GSK

GSK Avoids Batch Loss with Aspen Process Pulse<sup>™</sup> and Aspen Unscrambler<sup>™</sup>

( aspentech | Case Study

# **100%** Early and accurate warning of product pH probe

O% Adverse damage done to cell culture

#### CHALLENGE

Eliminate pH variability in bioreactors that could potentially jeopardize the batch of product

Reduce process drift and equipment failures

Implement monitoring strategy that process operators could easily interpret

## **SOLUTION**

- Aspen Process Pulse
- Aspen Unscrambler

### **VALUE CREATED**

- Effective diagnosis of historical issues
- Real-time identification of process drift and equipment failures
- Fast deployment and expansion

# Overview

GSK, a leading multinational pharmaceutical and biotechnology company, delivers world-class innovation in vaccines and specialty medicines. The company places a strong focus on research and development to quickly bring to market new medical treatments, and often leverages new technologies like artificial intelligence (AI) and machine learning (ML) to improve speed and scale. Trust is a core component of their product delivery, so timeliness and quality are key criteria for production. Variability in the production process can result in delays or scrapped product, and the sensitivity of the materials and regulations mean real-time monitoring to detect potential issues is essential.



Machine Learning

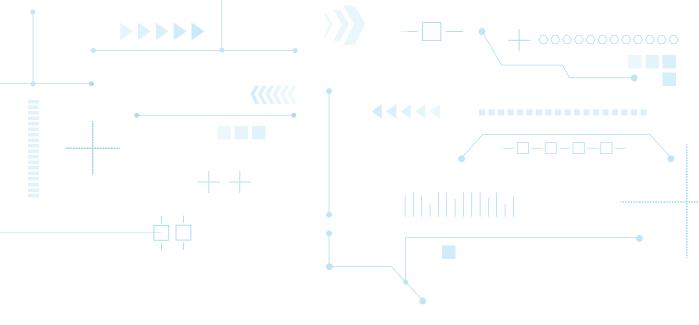
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## From Faulty to Accurate pH

GSK was looking for a monitoring strategy for their bioreactors that could detect process drift and equipment failures in real time while being simple enough for process operators to interpret. The bioreactor process is highly sensitive to pH levels and is controlled within a small, proven, acceptable pH range. Continuing the process with a faulty pH probe could jeopardize the batch of product used to produce a biopharma drug substance. An off-spec batch would result in significant revenue losses. GSK sought out AspenTech<sup>®</sup> solutions to help circumvent these challenges. Initially, historical process data was extracted from Aspen IP.21<sup>®</sup> and used to train the Batch Trajectory and Static PCA (Principal Component Analysis) models in Aspen Unscrambler. These models were then deployed to Aspen Process Pulse for live monitoring of production bioreactor batches. Aspen Process Pulse correctly flagged a faulty pH probe before any adverse damage was done to the cell culture, which was involved in producing a biopharma drug substance worth over \$5 million. Operators changed the controlling pH probe to ensure no erroneous amounts of acid or base were added to the media.





# Expansion to All Assets

The use of Aspen Process Pulse has been operationalized at the GSK manufacturing site and expanded to the entire seed train. The Aspen Process Pulse models will also be deployed for every new asset coming to the facility.



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#### About Aspen Technology

Aspen Technology, Inc. (NASDAQ: AZPN) is a global software leader helping industries at the forefront of the world's dual challenge meet the increasing demand for resources from a rapidly growing population in a profitable and sustainable manner. AspenTech solutions address complex environments where it is critical to optimize the asset design, operation and maintenance lifecycle. Through our unique combination of deep domain expertise and innovation, customers in capital-intensive industries can run their assets safer, greener, longer and faster to improve their operational excellence.

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