



## CUSTOMER CASE STUDY

---

# Boehringer Ingelheim and the quest for the golden batch

Boehringer Ingelheim

Industry - Pharmaceutical and life sciences

Partner - Sartorius Stedim Data Analytics

## Challenge

- Understand variation in biological batch processes

## Solution

- Employ AVEVA™ PI System™ to facilitate multivariate data analysis techniques and attribute data

## Result

- Reduce production variance, generate greater batch potency, reduce batch destruction, and increase yield

The story of pharmaceutical production is often a quest for the golden batch: a repeatable process that consistently optimizes yield and quality. Recently, an animal health subsidiary of Boehringer Ingelheim, a top international pharmaceutical company, began collaborating with Sartorius Stedim Data Analytics. The joint project uses multivariate data analysis techniques (MVDA) to create golden-batch trajectories based on historic data. These trajectories can then be used for real-time monitoring and prescriptive process control for higher-potency batches.

Compliance is always a chief concern for biopharmaceuticals. Results must fall within a proven acceptable range (PAR) of acceptable variability. “It’s about demonstrating that your batch is under control – that’s the compliance aspect of this,” said Will A. Penland, principal data scientist for animal health at Boehringer Ingelheim. “The government takes that very seriously. You need to demonstrate that your process is under control and that you are capable of meeting the specification limits.”

Minimizing batch variation and understanding the causes of variability is a crucial but difficult task. “When you are dependent on biological processes for the creation of your product, there is a lot of inherent variability that you have to contend with,” Penland added. “With a biofermentation process, you can put the same thing in, and if you have production variances, you can get something quite different day by day.”

The problem is that variation can arise at many points in the process. Part of the mystery is always which process attributes or conditions are responsible for the greatest degree of variation. The sheer number of potential sources of variation makes this a critical but difficult question to answer when pursuing the golden batch.

## What if?

Penland and his team began by asking themselves a simple question: “What if?” What if they could reduce production variation? What if they could identify crucial process attributes? And then, what if they could target those key process components to reduce production variance, generate greater batch potency, reduce batch destruction, and increase yield?

The answer seemed to lie with MVDA and advanced statistical-modeling techniques like principal-component analysis (PCA) and partial least squares (PLS). But implementing MVDA presented another set of obstacles. Gaining a better understanding of process variability meant monitoring the process at many levels. This complex monitoring generates many kinds of data.

In order to use the company’s data-analytic software, SIMCA, it needed a way to first aggregate and contextualize the data from these potential sources of variation.

## Managing data is the hard part

“Eighty to 95% of the work is managing your data,” Penland explained. This is where AVEVA PI System came to Boehringer Ingelheim’s rescue. Using the asset framework of AVEVA™ PI Server, the company created data tags of different classes for various types of data streams related to the fermentation process.

AVEVA PI System allowed it to bring its diverse data streams together, aligning its SCADA, LIMS, process control, and attribute data, with its time-resolved spectroscopic data.

Boehringer Ingelheim also triggered process steps within its programmable logic controller and used a step numbering system to create event frames. It now uses a parent-child event-frame model to keep a close eye on the various stages of the fermentation process, particularly the growth phase. The parent event represents the batch, and the child events are the various steps within the fermentation process.

---

“If we come to a customer and they have PI with a good configuration, then we can have a monitoring process, advanced analytics – the whole thing – up and running in a matter of days.”

-

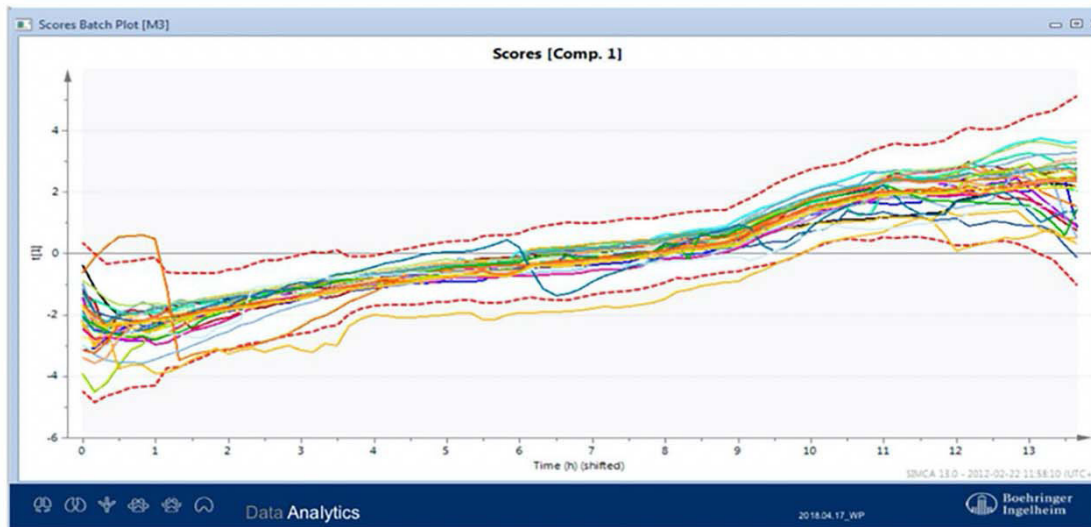
**Chris McCready**

Lead Data Scientist, Sartorius Stedim Data Analytics

## Batch evolution model

Each line = 1 batch

Multivariate control chart



Multivariate data analysis and batch-evolution modeling enable Boehringer Ingelheim to gain insight into its fermentation process.

Templates enable the company to ensure consistent configuration of its process stages. Templates are crucial for a large international company like Boehringer Ingelheim. “The analytics is one thing, but the challenge these days is to make these things scalable, reproducible, and easy to template to move across platforms,” said Chris McCreedy, lead data scientist at Sartorius Stedim Data Analytics. “If we come to a customer and they have PI with a good configuration, then we can have a monitoring process, advanced analytics – the whole thing – up and running in a matter of days. And if they have asset framework, then we can take what we did in New York and we can apply it in Singapore. It’s very cut-and-paste.”

Now that AVEVA PI System enables Boehringer Ingelheim’s advanced data analytics and batch-evolution modeling, the company is becoming more data-driven, predictive, and proactive. It can now see things as they are happening or before they happen with each batch. “We have a data-driven mindset now,” Penland said. “We are asking, ‘How do we interpret this, and what is the data telling us?’ rather than having a more reactive, knee-jerk response, fighting fires all the time.”

For more information about Boehringer Ingelheim and AVEVA PI System, watch the [full presentation here](#).

**AVEVA**

aveva.com

© 2023 AVEVA Group plc and its subsidiaries. All rights reserved.  
AVEVA and the AVEVA logo are a trademark or registered trademark of AVEVA Group plc in the U.S. and other countries.  
All product names mentioned are the trademarks of their respective holders.