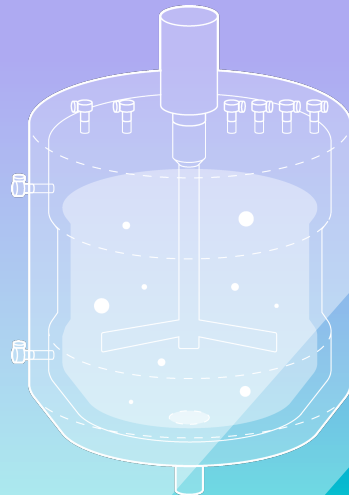




Case Studies



How Recordati Improved Yield by 1.5% in 3 Months

SITUATION

A single-drug facility experienced a temporary yield decrease of more than 4% along with higher yield variability ($\pm 7\%$), and Recordati wanted to understand why.

CONTEXT

Three critical factors were preempting Recordati from understanding the 'Why':

- 1) Data silos: paper-based batch records; production data in 3rd-party system; quality certificates in PDF format
- 2) Limited resources available for analytics
- 3) Compliance never compromised $\rightarrow$ no easy solution

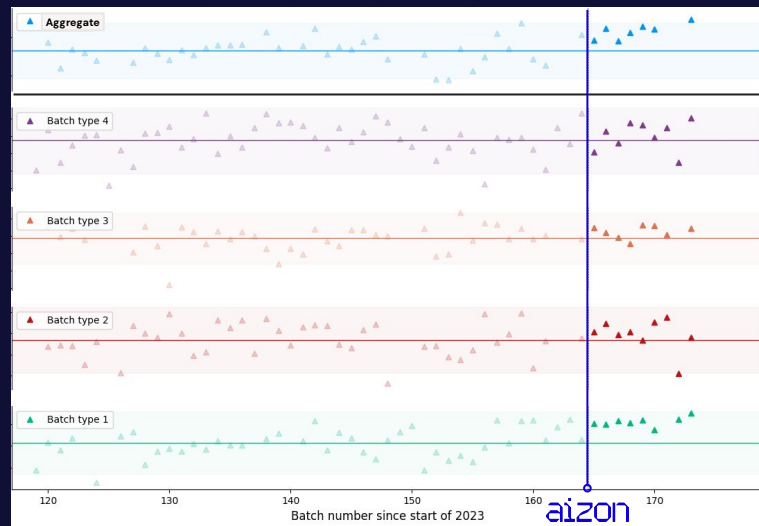
ACTIONS

Defined perimeter, integrated and contextualized multiple data sources in Unify. Then, used a CRISP-DM methodology within an agile framework with iterative feedback.

After applying data-driven recommendations to proof real-life outcomes, enabled in-process preventive real-time monitoring.

BATCHES VS OPTIMAL YIELD

From 48% batches over optimal yield to 100%



How Grifols Scaled Yield Optimization With Unified Data and AI

SITUATION

Grifols needed to improve yields across its plasma-derived product lines but lacked the multivariate analytical infrastructure to move beyond reactive, siloed evaluations. Fragmented data across batch records, QC systems, ERP, and automation made it impossible to maintain a unified view of performance drivers across sites.

CONTEXT

Plasma fractionation is inherently complex: a heterogeneous starting material from thousands of donations is purified into multiple therapeutic proteins with interdependencies across downstream products. Manufacturing spans multiple facilities with intermediates transferring between sites, creating cross-site dependencies and intricate batch genealogy.

ACTION

Aizon and Grifols deployed a progressive crawl-walk-run approach. IT and OT data was unified in a GMP Data Fabric (Aizon Unify), then AI-driven multivariate analysis (Aizon Predict) was layered on to surface actionable critical process parameters and detect adverse yield trends early via predicted-vs.-actual monitoring.

AVG. YIELD INCREASE VS BASELINE



How a CDMO gained 40%+ efficiency by generating automated annual PQR

SITUATION

With over 350 PQR reports/year per site (and growing), Client aimed to automate this process to increase efficiency.

CONTEXT

PQR was performed manually, spending ingent time on collecting data from different systems (e.g., Trackwise QMS, SAP, several Excel spreadsheets, and historian Aspen21).

