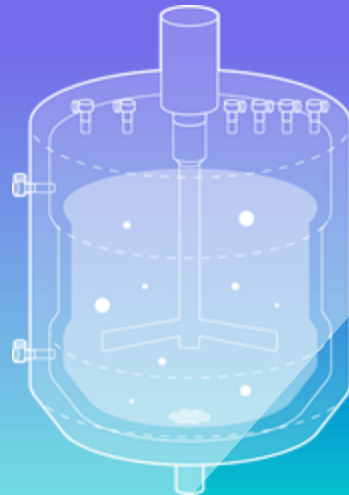


Generando valor con la unificación y contextualización de datos

Octubre 2024

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Aizon VP Technical Sales & Partnership



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Be pragmatic : **focus on value first.**



GOLDEN BATCH
COMPARISON TO
IMPROVE YIELD

Why modern, contextualized intelligent lake houses are the ultimate tools to break data silos, collaborate cross-functionally and prevent blind spots.



FROM NO DATA TO
CONTINUOUS PROCESS
OPTIMIZATION

How a leading CDMO reduced variability with automated batch comparisons using Aizon Unify — a scalable, comprehensive data analysis solution.



40% INCREASE IN
EFFICIENCY
ON QUALITY PQR
PROCESS

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

Not taking a first step will leave you behind

TODAY'S REALITIES

90%+ of companies

Classic Manufacturing

Paper batch records

Static systems & processes

Manual & inefficient operations

Limited use of available data

TODAY'S EXPECTATIONS

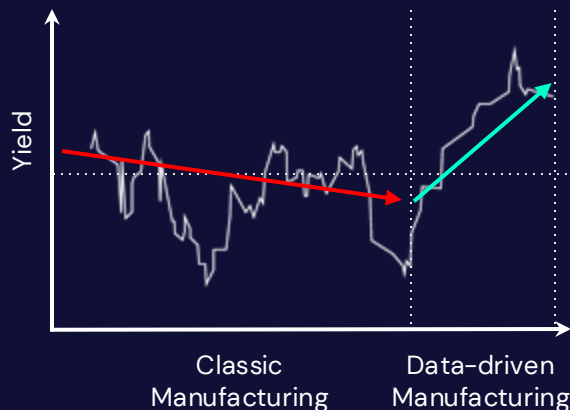
<10% of companies

Data-driven Manufacturing

Real-time insights & alerts

Automated & flexible processes

Predictive & data driven operations



Combating complexity with AI: 18k+ process variables for real-time contextualization

SITUATION

Leading API manufacturer wanted to improve their yield comparing batches.

CONTEXT

- Information was siloed: 8 yr of process data (18K+ tags/process) in local DCS; CQA context information in QMS; yield data in ERP. On top, phasing data was missing for many years.
- Had narrowed down a few Historians, but hectic data processing efforts were required to perform batch comparison, and contextualization capabilities were limited.

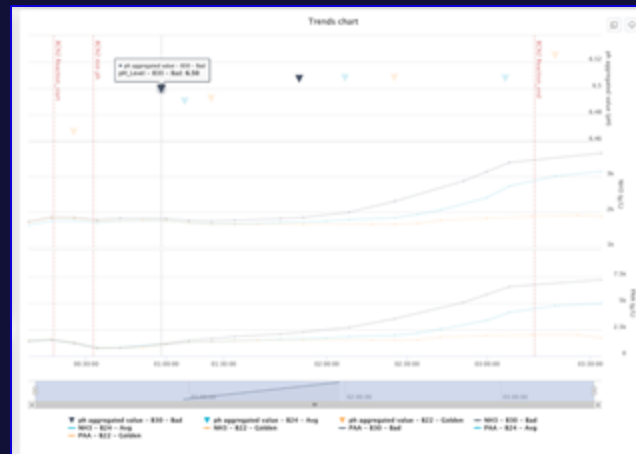
ACTION

- Developed an AI model to generate phasing information from historical data.
- Integrated all the data in Unify (contextualized historian), making it readily available in 6 weeks for dashboarding an analytics purposes.
- Leveraged the Unify Batch Comparison solution to:
 - Perform faster/better (AI-powered, holistic) root-cause analysis; quantify correlations between CPPs and CQAs across several business units and data sources; understand what was moving the needle for good/bad batches.
 - Aizon Consulting Services supported the Client on the implementation and monitoring of process improvements, leading to substantial impact.

