The pharmaceutical manufacturing simulation results provided a better understanding of timing issues for fine-tuning the buffer size.

Dynamic events, hold blocks, and timeouts were used to manage how agents moved through resource-constrained points in the process, sometimes removing them from certain process flow blocks and inserting them in a previous part of the flow. The current and future state of every agent and resulting schedule flexibility were tracked and passed to the scheduler.

Seeding the latest call of the model with the most recent solution allowed for a significant reduction of

The pharmaceutical manufacturing simulation saved months of development time and enabled the biotech startup to evaluate potential manufacturing process changes before its facility was complete. The model was instrumental for the fine-tuning of process areas most likely to result in failures or excessive resource usage. As a result, a better, more reliable planning algorithm was developed.

Based on the simulation results, Princeton Consultants determined that some of the proposed changes would lead to a better process architecture, but would also impose additional resource requirements for the already limited system. The company leaders decided to focus research efforts on critical areas to shorten heavy resource utilization points. Simulation facilitated determining how many orders could be processed for a certain period of time, and the recommended time to complete those orders. The company collected high-value insights of the pharmaceutical manufacturing process and, as a result, defined scheduling policies to best use operators without excessive overtimes or overstaffing.

Watch the video of Patricia Randall, presenting this case study at [The AnyLogic Conference](#), or download the [presentation](#).



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