aizon

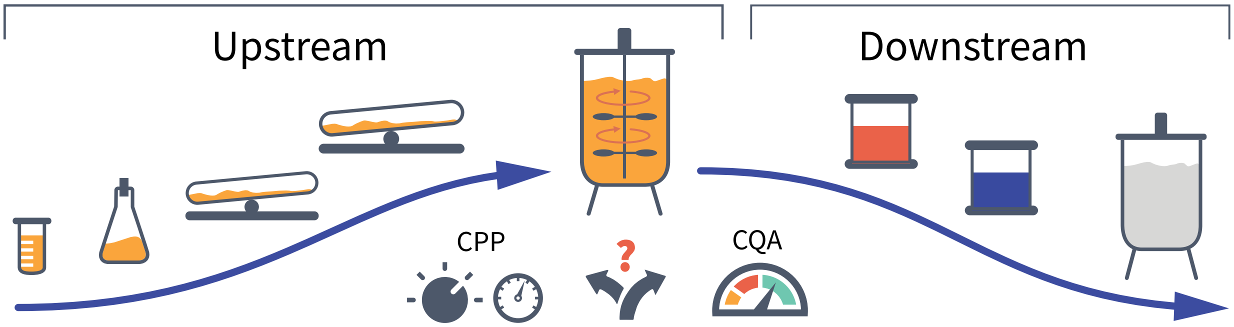
CASE STUDY

Predictive Pooling Strategy: Global Biotech Company Reduces Risk in Downstream Purification

Customer: Large Global Biotechnology Company

The Problem

A site for a large global biotechnology company was looking to explore predictive models to improve the yield of their downstream bioprocess using historical data. The site produces a rare disease medicine where the value per gram can be hundreds of thousands of dollars, making it important to optimize for every gram per batch. As a former 'Facility of the Year' award winning site, it has a relatively mature data infrastructure. Even with that, data was still manually collected into spreadsheets and could take a full day of manual effort to chase and organize the relevant information to prepare downstream purification production runs. Furthermore, relying on the manual effort for data collection and analysis, there was not a high confidence in the "goodness" of each planned batch and ran on trial and error to try to optimize those batches.



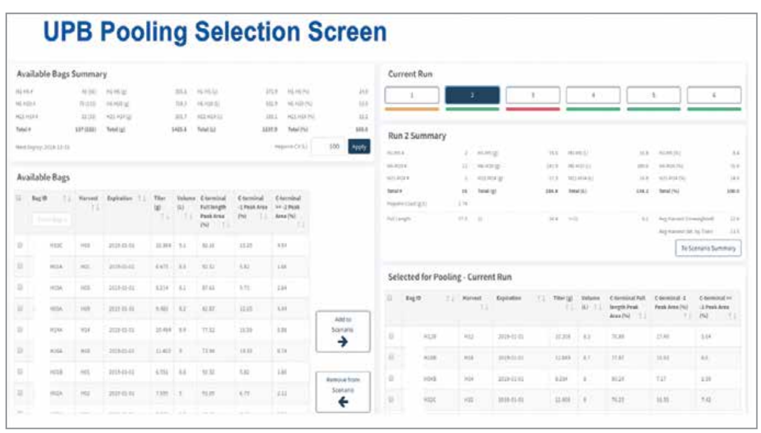
They had a very modern perfusion (continuous) upstream process. The unpurified bulk (UPB) material is harvested each day into single use bags and stored in a deep freeze inventory. As required by the site production plan, these bags are later pooled into a campaign of multiple batches for the downstream purification process. Each campaign is typically 5 to 6 runs. The operations team pools up to 20 bags of material with 25L in each into a single downstream run for a total of ~120 bags per campaign being pulled from inventory.

Their goal was to figure out how to choose the best selection of available bags in inventory that, across 6 runs, would provide the optimal total yield of protein, without risk of sacrificing the yield of later runs by using the 'best bags' in the early runs of a campaign. How could they pool selection of bags in each run, and 1) fulfill the 'hard requirements' per the control strategy (e.g. total start protein concentration, harvest day distribution, etc.) and 2) optimize to predicted yield per run and in aggregate for the campaign?

The Solution

The initial step was to ingest data from five different data sources into the Aizon platform, pertaining to how each bag was made in the upstream fermentation process. This included material genealogy, electronic batch records, process data (Critical Process Parameters (CPPs)), ERP planning data, and LIMS data (Critical Quality Attributes (CQAs)). Aizon's award-winning platform provides flexible contextual models to link and relate information from multiple disparate data sources, and ensures the data is stored in a compliant way in an underlying cloud data lake.

Aizon then developed the basis for predictive models using Principal Component Analysis (PCA). The thousand variables available were reduced to 36 variables) which were identified as having a meaningful contribution to explain variations in the content of the bags. To develop the predictive model with an artificial intelligence algorithm, Aizon used LIMS data from 104 different downstream runs that were identified as having meaningful data and used those to train the model.



Once the model was produced, the AI-powered, GxP-qualified platform was configured to allocate bags from inventory to the desired number of batches, solve for the specific constraints and predicting the expected yield for each run, as well as in aggregate for the campaign of batches. In the application, the user has a real-time view of all bags in inventory, with the ability to manually allocate or deallocate individual bags to each run. At every point, the application reruns the prediction algorithm and automatically provides the operator with a summary of each run. Within minutes the user can perform multiple what-if scenario models, and rapidly gain increased confidence in the optimal allocation of bags for the pooling strategies.

The Results

For many years, the operations team for this site has spent a lot less effort to do the pooling strategies in taking bags out of inventory and setting up for a run and reduces the risk of suffering one or more poor runs. With the Aizon platform, they saw a 93% reduction in pooling time. What could take a full day or more to pull data together and try to extract how to combine the bags, now takes minutes to optimize and explore various scenarios. It is also less effort for other groups like quality to sign off because of the higher confidence in the pooling strategies for campaign batches. This digital process, leveraging the AI-based predictive models, simulates decisions, allows them to see likely outcomes, and ultimately get the optimal results with lower risk and higher degree of confidence.

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