CQA FROM QMS AND ERP YIELD INFORMATION

Batch	Start	End	Quantity	Plant	Year	Yield	Quality	Batch Count
B01	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B02	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B03	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B04	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B05	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B06	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B07	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B08	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B09	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B10	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B11	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B12	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B13	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B14	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B15	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B16	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B17	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B18	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B19	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B20	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B21	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B22	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B23	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B24	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B25	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B26	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B27	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B28	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B29	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B30	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B31	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B32	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B33	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B34	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B35	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B36	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B37	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B38	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B39	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B40	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B41	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B42	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B43	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B44	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B45	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B46	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B47	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B48	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B49	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B50	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B51	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B52	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B53	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B54	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B55	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B56	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B57	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B58	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B59	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B60	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B61	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B62	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B63	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B64	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B65	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B66	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B67	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B68	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B69	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
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B71	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B72	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B73	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B74	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B75	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B76	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
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B79	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B80	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B81	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B82	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B83	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B84	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B85	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B86	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B87	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B88	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B89	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B90	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B91	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B92	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B93	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B94	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B95	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B96	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B97	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B98	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B99	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1
B100	01/01/2020	01/01/2020	Good	01	2020	100.00	100.00	1

PROCESS DATA WITH AUTOMATIC CONTEXTUALIZATION





Select batches

3 entries selected.



☐	Batch	Start	Quality	Final_yield	Unit	NH3_AVG	Viscosity_AVG	Outlier_count	PAA_AVG
☐	B15	07/02/2021 17:42:32.000	Good	27.71	BCN_FR_103	1740.264	48.77	102	1198.23
☐	B17	07/03/2021 00:33:22.000	Good	26.89	BCN_FR_103	1637.823	47.17	114	1189.01
☐	B19	07/03/2021 07:31:32.000	Avg	19.31	BCN_FR_103	1946.452	49.35	119	2022.71
☐	B20	07/03/2021 10:58:32.000	Good	29.45	BCN_FR_206	1918.5	50.59	127	1441.06
☐	B21	07/03/2021 14:48:32.000	Good	22.75	BCN_FR_206	1915.675	47.1	135	1605.48
☒	B22	07/03/2021 18:36:32.000	Golden	32.31	BCN_FR_103	1757.28	47.73	130	1500.07
☒	B24	07/04/2021 02:50:32.000	Avg	16.13	BCN_FR_206	2108.571	50.58	130	2413.48
☐	B25	07/04/2021 06:40:32.000	Bad	12.26	BCN_FR_205	2421.486	49.83	146	2818.26
☐	B26	07/04/2021 11:01:32.000	Golden	30.1	BCN_FR_206	1767.338	52.46	127	1531.41
☐	B27	07/04/2021 14:51:32.000	Good	27.31	BCN_FR_206	1841.668	53.61	115	1440.35
☒	B30	07/05/2021 03:02:32.000	Bad	9.74	BCN_FR_206	2420.466	53.68	126	3490.28
☐	B61	07/05/2021 06:42:32.000	Good	27.29	BCN_FR_103	1679.0863	49.78	127	1226.75
☐	B62	07/05/2021 10:53:32.000	Golden	32.2	BCN_FR_206	1826.404	52.96	122	1221.84
☐	B63	07/05/2021 14:43:32.000	Good	28.69	BCN_FR_103	1742.433	50.52	123	1227.25
☐	B64	07/05/2021 18:33:32.000	Golden	30.81	BCN_FR_103	1623.119	53.09	125	1229.71
☐	B65	07/05/2021 22:23:32.000	Golden	32.18	BCN_FR_103	1748.623	51.34	123	1218.84
☐	B68	07/06/2021 08:51:32.000	Good	29.75	BCN_FR_103	1759.904	55.05	115	1217.99

