DATAHOW

Impact of DataHowLab in Manufacturing operations

Explaining and preventing process deviations remains a core challenge in biomanufacturing. DataHowLab enables MSAT and Manufacturing teams to gain deep insight into process behaviour, supporting proactive decision-making and ensuring a more robust operation.

The Challenge of Root-cause in Manufacturing

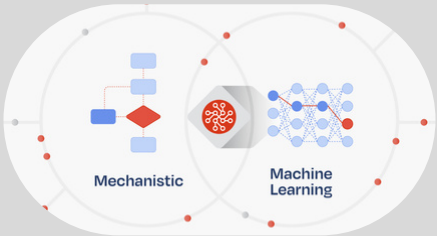
Identifying root cause in biomanufacturing is inherently difficult due to the complexity of biological systems, process interdependencies, and fragmented data sources.

Even under controlled conditions, minor variability can drive unexpected outcomes. With limited variability in data to learn from, conventional analysis methods often lack the depth or sensitivity to uncover underlying drivers.

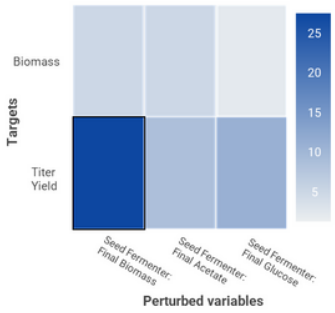
AI-enabled hybrid modeling offers new opportunities for operators to generate high-value process intelligence and consistently improve outcomes.

What is a Hybrid Model

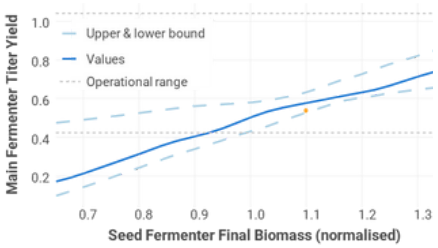
DataHowLabs Hybrid models are a balance of structured mechanistic knowledge and flexible data-driven learning that are perfectly adapted to the complex, yet data-scarce environment of bioprocessing.



With limited insights from the main fermentor data alone, a hybrid model was trained in DataHowLab using **combined data from the seed and main** fermentors, and a robustness analysis was performed.



The **seed bioreactor biomass** was identified as the strong driver of titer yield in the main fermenter.



The sensitivity analysis reveals a clear impact of the seed reactor biomass on the final fermenter yield.

DataHowLab's hybrid models delivered critical process intelligence, even when working with a high volume of data from diverse sources

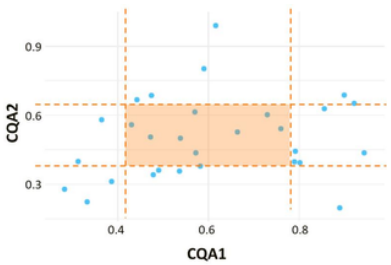
With high analytical sensitivity, DataHowLab uncovered root causes of variability in tightly controlled processes

Case 1 - Root Cause Analysis for Productivity

A CDMO running a **microbial** manufacturing process conducted 18 experiments in both the seed and main fermenters. Despite consistent execution, variations in titer were still observed.

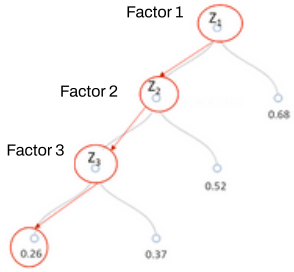
Goal: Leverage DataHowLab's hybrid modeling capabilities to investigate the drivers of titer variability.

