



Aizon Bioreactor Application

Built on the award-winning* Aizon platform, the GxP-ready, AI-powered Aizon Bioreactor Application is a seamlessly customizable and scalable graphical UI solution designed for biotechnology and pharma manufacturing environments. A unique step forward in the progression of Pharma 4.0, the Bioreactor Application leverages AI, ML, cloud technologies, IIoT, and contextualizing tools to help users fully use, monitor, analyze, understand, and control the upstream manufacturing process.

Audience

The Aizon Bioreactor Application is designed with a focus on a multidisciplinary team who spend a large part of their working day involved in some or all aspects of the upstream manufacturing process. Primary users of the Aizon Bioreactor Application include business owners, operators, process engineers, process experts, plant managers, as well as those involved in quality assurance and quality control. Other users include those involved in science and technology (e.g., product developers, data scientists, PAT specialists, etc.) and those in automation and IT (e.g., automation engineers, system managers, and IT experts).

Benefits

As well as being a significant step towards continued process verification (CPV), the Aizon Bioreactor Application:

- Is differentiated in the industry as the turnkey, GxP-ready solution that predicts modern manufacturing outcomes and deviations.
- Accelerates time-to-market (TTM); optimizing process understanding and efficiency.

Key Features

- **Process Discovery:**
Identify hidden relevant factors and create powerful AI models to use throughout the application
- **Live and Predictive Monitoring:**
Leverage advanced analytics and powerful AI tools for real-time data analysis, deviation detection, and yield prediction
- **Root Cause Analysis and Historical Batch Comparison:**
Retrieve, compare and analyze batches for advanced insights and deviation detection

Key Benefits

- Predicts upstream manufacturing process deviations and outcomes
- Accelerates the time-to-market; optimizing efficiency and process understanding
- Optimizes batch yield, quality, and profitability
- Improves manufacturing process performance and ensures Right First Time (RFT)

- Optimizes batch yield by improving consistency and reducing batch rejection.
- Improves upstream manufacturing process performance and ensures Right First Time (RFT).
- Is ready for compliance 21 CFR Part 11, Data integrity and Annex 11 (Eu-cGMP).
- Developed following GAMP 5 best practices under a certified Integrated Management System (ISO 9001, ISO 27001, and ISO 27017).
- Harnesses Aizon's IIoT software technology for immediate data dispatch to the GxP cloud data lake.
- Uses advanced AI/ML tools, monitoring capabilities, as well as multivariate statistical analysis to facilitate real-time release testing (RTRT). In this instance, RTRT defines the ability to use process data (e.g., measured material attributes, process controls, etc.) to evaluate and ensure the quality of the fermentation process and final yield.

Features

Nine modules are accessible from the Aizon Bioreactor Application's main screen. They are:

- **Setup** – Users can define the site or plant location time zone, select process recipes and phases, populate critical process parameters (CPPs), select additional process parameters (APPs), as well as contextual data (i.e., data not directly related to the application, for example, the manufacturing site and plant, ID tags, process structures, etc.).
- **Relevant factors identification** – Users can analyze the data and identify which variables may impact the manufacturing process and, therefore, react in time.
- **AI models creation** – Users can select and configure AI widgets to generate AI models (Principal Component Analysis, Outlier Detection, Causality Detection, Dependence Test) by batch or by phase for use throughout the application, and define and tailor date and time ranges to specific AI models.
- **Diagram** – Users can monitor the upstream manufacturing process in real time to detect process anomalies and deviations.
- **Trends** – Further to performing real-time batch data trend analysis, users can use a PCA chart to compare the current batch status against a selected reference batch.
- **Notifications** – Users can review manufacturing process deviation alerts and alarms in real time.
- **Compare runs** – Users can use the application's advanced filtering tools and incorporate offline laboratory and final quality data to perform a root cause analysis (RCA) of specific historical batch deviations.

- **Process indicator analysis** – Users can view batch KPIs and related variables, as well as trend historical values of a given analysis, aggregated value, yield, etc. for the selected batch KPIs.
- **Yield prediction** – Users can use the application’s RCA tools to monitor the predicted yield of a current batch run and correct deviations that might cause the batch to fail. If the batch run values are too low, then users can save time and optimize resources by rejecting the batch early on in the process.