Select process parameters

Process parameters

ph aggregated value ✕

NH3 ✕

PAA ✕

Apply

Select events to plot

All ✕

BCN2 Reaction_start

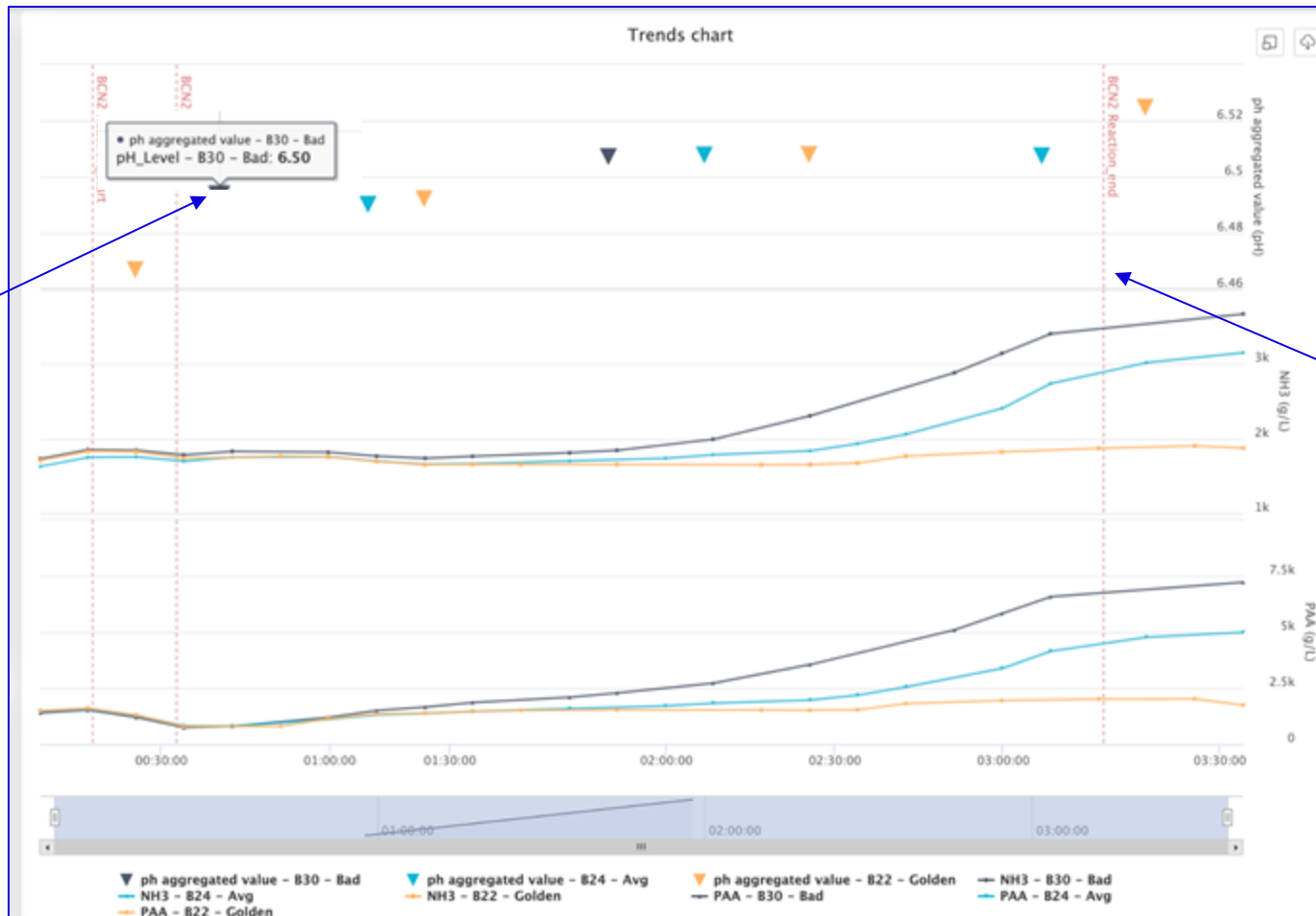
BCN2 min ph

BCN2 Reaction_end

BCN1 Reaction_start

BCN1 Reaction_end

CQA



EVENTS

Phases

Samples

....

