

Enterprise AI for Pharmaceuticals



Improving Drug Manufacturing Reliability and Performance

A global pharmaceutical company produces, distributes, and markets 40 distinct drugs to over 120 million patients annually. Its drug portfolio combats a wide range of life-threatening conditions, including cancer, diabetes, heart failure, chronic obstructive pulmonary disease, and influenza. The company's top priority is to ensure patients receive uninterrupted supplies of therapy, which requires minimizing manufacturing production delays.

Drug manufacturing is a highly sophisticated process. In the company's largest biologics manufacturing plant, 100+ distinct systems must operate continuously and seamlessly throughout a two-month cycle to produce a single batch of drugs. An unanticipated system failure may compromise the drug quality and lead to scrapped batches or production delays. Lost revenue from unanticipated system failures can amount to \$40,000 – \$70,000 per hour

at this single plant, or up to over \$50 million per year depending on the severity of the delays.

Prior to engaging C3 AI, the company lacked an effective approach to anticipate and prevent system failures, relying instead on rule-based alerts and emergency response teams to address system failures after they had occurred.

The C3 AI® team configured the C3 AI Reliability application to predict system failures in this company's largest biologics manufacturing plant with \$3 billion annual revenues. With C3 AI Reliability, the company can monitor system health and performance across the plant, anticipate failures up to 10 days in advance, take preventative action, and increase throughput by decreasing production delays and scrapped batches.

Project Objectives

- Integrate and unify data from 6 disparate data sources (e.g., sensor data, sensor specs, workorders, batch records, plant alarms)
- Apply machine learning algorithms to predict or detect system failures and avoid production delays
- Configure the C3 AI Reliability user interface and expose AI insights and unified analytics to end users

Results

\$150M

potential annual economic benefit across all plants

90%+

reduction in false positive alerts

75%

of all asset failures predicted across 2 production systems

10 days

Early warning of failures events up to 10 days in advance

Challenges

The global pharmaceutical company operates more than 100 distinct systems in a 400,000 square foot biologics manufacturing plant. These systems must run continuously (at or near 100%) throughout a two-month cycle in order to produce a successful batch of biologics. However, recent reliability challenges with two critical systems—Clean-In-Place (CIP) Skids and Water-for-Injection (WFI) pumps have caused mounting production delays.

The company had attempted to address reliability challenges using traditional rules-based monitoring and alerting solutions. However, most alerts generated by legacy systems were false and provided only minutes of advanced warning. Technicians were unable to diagnose issues, take preventive actions, reduce downtime or avoid breaches to sterility protocols prior to system failures.

The company previously used business intelligence software and manual spreadsheets to address reliability challenges. However, the following challenges had continued to impact their ability to anticipate system failures:

- Statistical outliers, invalid timestamps, and system downtime were difficult to detect and mask, making it impossible to train AI algorithms with accurate data
- Real-time sensor readings, setpoints and historical failures were stored in disparate databases, including a process historian, Advance Process Control (APC) solution, and Maintenance Management System, making it challenging to correlate operational data, model routine system behavior or flag anomalies
- The lack of a robust data integration and normalization engine meant that data scientists could only work against one month of historical data extracted from two or three disparate data sources at a time, which was insufficient for training robust AI models
- Comprehensive timeseries analytics could not be constructed using legacy tooling, failing to capture useful failure signatures required for predictive algorithms

About the Global Pharmaceutical Company

- \$24 billion annual revenue in 2019
- 120 million patient lives impacted
- 30 manufacturing plants worldwide
- 70,000 employees

Project Highlights

- 12 weeks from kickoff to pre-production application completion
- Integrated 5 years of historical data, comprising of 2 billion rows of data from 6 enterprise IT systems across 3 data networks
- Built an extensible data model with 27 C3 AI logical objects
- Developed 3,700+ timeseries analytics for machine learning models and application UI
- Configured and tested 800+ machine learning model permutations to predict system failures and detect anomalies
- Configured the C3 AI Reliability application user interface

Approach

Over 12 weeks, C3 AI configured the C3 AI Reliability application for two critical systems in a \$3 billion biologics plant of the global pharmaceutical manufacturer: Clean-in-Place (CIP) skids and Water-for-Injection (WFI) pumps.

