



Where software concepts come alive™

Business Domain

Biotech&Pharma

Project Type

Cloud-based platform

From Raw Sensor Data to Insights: Mining Subtle Quality Factors from Large-Scale, Curated Datasets

Reduction of Batch Variability by 12% in Industry Leader Tests

Client

A global leader in bioprocessing technologies, providing innovative bioreactors, controllers, and automation systems for pharmaceutical and biotech production worldwide.

Project

A custom bioprocess control software platform enabling instrumental data collection, storing, processing, and analyzing for data-driven process optimization, adhering to GxP guidelines.

Objective

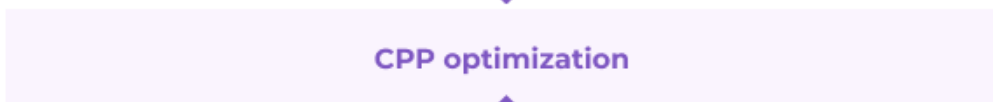
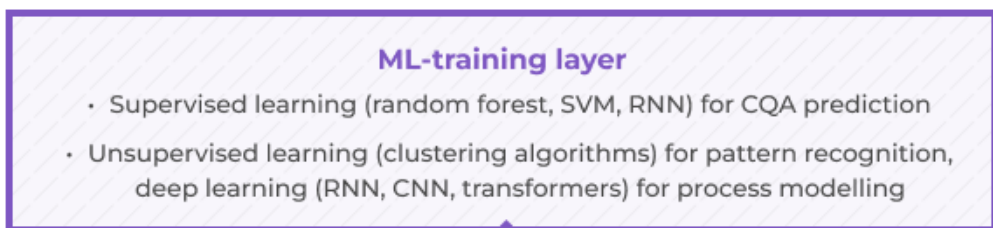
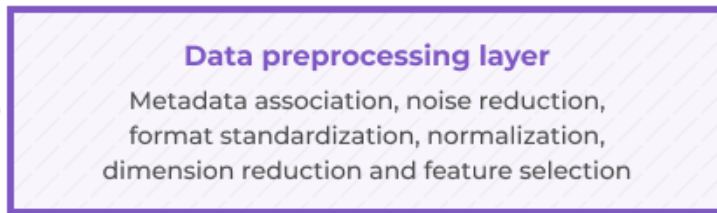
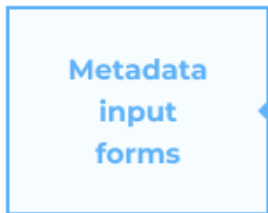
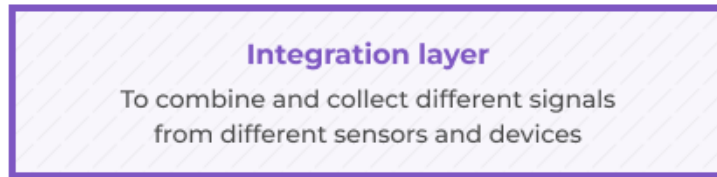
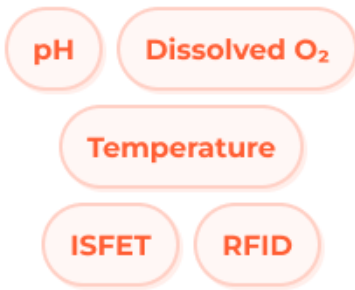
The client aimed to develop a next-generation solution to control Critical Process Parameters (CPP) that impacts Critical Quality Attributes (CQA) of final products. It collects, processes, and unifies data from diverse lab and production environments, ensures regulatory compliance (GxP/FDA), and enables AI-driven process insights. The goal was to collect large-scale sensor data typically discarded for building well-structured datasets, their storage, processing, and the search for subtle factors affecting end-product quality, process scalability, and yield.

Team Reinforcement

Intetics established a **Remote In-Sourcing® dedicated development team**, seamlessly integrated with the client's R&D and automation divisions. The partnership included **full-cycle software development, data science, DevOps, and regulatory QA** expertise.

SENSORS

Advanced remote sensors



Challenge

Developing a scalable, compliant, and data-driven system for collecting data on CPP and analyzing it was technically demanding due to:

- The need for seamless integration with existing hardware and DeltaV-like control architecture.
- Compliance with strict GxP in the context of the FDA 21 CFR Part 11 standards for storing and handling digital data.
- Managing diverse data sources (IoT sensors, controllers, analytical devices)
- Ensuring system scalability across R&D, pilot, and production environments

The client faced growing inefficiencies in managing and scaling bioprocess operations due to fragmented control systems and ignoring data streams that have a hidden influence on the CQAs of the final product. The client's team lacked in-house resources with experience in cloud-native software design, data integration frameworks, and development, installation, qualification and validation of GxP compliant digital systems, which were critical to building a scalable and validated control solution.

Benefits and Results

- ★ 35% faster batch setup and critical process parameters (CPP) control.
- ★ 40% reduction in manual data handling and errors.
- ★ Real-time monitoring and 24/7 remote control capabilities.
- ★ Enhanced compliance readiness through built-in audit and traceability tool.
- ★ Producing and storing well-structured curated data-sets, the basis for bioprocess digitalization.
- ★ Over an **18-month collaboration**, Intetics delivered a modular, cloud-ready control platform aligned with the client's long-term digitalization strategy.
- ★ Better CPP control enabled the client to elevate yields and shorten its production cycles by 15% through fine process optimization.

Client Reference

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Thanks to the Intetics team, we achieved full visibility into our bioprocesses and significantly reduced batch setup time. Their ability to merge regulatory expertise with advanced analytics made this collaboration a real success.

Technologies

.NET Core, React, MS Azure, SignalR, Docker, SQL Server, TensorFlow, REST APIs, OPC-UA integration, TSDB, and ML-systems and infrastructure.