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

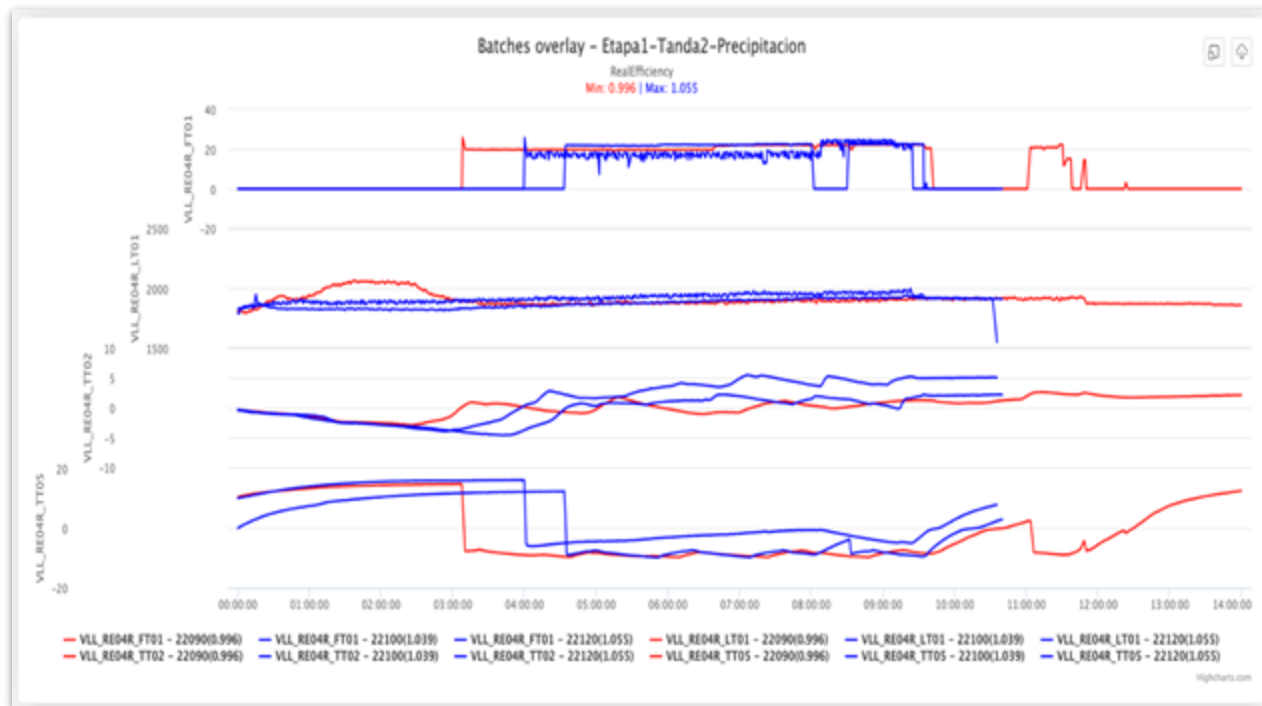


GOLDEN BATCH PROFILE TO MONITOR BATCH EVOLUTION IN REAL TIME

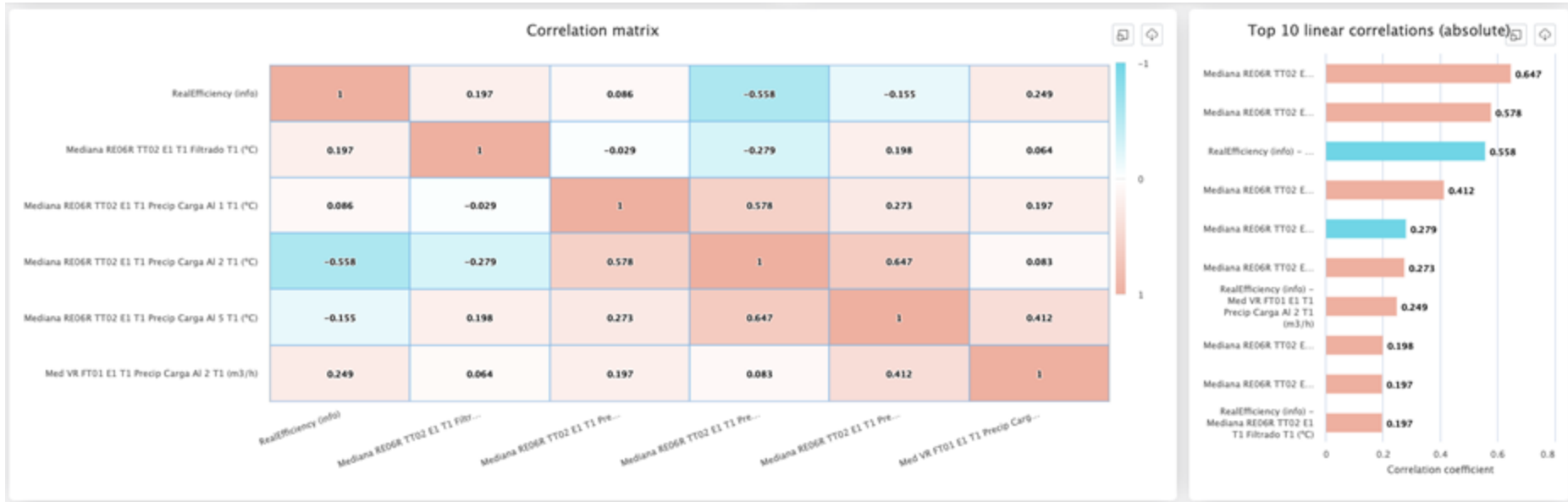


Dynamic Comparison Capability

- Dynamic batch comparison across multiple dimensions
- Multi variable selection (dynamically introduces each time series indicator)
- Supports grouping by site, product, phase, equipment, batch, etc.