The team began by ingesting, cleansing, and unifying 5 years of historical sensor, enterprise, and external data comprised of more than 2 billion rows of data from 6 enterprise IT systems. This unified federated data image, which stores sensor data, sensor specs, workorders, plant alarms, and batch records, enabled the company to deploy and operate the C3 AI Reliability application on up-to-date data pulled from all relevant sources. It also formed the foundation for addressing additional AI use cases in manufacturing including yield optimization, inventory optimization, and supply chain visibility.

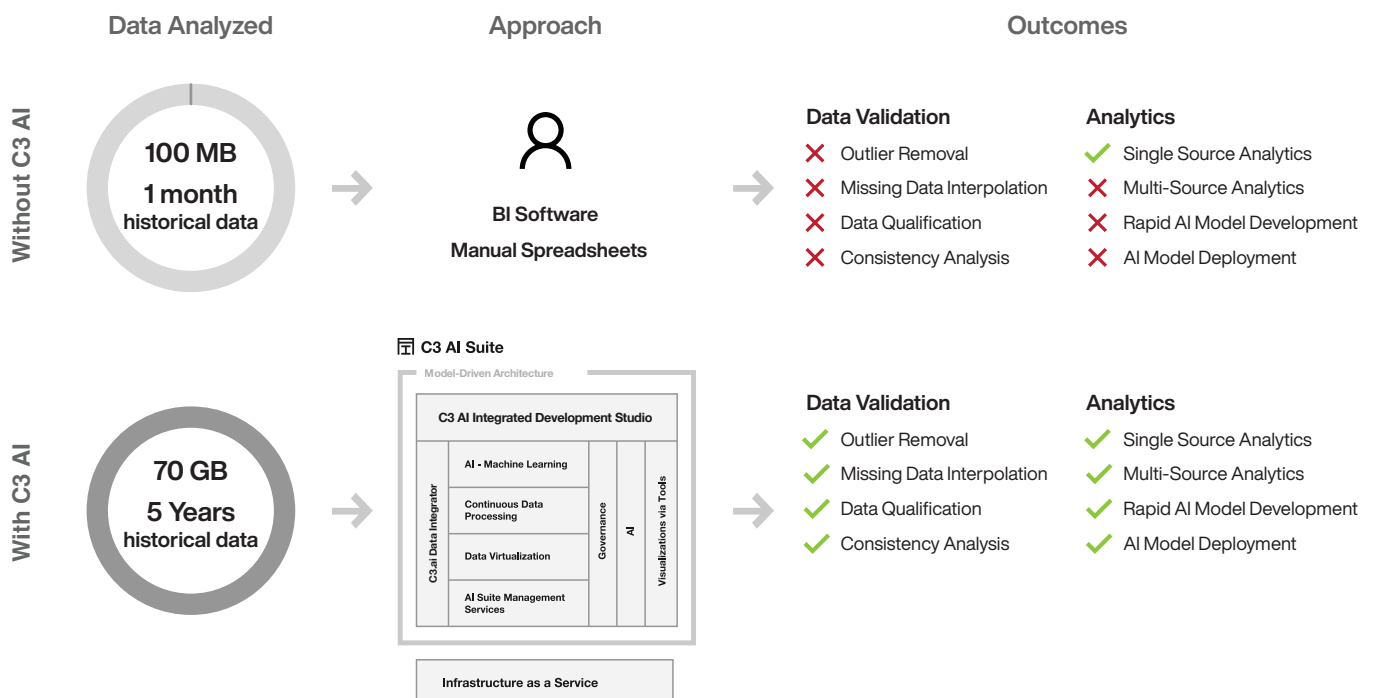
In the project, both supervised and unsupervised algorithms were adopted to improve the reliability of the two systems with varying data availability. For CIP Skids, which have ample failure labels across the operating

history, 600+ supervised machine learning models were configured to generate failure predictions one day in advance of failure, giving technicians sufficient time to take preventive action and avoid downtime. For WFI Pumps which have no recorded historical failures, 200+ unsupervised machine learning models were configured to detect anomalies that indicate the possibility of failures in the next 10 days; this advanced warning allows operators to diagnose issues and make changes in advance of failure.