ACTION

Integrated all the data sources in Aizon Unify contextualized lakehouse, enabling aggregation of all data, provided real-time and historical visibility and data contextualization. Client increased audit-readiness with automatic generation of standard reports, including batch results vs expected thresholds, details, changes, deviations, testing and conclusions.

AUTOMATED ANNUAL PQR, SELECTED SCREENSHOTS



The screenshot shows an automated PQR report interface. It includes a table of data and a summary of deviations and CAPA contributions.

Batch	Product	Batch Size	Batch Date	Batch Status
1-100000	Acetaminophen 325 mg tablets	100,000	2023-01-01	Completed
1-100001	Acetaminophen 325 mg tablets	100,000	2023-01-02	Completed
1-100002	Acetaminophen 325 mg tablets	100,000	2023-01-03	Completed
1-100003	Acetaminophen 325 mg tablets	100,000	2023-01-04	Completed
1-100004	Acetaminophen 325 mg tablets	100,000	2023-01-05	Completed

Deviations and CAPA Contributions

Batch	Product	Batch Size	Batch Date	Batch Status
1-100000	Acetaminophen 325 mg tablets	100,000	2023-01-01	Completed
1-100001	Acetaminophen 325 mg tablets	100,000	2023-01-02	Completed
1-100002	Acetaminophen 325 mg tablets	100,000	2023-01-03	Completed
1-100003	Acetaminophen 325 mg tablets	100,000	2023-01-04	Completed
1-100004	Acetaminophen 325 mg tablets	100,000	2023-01-05	Completed

Improved yield and reduced OOS by enabling Continuous Process Optimization

SITUATION

A large CDMO experienced variations in chemical reactions that heavily impacted production, causing fluctuations in yield and quality.

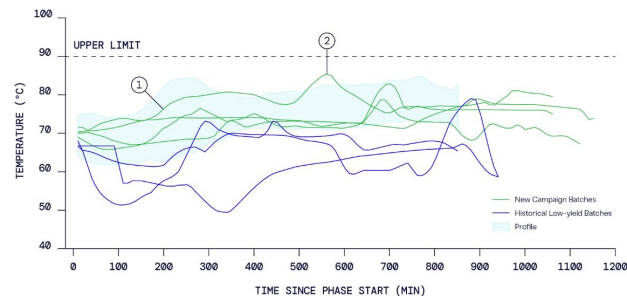
CONTEXT

Difficulties in consolidating data from multiple sources hindered the ability to fully understand the reasons behind this variability. Previous attempts failed because external data scientists lacked the pharma knowledge and results were not easy to industrialize.

ACTION

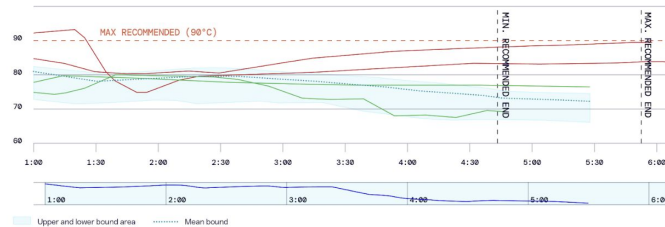
Centralized data in Unify, integrating real-time sensor and manual batch data. Compared batch performance with "Golden" batches, then identified key root causes driving deviations by looking at critical process parameters correlation with critical quality attributes. Once industrialized, scaled from 1 to 3 products in just a week.

BATCH COMPARISON TOOL



- ①: New batches follow recommended profile in 0-800 min range
- ②: New batches stay within temperature limits of 90°C

GOLDEN BATCH PROFILE TO MONITOR BATCH EVOLUTION IN REAL TIME



INFO@AIZON.AI

AIZON.AI

T +34 937 68 78 / +34 932 71 82

SAN FRANCISCO

44 MONTGOMERY ST,
3RD FLOOR SAN FRANCISCO,
CALIFORNIA 94104 USA

BARCELONA

CARRER DE CORSEGA
301-303, ENTRESÒL 1A,
BARCELONA, 08008 SPAIN

aizon