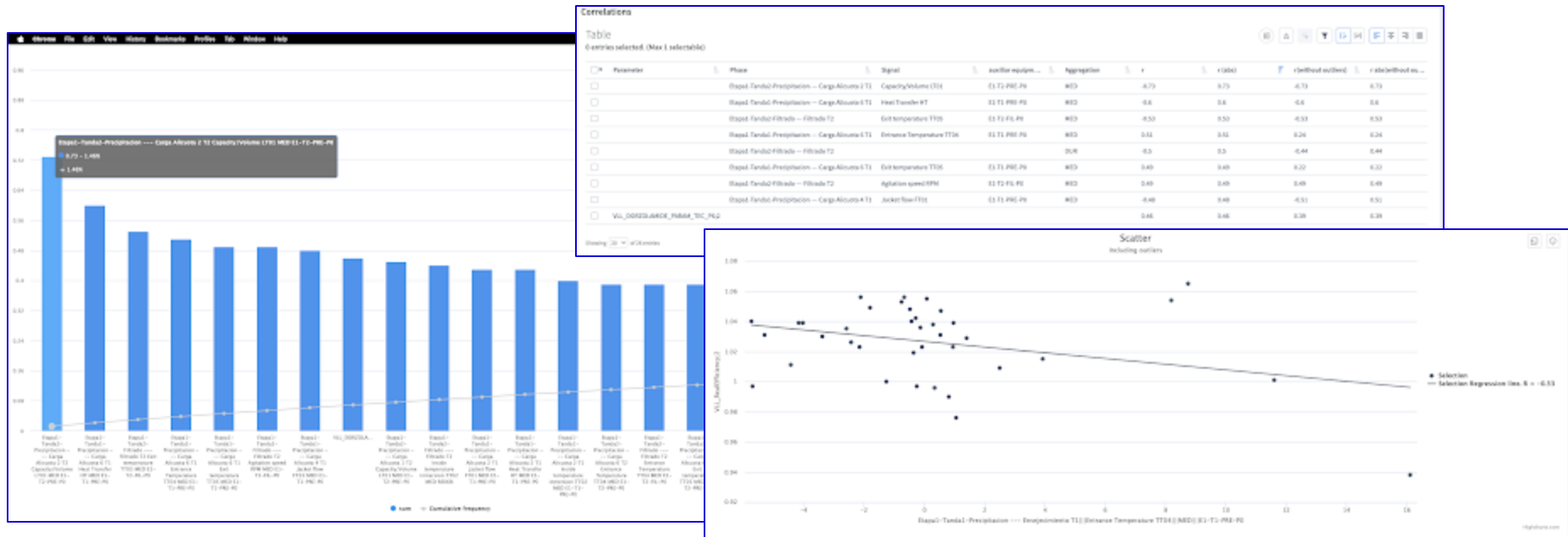


Smart Manufacturing Platform Overview



Yield Correlations: Advanced Analytical tools that allow the user to find the most relevant CPP impacting the yield of the process. The outcome enables the user to take the best decisions to optimize and improve the process continuously

Smart Manufacturing Platform Overview



Yield Correlations: Advanced Analytical tools that allow the user to find the most relevant CPP impacting the yield of the process. The outcome enables the user to take the best decisions to optimize and improve the process continuously

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



Batch	Type	Status	Batch	Quantity	Batch Date
1-00000	Batch 1	Success	1-00000	100.000	1-00000
2-00000	Batch 2	Success	2-00000	100.000	2-00000

Main Menu

Select product

Product1

12/06/2024 00:00 - 12/06/2024 23:59



Batch Info



Yield Review



CPP & CQA Review

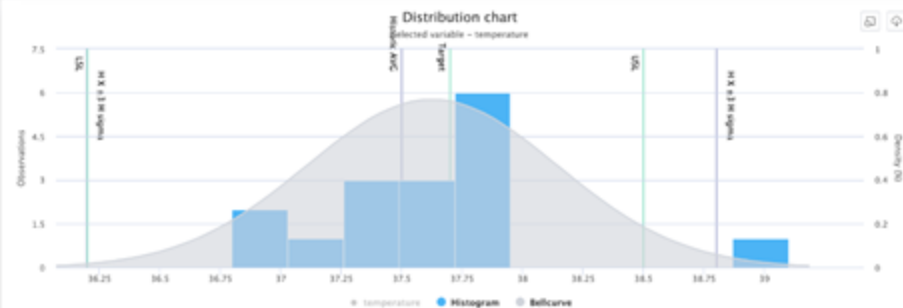
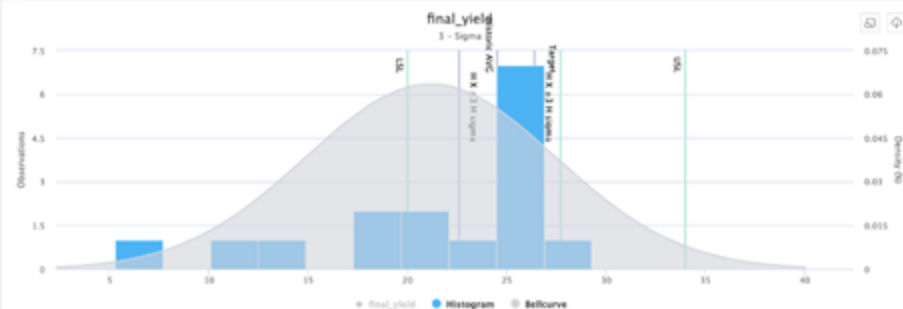
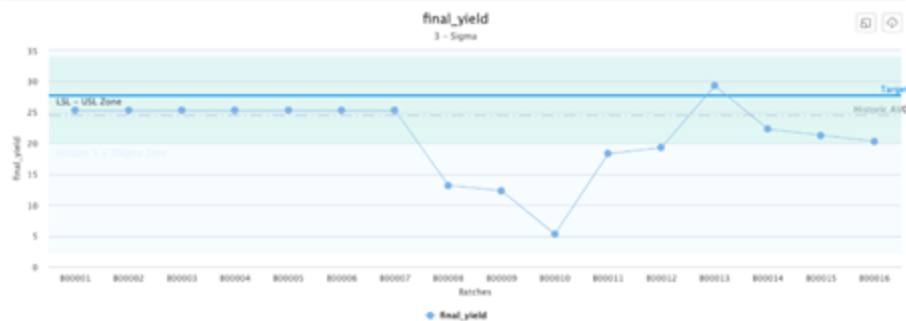