Using one or more of the features described, the Aizon Bioreactor Application supports the following functionalities:

Process Discovery

Relevant factors identification

- Accelerates the upstream manufacturing process development by identifying CPPs.
- Helps identify hidden process variable dependencies that are not observable using standard analyses.
- Integrates external laboratory data sources into the analysis.

Create AI data models

- Creates and manages AI data models to help obtain the most value from all Aizon Bioreactor Application features.

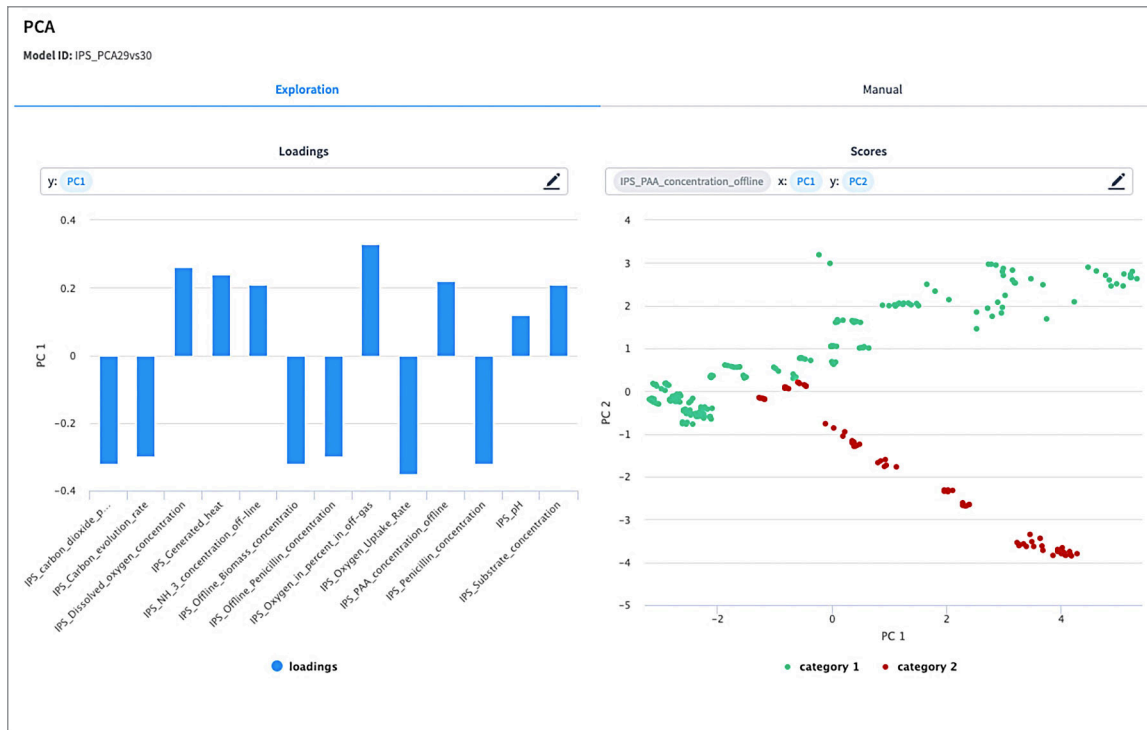


Image 1: Principal Components Analysis (PCA)

PCA chart used to help identify the relevant factors for a process.

Live and Predictive Monitoring

Monitor the plant's current status

- Provides the tools that help users (including those with access to upstream manufacturing monitoring systems) discover valuable insights, which in turn, allow the resolution or improvement of deviations that arise during the manufacturing process. As a result, the chances of batches failing during the process are reduced.
- Saves users from accessing separate systems to perform advanced monitoring.
- Provides the potential to graph data from multiple plant monitoring systems and, as a result, breaks data silos.

Basic trending of real-time processes

- The Trends screen of the Bioreactor Application allows users to select and to monitor additional advanced feature information (multivariate and AI alerts, CPP deviation trends, etc.) on top of classic univariate trends.

