



**Japanese Pharmaceutical Company Improves
Quality with Aspen Plus[®]**



96%

Reduction in Crystallization Time and Impurity Production

CHALLENGE

- Scale up production of a new active pharmaceutical ingredient (API) while improving the purity of the product.

SOLUTION

Aspen Plus provided an in-depth understanding of a new API process leading to equipment improvements and optimized recipes that enabled development of a continuous process.

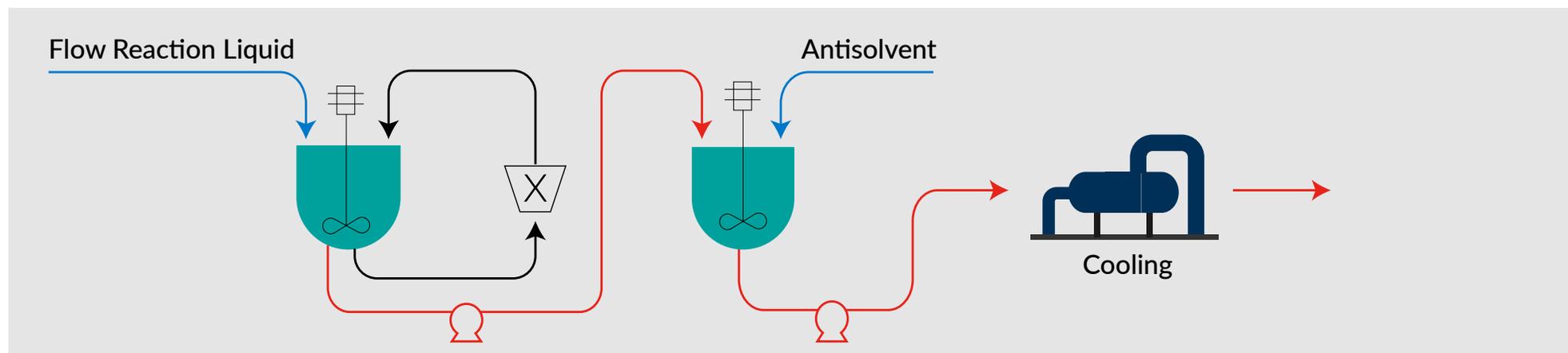
BENEFITS

Aspen Plus delivered multiple benefits:

- impurities decreased from 500 ppm to 20 ppm
- crystallization time dropped from 8 hours with a batch process to just 20 minutes with a continuous process
- shorter research and development time for the new API

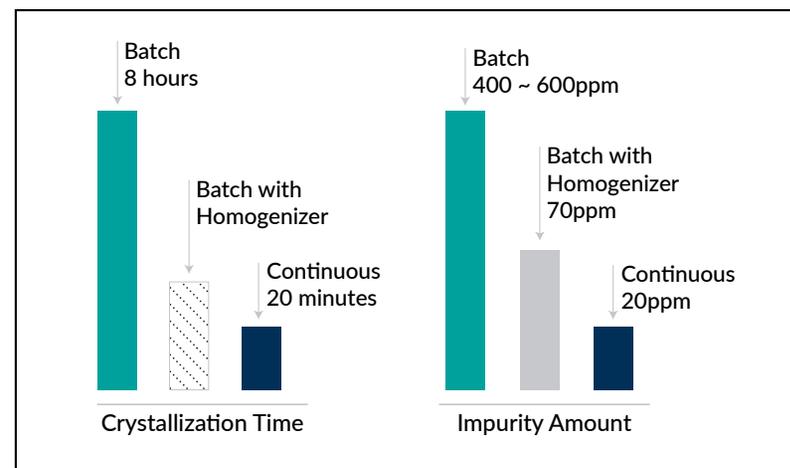
A 140-year-old global pharmaceutical company with headquarters in Japan adopted Aspen Plus to improve the synthesis of a new active pharmaceutical ingredient (API). The company researches, develops, manufactures and distributes pharmaceuticals and medical devices, with a focus on new drug discovery.

Understanding the Batch Process and Identifying Crucial Variable in Byproduct Production



Aspen Plus allowed the company to better understand the reaction and crystallization kinetics and the key drivers leading to the generation of impurities. After calibrating the model against lab data, they applied the model to evaluate options to reduce cycle time and limit byproduct formation. Compiling a risk assessment for the batch process highlighted the most sensitive factors leading to undesirable byproducts. With this knowledge, the company found a solution using a homogenizer to accelerate crystallization.

With new insight gained from simulation, process engineers designed mechanical improvements to the reactor to reduce crystallization time and byproduct formation. Now the company is using the model to develop a continuous process to further improve quality and throughput.





Moving from Batch to Continuous for Better Quality

The company had two goals, which were closely connected: improving product quality and moving from a batch process to continuous manufacturing.