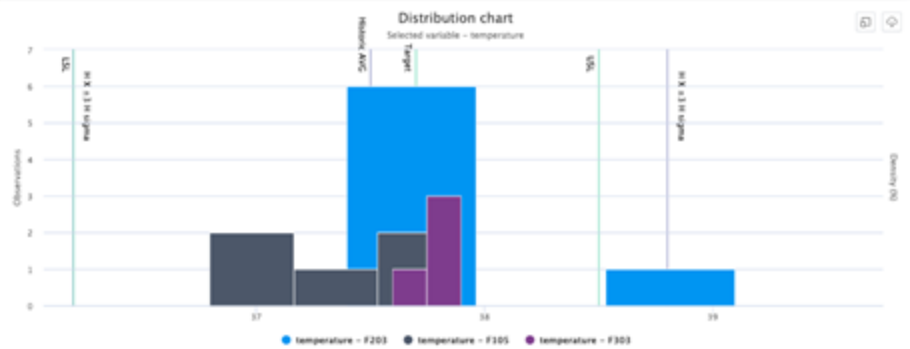
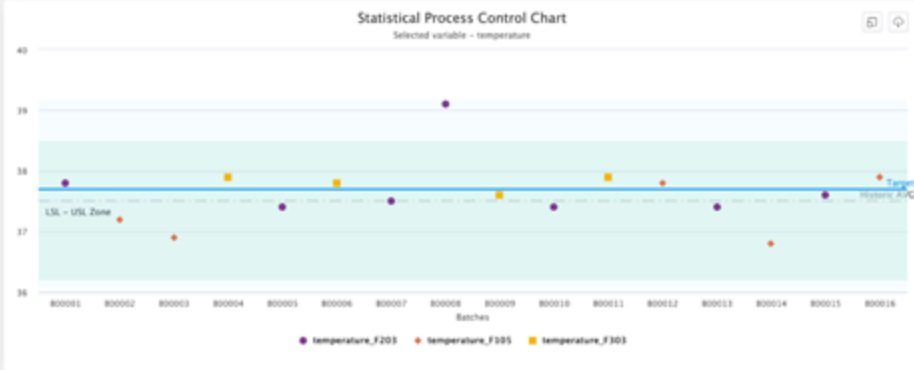
Summary of Deviations and CAPA's

Batch list



Campaign	Batch ID	Reactor	Temperature	pH	Conductivity	Air Flow	Speed	Label
2022_K1	Batch1	F203	37.8	7.2	0.036	17.53	21.06	Good
2022_K1	Batch2	F105	37.2	7.28	0.038	17.11	20.29	Average
2022_K1	Batch3	F105	36.9	7.8	0.032	17.12	20.04	Bad
2022_K1	Batch4	F303	37.9	7.1	0.032	17.1	20.03	Bad
2022_K1	Batch5	F203	37.4	7	0.033	17.17	24.63	Good
2022_K1	Batch6	F303	37.8	7.13	0.032	17.19	20.02	Golden
2022_K1	Batch7	F203	37.5	7.6	0.032	17.07	20.02	Good