Automated current batch process deviation detection

- Provides alerts and alarms for the early detection of deviations that surface during the upstream manufacturing process.
- Provides the tools that offer users additional process insights and, therefore, help users resolve process deviations that fall outside known classical conditions, and before known indicators can raise an alert. The anomaly detection tool helps reduce poor performance outcomes.
- Actively pushes deviation notifications to plant personnel; therefore, reducing the effort required for monitoring the manufacturing process.
- Provides users the option to monitor data from multiple plant monitoring systems (e.g., room light, external vibrations, etc.) and, as a result, break data silos.

Early process yield prediction

- Uses the current batch status to predict process outcomes, and provides a wider time window to allow users to make corrections.

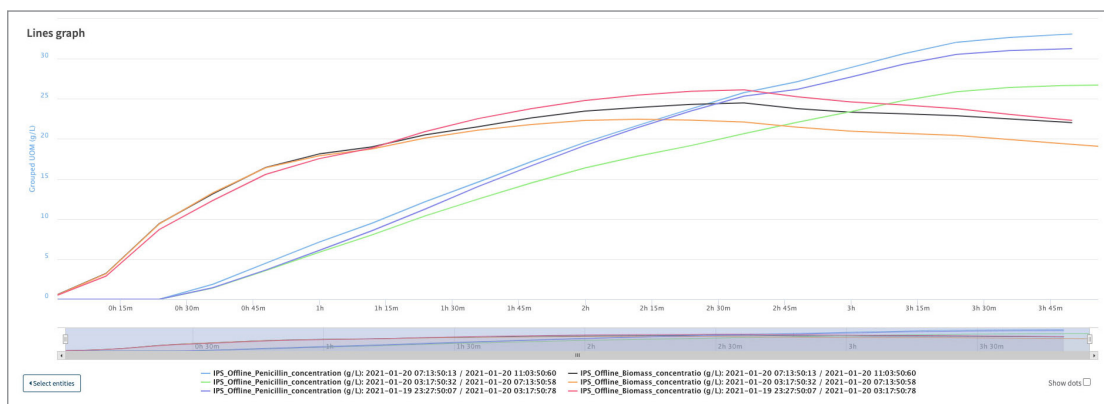


Image 2: Predictive Monitoring

A monitoring screen displaying a chart showing CPP trends, yield prediction, last outlier detected, and conventional OOS alarms.

Root Cause Analysis and Historical Batch Comparison

Batch retrieval and comparison

- Provides AI/ML tools for quick visual data insights into individual batch CPPs.
- Allows users to filter, group, and navigate between batches, which are based on predefined, user-created criteria (e.g., high or low batch yields). These predefined criteria are usable throughout the app (e.g., on the AI model creation and Compare Runs screens).
- Helps reduce user effort and time spent on Root Cause Analysis (RCA).

Advanced analytics batch comparison

- Uses multivariate statistics to detect deviations that are beyond the scope of classic (i.e., univariate) alarms.
- Easily integrates data from multiple sources (e.g., QMS, ERP, MES, LIMS systems) into the analysis.

Process indicator analysis

- Provides users with quick visual data insights of batch KPI trends and their tendency over time.
- Performs quick process capability tests and detects variability; for example, trends, box plots, and Pearson correlation visuals of specific variables (e.g., yield).
- Helps reduce user effort and time spent monitoring KPIs.

Additional multivariate analysis insights

- Helps users to detect underlying variability causes.
- Identifies abnormal batches that fall outside known univariate boundaries.
- Analyzes process data combined with laboratory analysis, and final quality data.



Image 3: Batch Comparison

Comparison of penicillin and biomass concentration for three bioreactor batches.

The Aizon Platform

One platform, endless applications.

Aizon is an AI software provider that transforms manufacturing operations with the use of advanced analytics, artificial intelligence, and other smart factory technologies focused on optimizing production within highly regulated industries. The Aizon AI platform seamlessly integrates unlimited sources of structured and unstructured data to deliver actionable insights across all manufacturing sites. Aizon offers an intuitive way to gain meaningful operational intelligence by enabling real-time visibility and predictive insights in a GxP compliant manner with end-to-end data integrity.

Let's discuss: sales@aizon.ai Learn more: <https://www.aizon.ai>



* [Frost & Sullivan 2020 Enabling Technology Leadership Award](#)