



“Right First Time” Operation for Improved Process Robustness

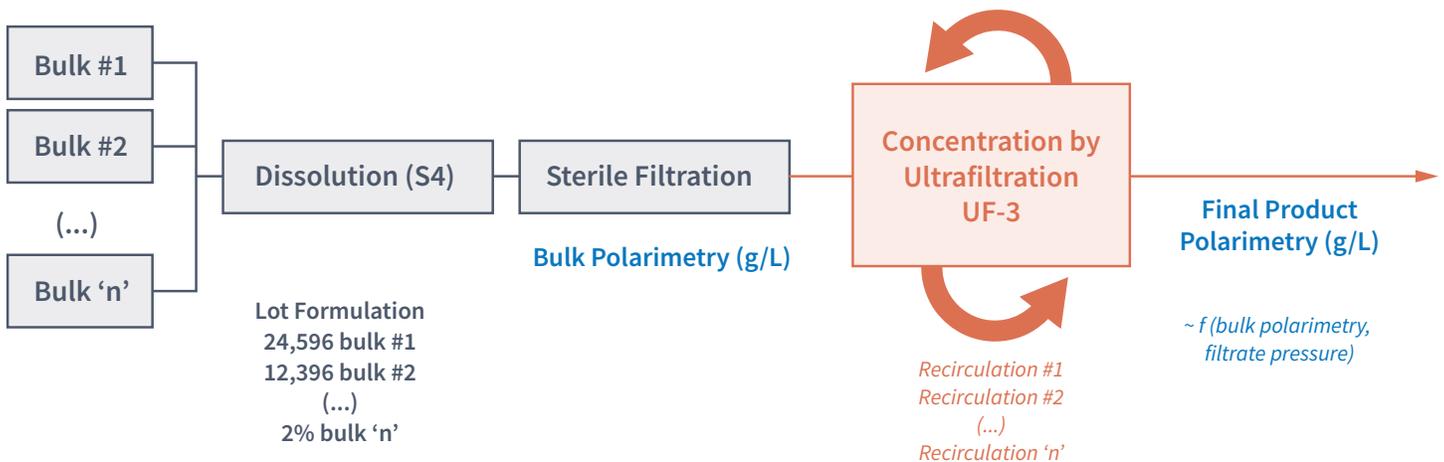
Multinational Biopharmaceutical Company Reduces Number of Downstream Ultrafiltration Recirculations via Predictive Analytics

The Problem

A multinational biopharmaceutical company was looking to reduce their operational inefficiencies and reduce costs by avoiding numerous recirculations at their ultrafiltration process step. Even with a lot of effort and analysis, they struggled to get the targeted concentration of the drug product (polarimetry) correct or “Right First Time.” The polarimetry is one of the Critical Quality Attributes (CQA) that represents the concentration (g/L) of the product and has to be between certain limits before moving to the next process step. Their process and material data was spread across different data silos like Oracle, DeltaV, and GLIMS. In fact, there were a lot of parameters that controlled the ultrafiltration process - over 100! Even if the data was centralized, there were too many factors involved to simply rely on classical statistical methods for any meaningful insights.

Two questions needed to be answered. Which is the Critical Process Parameter (CPP) that has the biggest impact on the polarimetry out of the Ultrafiltration unit? Then, what is the CPP set point to obtain the optimal polarimetry to avoid recirculation?

Getting answers to these questions would require a platform capable of ingesting and managing data in a compliant way with the ability to apply machine learning (ML) algorithms.



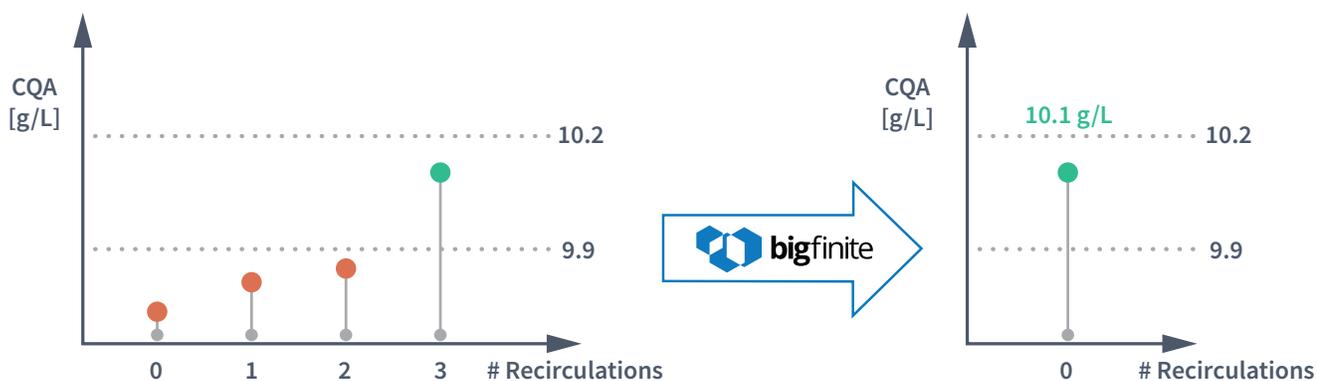
Case Study: “Right First Time” Operation for Improved Process Robustness

The Solution

First, their data needed to be collected and normalized into a central location. Bigfinite’s award-winning platform connects and ingests data real-time, from multiple disparate data sources, and ensures the data is stored in a compliant way in the underlying cloud data lake. Now, They could monitor and analyze critical parameters across several unit operations and multiple data sources to get a more holistic understanding of their processes.

With the data now centralized, they could use Bigfinite’s real-time continuous Principal Component Analysis (PCA) functionality to discover and analyze the co-dependent relationships between all of these process variables. With that, they were able to reduce the complexity of all of their variables and determine that the speed of the pump supplying the bulk material through the filtration unit had the single biggest effect on target polarimetry parameter.

Finally, having quantified to which extent the pump speed was affecting the CQA, Bigfinite was able to bring in artificial intelligence (AI) to predict the optimal pump speed to obtain the CQA value in the target range - thereby avoiding recirculations. Through an iterative process, Bigfinite was able to establish a highly accurate machine learning model where the team was able to predict which value for the pump speed that should be applied to get the targeted polarimetry after the filtration process.



The Results

Leveraging an accurate prediction model, this biopharmaceutical company has proven the ability to go from multiple recirculations to getting the ultrafiltration process step “Right First Time.” Recirculations are now no longer necessary and they estimated a 61% reduction in the total number of runs and a 53% boost in process effectiveness. Moving forward, they now have all of the data they need for a good AI approach. The data is no longer lost and it is all captured in a GxP-compliant manner making any future audits easier, too.



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