Case 2 - Root Cause Analysis for Quality



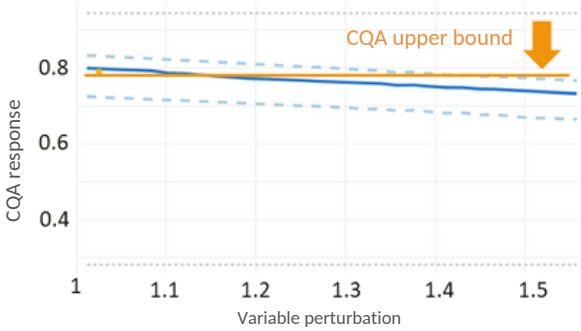
Despite running a controlled **gene therapy process**, two CQAs regularly fell out of specification, resulting in additional costs and workload.

Goal: Leverage DataHowLab to understand the factors contributing to out-of-specification results.



Decision tree analysis identified a specific **combination** of three influential factors—such as the medium lot—that were driving the CQAs outside their target range

The analysis was expanded towards **predictive deviation management** based on a hybrid model. The underlying goal is even more ambitious: forecast the outcome of an ongoing manufacturing run and, in case of deviation risk, suggest a proactive mitigation strategy.



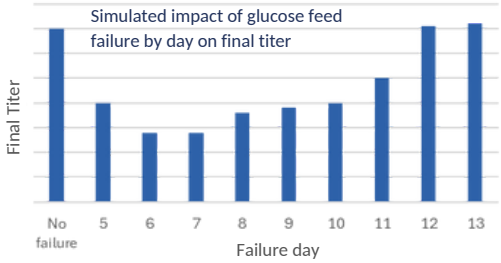
In the example above of a single manufacturing run, DataHowLab's hybrid model predicted a high risk of falling out of specification due to deviations highlighted in the decision tree.

However, a robustness analysis identified that by increasing a certain tuneable process parameter, the risk of failure was significantly reduced, providing a proactive mitigation strategy for the process.

- DataHowLab identified the complex root causes of deviation, even in manufacturing datasets with limited variability in process parameters
- Scientists were able to identify the key process parameters driving deviations and determine the appropriate control strategies to mitigate them.
- DataHowLab enables proactive deviation management of costly manufacturing runs.

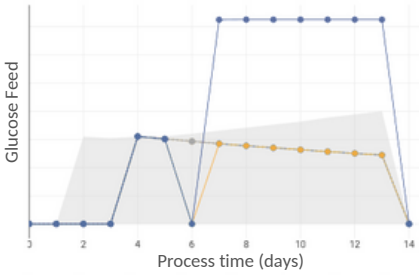
Case 3 - Operation Failure Mitigation

In a scale-up use case, where 22 development and 8 manufacturing-scale runs of a **mammalian process** were analysed, glucose feed was identified as a key factor impacting titer. Feed errors were therefore assessed as a major risk for process failure.

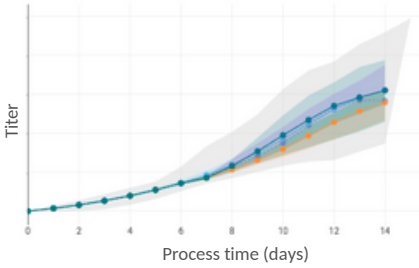


Goal: Assess whether DataHowLab can generate timely failure mitigation strategies in case of feed errors

Simulating a failure on day 6 (the largest assessed impact), DataHowLab recommended and simulated an adjusted feeding strategy which would result in the final titer value being returned to original targets.



Recommended mitigation strategy (blue) for glucose feed after failure on day 6.



Final titer is not impacted after implementing the mitigation strategy vs. if not implemented.

Operators can fall back on a standard procedure in DataHowLab once failure is detected: **Simulate Loss → Simulate recovery scenarios → Implement optimal solution**

- Failure mitigation strategies can be rapidly evaluated and applied when errors arise, minimizing negative impacts
- DataHowLab supports efficient prevention of run failures and major deviations by leveraging advanced process intelligence and enabling recovery procedures

Highly Sensitive Root Cause Analysis

Make timely decisions under pressure

Proactive Deviation Management

Reduce Downtime & Process Failure