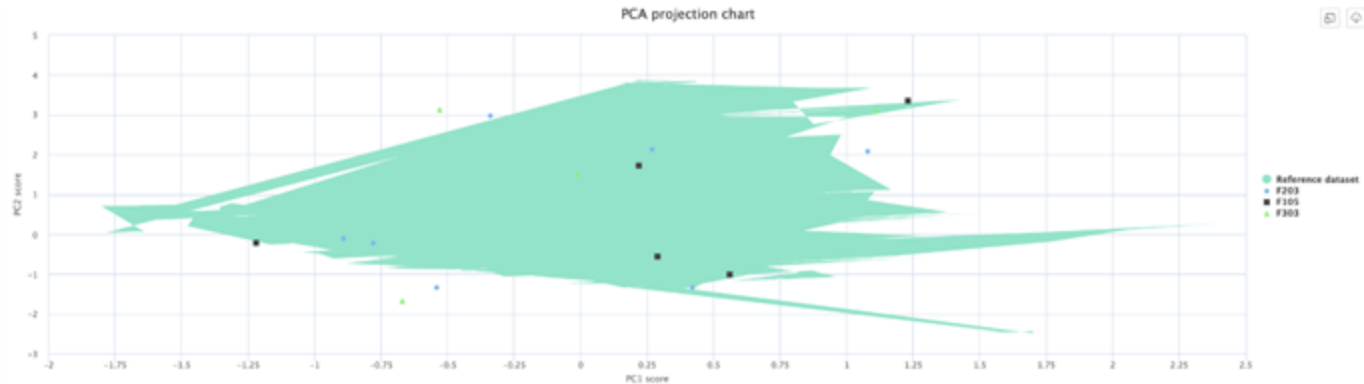


Statistics summary

Sample count	Average	Standard deviation	PPK	PP	CPK	CP
16	37.425	0.52	0.561	0.738	0.768	0.883

PCA projection

The PCA projection chart allows viewing the projected scores of the selected batches in the space created by a given PCA model. The scores are overlaid on top of the area formed by the scores of the training dataset. Scores outside this area represent a deviation in the multivariate space.



Filter selection for Deviations List

Select Category

Severity

Select Value

Critical X Major X Minor X

Apply

Select deviations to view / print graph

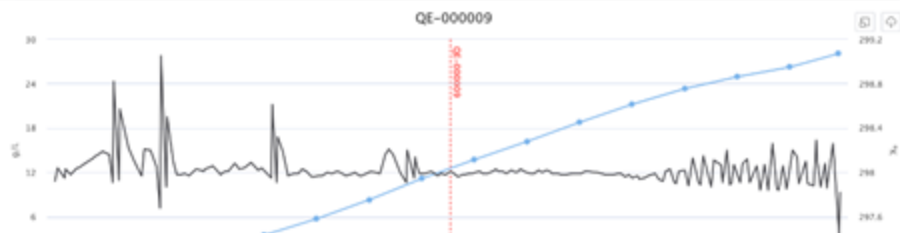
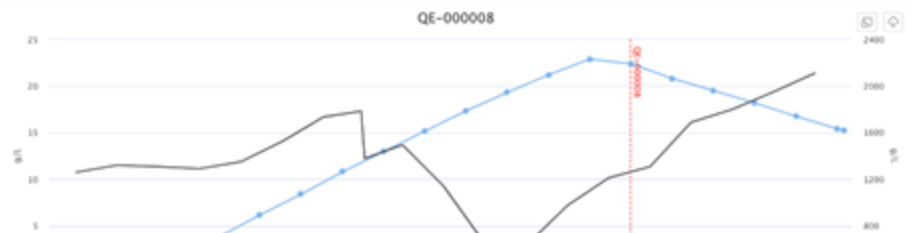
2 entries selected. (Max 2 selectable)



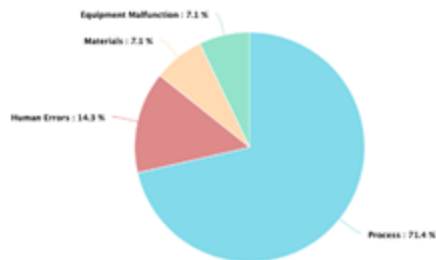
Name	Title	Product	Batch	Severity	Root Cause	Lifecycle State	Date Closed
☒ QE-000008	Deviation_Demo_B004_PAA Concentration OOS	Penicillin	IPS_B0004	Critical	RC-000001	Closed	06/03/2022
☒ QE-000009	Deviation_Demo_Temperature Peak	Penicillin	IPS_B0006	Minor	RC-000002	Closed	06/06/2022
☐ QE-000010	Deviation_Demo_B0009_OOS	Penicillin	IPS_B0009	Critical	RC-000003	Closed	06/09/2022
☐ QE-000011	Deviation_Demo_High Substrate_B0010	Penicillin	IPS_B0010	Critical	RC-000004	Closed	06/01/2022
☐ QE-000012	Deviation_Demo_Phenylacetic acid OOS	Penicillin	IPS_B0019	Critical	RC-000005	Closed	06/06/2022
☐ QE-000013	Deviation_Demo_Phenylacetic acid OOS	Penicillin	IPS_B0021	Critical	RC-000006	Closed	06/06/2022



