

# Batch Quality Prediction



ALL INDUSTRY VERTICALS

## Data Sources

- OSIsoft PI: Process data
- OSIsoft PI Event Frames: Batch execution information
- Microsoft SQL: Batch lab results

## Data Cleansing

- Filtered data to build model based on reactor heating operation

## Calculations & Conditions

- Define operations for the batch process
- Calculate critical process parameters
- Create predictive model for yield

## Reporting & Collaboration

- Model deployed online with dashboard visualization
- Enabled rapid fault detection and root cause analysis

## Challenge

Quality is the most critical metric in pharmaceutical manufacturing—after all, nothing is more important than protecting patient health. Drug companies need to test each batch to ensure it meets quality standards.

However, predicting the quality of a batch has traditionally been a challenge for drug manufacturers. The usual process is to take samples while a process is running and send it to the lab for analysis. But waiting for lab results adds time—often several hours—to the process. Inadequate lab results can require time consuming changes or expensive reworks if it is even possible to recover the batch. If the batch does not meet the quality requirements, the manufacturer can lose anywhere from hundreds of thousands to millions of dollars for a lost batch.

A large molecule pharmaceutical manufacturer was struggling to predict batch quality results in near real-time. Delayed lab results made it difficult for the company to optimize process inputs to control the batch yield. The company's process inputs were set without optimizing the process, resulting in the potential of wasted energy and raw materials or reduced product quality and yield. The company needed a better way to predict batch quality, enabling process optimization.

## Solution

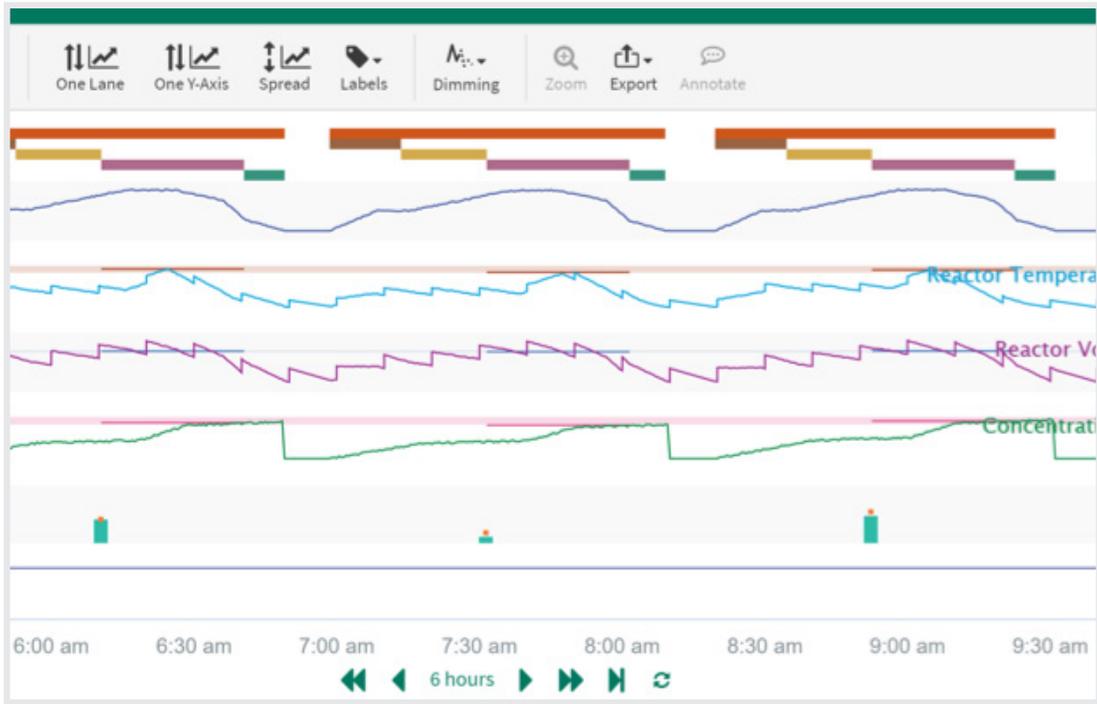
Using Seeq, the scientists built a model of process quality based on data from the OSIsoft PI data historian. The team uses the model to predict the quality of during in progress batches, enabling modifications during production before a batch needs to be scrapped for a quality issue.

This analysis uses typical process measurements such as the reactor temperature, volume, and concentration as process parameters for controlling yield. The raw data is filtered to the desired operation of interest, the reactor heating portion of the process. A predictive model for yield is then generated based on statistically significant process parameters. The model was deployed online to detect abnormal batches.

## Results

Instead of waiting for quality tests to come back from the lab, the manufacturer has potentially saved millions of dollars by gaining the ability to rapidly identify and analyze root cause analysis of abnormal batches via modeling. It can reduce the number of out-of-specification batches by adjusting process parameters during the batch. The company also saved on the reduction of wasted energy and materials.

Developing and deploying an online predictive model of the product quality and yield can aid in fault detection and enable rapid root cause analysis, helping to ensure quality standards are maintained with every batch.



Batch quality prediction model compared to online data for the reactor heating portion of the batch.

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