Using simulation modelling would allow the company to show a Quality by Design approach to product development, a priority for drug makers to demonstrate that they've challenged raw materials and processes to ensure products are performing not only as intended, but as optimally as possible given the inputs.

Insight from Aspen Plus Drives Process Improvements

Using Aspen Plus to model the process allowed the company to find conditions which would speed crystallization, reduce byproducts and increase quality and yield. The process engineering team appreciated the extensive database of material properties and library of models included in Aspen Plus, which helped them get up and running quickly. With the ability to easily add or customize models, process engineers were able to quickly create accurate solids and process models. The company saw results and return just a few months from the time they implemented Aspen Plus.

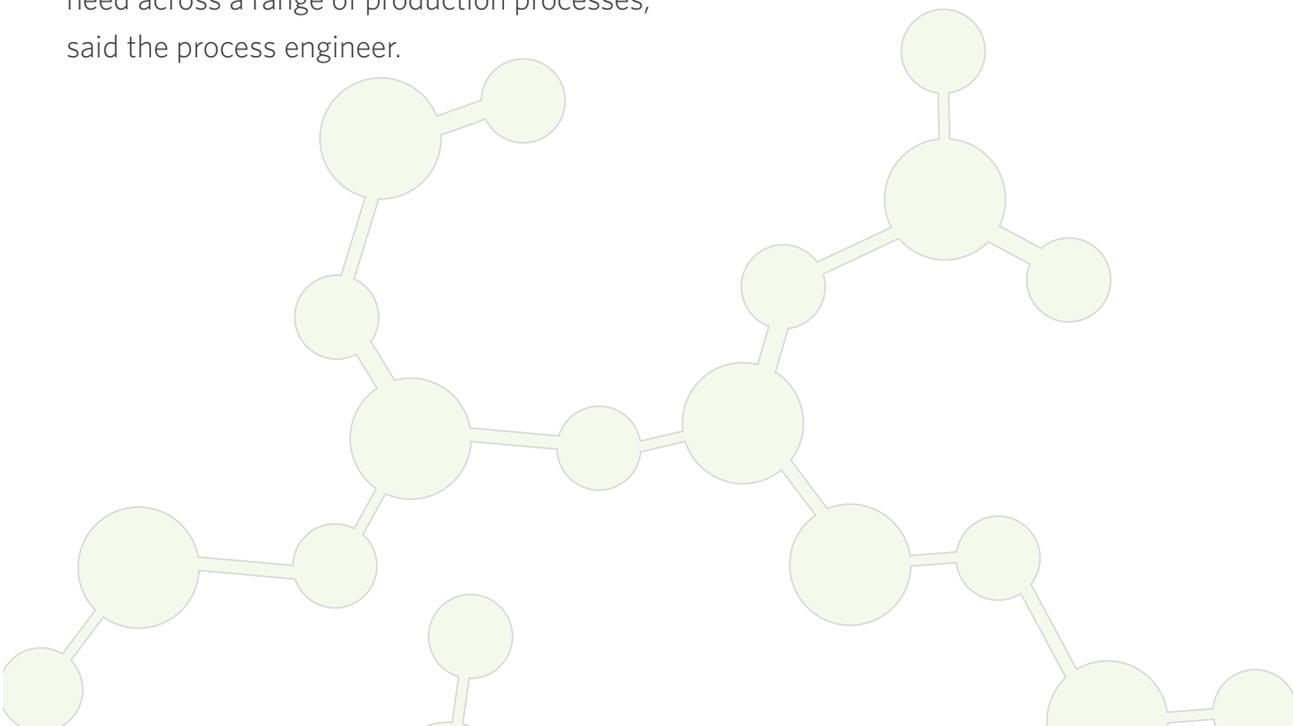
The company saw AspenTech's regional presence and localized software as additional benefits. "We can get support and replies in Japanese during our typical business hours. Advice from an experienced solution consultant has been very helpful," said one of the process engineers in new drug discovery.

While he and some others use the English language version of Aspen Plus, most users at the company use the Japanese version.

The breadth of AspenTech's products impressed the company as well. "With modeling, AI, machine learning, and control systems, AspenTech's products cover what we need across a range of production processes," said the process engineer.

Expanding for the Future

While the company is currently using Aspen Plus for continuous flow process engineering, the company would like to expand use to its process chemists for reaction simulations to reduce the number of tests required during new product development.



About Aspen Technology

Aspen Technology (AspenTech) is a leading software supplier for optimizing asset performance. Our products thrive in complex, industrial environments where it is critical to optimize the asset design, operation and maintenance lifecycle. AspenTech uniquely combines decades of process modeling expertise with machine learning. Our purpose-built software platform automates knowledge work and builds sustainable competitive advantage by delivering high returns over the entire asset lifecycle. As a result, companies in capital-intensive industries can maximize uptime and push the limits of performance, running their assets safer, greener, longer and faster. Visit [AspenTech.com](https://www.aspentech.com) to find out more.

