

Pharmaceutical Company Increases Yield in Batch Manufacturing with Al Insights



A global pharmaceutical company is a leading producer of vaccines, oncology, and general medicines, with operations in over 60 countries worldwide. The company was challenged with suboptimal yield and sought a solution to address the problem.

In biologics manufacturing, as in all batch processes, ensuring quality and maximizing yield for each batch is critical to the company's bottom line. Low yield batches waste raw materials, limit production line capacity, and can require long and time-intensive investigations. In biologics processes, live cells are cultivated to produce proteins or antibodies. Cell cultures have inherent batch-to-batch variability across reactors, processing steps, and production lines. Operators often struggle to maximize yield in the face of this variation.

Prior to engaging C3 AI, the company made an executive commitment to leverage AI and machine learning (ML) in every facet of its business. Internal teams had built offline data science experiments to help optimize yield but struggled to deploy them in a usable format for manufacturing production. With the in-house solution, yield insights were sent to process engineers

late in the batch process, hindering their ability to take action with the information. Engineers also spent 3-5 hours on manual data analysis to understand historical batch performance. To overcome these challenges, the company needed real-time yield prediction and optimization, as well as quick access to information from historical data and operating documents.

The company chose to partner with C3 Al to implement Al solutions for manufacturing and to improve biologics yield. The team started by deploying C3 Al Process Optimization with embedded generative Al search and chat. In 6 months, the C3 Al team configured C3 Al Process Optimization to predict two critical properties of batch yield – viability and product concentration – in 3 days, eliminating 7 days of delay. This enabled an estimated 1.5% increase in annual yield, representing up to \$2 million in potential annual economic benefit at the facility from increased production. Generative Al search enables engineers to access information from batch data in minutes rather than hours, with up to 96% accurate responses.

Project Objectives

- Generate timely batch predictions so engineers can act early to maximize yield
- Accelerate time-to-insight with generative Al search for structured and unstructured data
- Unify data from siloed systems to provide operators comprehensive ML insights on yield performance
- Configure C3 Al Process Optimization to offer ML insights in an intuitive user interface

Results

\$10M+

potential annual economic benefit when deployed across 5 facilities

70%

reduction in time to insights, from 10 days to 3 days

1.5%

estimated increase in annual yield

96%

accuracy rate in generative AI responses

Challenges

Before partnering with C3 AI, the company had limited capability to predict yield in its biologics manufacturing process. Process engineers and production personnel relied on manual analysis in spreadsheets to assess yield late in the final stage of a batch's run, on day 10 of 14.

The lack of yield insights early and throughout the manufacturing process forced the company to assume a fixed duration for each batch in the largest and final bioreactors of the production line. The optimal harvest point varied widely, however, and could be either longer or shorter than the fixed duration by multiple days. The inability to adjust production based on optimal harvest points caused multiple issues, including lost production when batches could not be extended, production schedule problems due to downstream processing constraints, and lower production concentration than desired. Without early insights into batch performance, these issues led to suboptimal yield and total production.

Engineers and operators were also hampered by siloed data sources, manual analysis processes, and a lack of effective software tools. To track each batch's progress, manufacturing engineers entered sample data into spreadsheets. Without an automated method to group data by batches and easily plot features, especially on live batches, personnel had to create each analysis across batches, bioreactors, and other variables on an ad hoc basis. Simple questions such as "Which batches were produced in the first quarter of 2023?" and "Which batches used a particular additive?" could take 3-5 hours to answer as engineers pieced together batch data and contextual information from operating procedures, engineering reports, and other documents, running 40+ data queries and manually transcribing 200+ data points.

About the Company

- \$20+ billion in annual revenue
- · 60+ countries of operation
- · 30+ manufacturing plants worldwide
- 60,000+ employees

Project Highlights

- 6 months from project kickoff to production-ready application
- 2+ years of historical batch data integrated from 3 siloed systems and 1000+ pages of documents
- 9 ML models configured and tested, with 60+ underlying features, to track and visualize batch yield
- Embedded generative AI search and chat powered by C3 Generative AI
- 3000+ structured questions that process engineers can query against operational documents and historical batch data
- Configured C3 AI Process Optimization application user interface

Approach

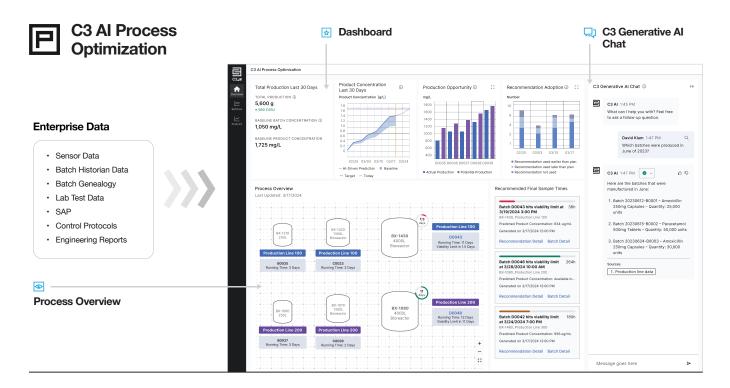
Over 6 months, C3 AI partnered with the company to configure and deploy C3 AI Process Optimization with generative AI search and chat for a biologics drug substance manufacturing facility. The team started by virtualizing, normalizing, and unifying 2+ years of historical batch data from 3 different systems. The data image included DeltaV batch historian sample and action records, IP21 time-series sensor readings, SAP batch genealogy data, and lab sample readings.

The joint team configured and tested 9 ML models that predicted key variables in determining batch harvest readiness. The models leveraged 60+ features that could be examined in detail through the application's Al evidence package. These models predict when the batch harvest viability limit will be reached 3 days into the batch, providing engineers with insights 7 days earlier and enabling a 1.5% improvement in annual yield. Predictions are routed to existing harvest scheduling processes through an in-app workflow to optimize the harvest schedule.



The C3 Al team configured the C3 Al Process Optimization user interface to the company's specifications, including batch analysis tools that allow engineers to monitor the process in near real-time and easily draw insights from trends analysis and batch comparison. Integrated generative Al search capabilities took this one step further, allowing engineers to ask over 3,000 simple questions about batch data and operating procedures with 96% accuracy rate in responses. In minutes, users can now gain insights that previously took hours.

Solution Architecture



Benefits

Unlock

\$10 million in potential annual economic benefit across 5 facilities by maximizing yield

Ask

over 3,000 questions about batch performance with 96% accuracy rate in generative Al responses

Increase

annual yield by 1.5% for batch manufacturing process with early yield predictions

Unify

disparate batch data from 3 different systems alongside data from operational documents

Minimize

delay in batch insightsby providing predictions
7+ days earlier

Scale

Al applications across manufacturing facilities using a flexible data foundation

Query

2+ years of batch data and over 1,000 documents to analyze and improve yield performance