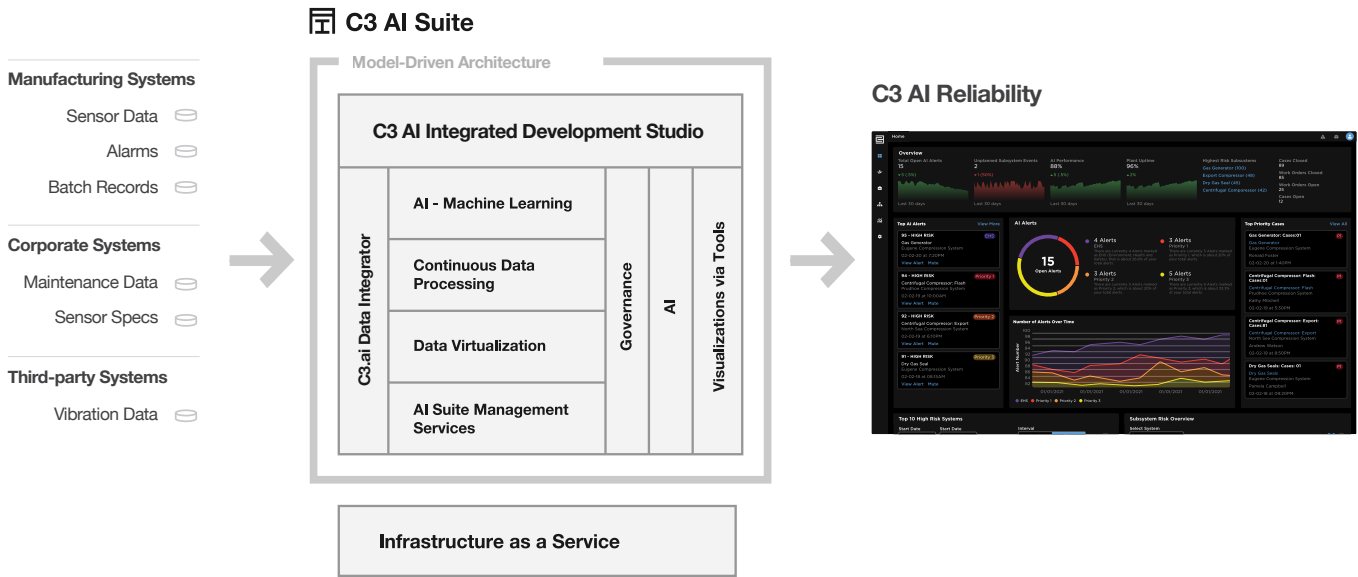
The team created over 3,700 machine learning features and applied advanced feature selection techniques to identify and exclude features that did not contribute significantly to model performance. These techniques allowed the team to include top 40 most relevant features in the final model without sacrificing performance, thereby enhancing model interpretability and enabling traceable root cause analysis.

Finally, the joint team built a multi-screen user interface to visualize AI-based insights and failure risk scores in addition to time series-based analytics across all manufacturing subsystems in scope.

Capabilities Unlocked by C3 AI



Solution Architecture



Benefits

By using the C3 AI Reliability application, the global pharmaceutical company can:

- Generate up to \$150 million of potential annual economic benefit across all plants
- Predict failures 1–10 days in advance for Clean-In-Place (CIP) skids and Water-for-Injection (WFI) pumps
- Drive a 90% reduction in false positive alerts while leveraging AI to predict:
 - 100% of all WFI pump failures
 - 75% of all CIP skid failures
- View top factors contributing to AI-based failure risk scores to guide troubleshooting
- Monitor system health and performance across the manufacturing plant in near-real time
- Reduce maintenance costs by up to 60% by shifting from reactive to proactive maintenance
- Improve manufacturing throughput and reduce production delays by 25%
- Leverage a data foundation which enables rapid design, development and deployment of a suite of manufacturing AI applications (e.g., Process Optimization, Inventory Optimization)

Proven Results in 8-12 Weeks

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