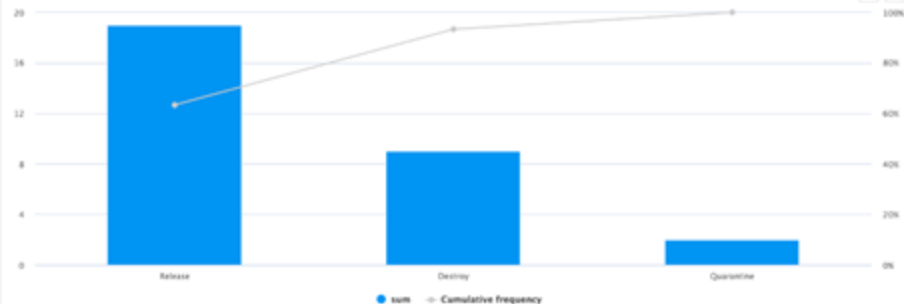
Name	Description	Root Cause Category	Root Cause Sub-Category	CAPA Plan Summary	Final Disposition
QE-000008	The final PAA concentration in Batch B004 was 5417.2 g/L. The specification for this CPP is 2700 g/L. Therefore, batch number 004 is considered out of specification.	Process	Out of Specification	CAPA-000001	Destroy
QE-000009	It was observed a temperature peak in Batch B006 at 09:19h on 06 May 2022. This temperature is out of trend for this phase of production.	Process	Out of Trend	empty	Quarantine
QE-000010	<p>On May 06th, 2022 It was observed that the PAA concentration on batch B009 started increasing significantly at around 18:00h. The final PAA concentration for this batch was 5442 g/L. Since the maximum li...	Process	Out of Specification	CAPA-000002	Destroy
QE-000011	<p>Batch B010 was produced on May 07th, 2022. It was observed a abnormal increase of substrate concentration, starting at 02:20am. The final substrate concentration was 41.8 g/L, which is out of specificatio...	Process	Out of Specification	CAPA-000003	Destroy
QE-000012	It was observed an extremely high Phenylacetic acid concentration in Batch B0019. The final concentration for this batch was 4389 g/L, while the limit is 2700 g/L.	Process	Out of Specification	empty	Destroy
QE-000013	The target range for the final substrate concentration in a IPS batch is 0.005 g/L. On batch B0021, the final conc was 22 g/L, therefore this batch was out of specification.	Process	Out of Specification	empty	Destroy



Deviation distribution by root cause category



Pareto



List of CAPAs

Status	Date Closed	Description	Lifecycle Stage	Title	Quality Event	Action Type	URL	Name	Due Date
Active	6/8/2022	Implement a monitorin...	Closed	Implement PMA monitoring alert	QE-00008	Preventative Action	https://vvtchpartner-alcon-qms.ve...	CAPA-000001	7/4/2022
Active	empty	Develop temperature control to ...	Initiated	PMA_OOS_Process Change	QE-00010	Preventative Action	https://vvtchpartner-alcon-qms.ve...	CAPA-000002	6/30/2022
Active	empty	Set up proactive monitoring for ...	Initiated	Substrate OOS	QE-00011	Preventative Action	https://vvtchpartner-alcon-qms.ve...	CAPA-000003	6/30/2022
Active	empty	Develop a proactive monitoring ...	Initiated	NH3 Proactive Monitoring	QE-00014	Preventative Action	https://vvtchpartner-alcon-qms.ve...	CAPA-000004	7/1/2022
Active	empty	Perform experiments to identify...	Initiated	Process Parameters Adjustment	QE-00015	Preventative Action	https://vvtchpartner-alcon-qms.ve...	CAPA-000005	7/1/2022

Deviations and CAPA Conclusion

review by quality

e-Signature

User: CristianMarfa

Password:

Comment: review

Signature meaning: not specified

Timestamp: 06/13/2024 11:20:10.835

SIGNED

But, you are not alone...





Predict

ADVANCED SOLUTIONS:

Deviation Reduction

Yield Optimization

Other:

Predictive Maintenance

Capacity Utilization

Customer Visibility

Sustaining Monitoring

More...

GxP AI Industrialization



Unify

CORE SOLUTIONS:

Digital Batch Review

Real-time Process Monitoring

Batch Comparison Analytics

Contextualized Intelligent Lakehouse



Execute

Intelligent Batch Record (iBR)

GxP Facility

- ◆ Excel files
- ◆ IOT Sensors
- ◆ Historians
- ◆ ERP
- ◆ QMS
- ◆ LIMS
- ◆ MES
- ◆ DCS
- ◆ CMMS
- ◆ BMS
- ◆ EMS
- ◆ Datalakes...

aizon

Thank You for Your Time

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