

Aizon Bioreactor Application

Built onto Aizon's award-winning* SaaS analytics platform, the GxP-ready, AI-powered Bioreactor Application is a customizable and scalable UI solution designed to optimize upstream processing in the biotechnology and pharmaceutical manufacturing industries.

A step towards the realization of Pharma 4.0, Aizon's Bioreactor Application leverages predictive artificial intelligence (AI) models, machine learning (ML), cloud technologies, the industrial internet of things (IIoT), and contextualizing tools to allow users to monitor, analyze, investigate, and extrapolate value from manufacturing process data. Accordingly, Aizon's smart manufacturing solution drives process improvement and increases process yield and profitability.

Audience

Specially designed for multidisciplinary teams who spend much of their working day involved in some or many aspects of the upstream manufacturing process, the Bioreactor Application's primary users will include equipment operators, process engineers and experts, and plant managers, as well as those involved in Quality Assurance and Quality Control. Others who will chiefly benefit from using the application are those involved in science and technology (product developers, data scientists) and those in automation and IT (automation engineers, system managers).

Benefits

To achieve continued process verification (CPV), the Aizon Bioreactor Application:

- Is differentiated in the industry as the turnkey, GxP-ready solution that predicts modern manufacturing deviations and outcomes.

Key Features

- **Process Discovery:**
Identify hidden relevant factors and create powerful AI models to use throughout the application. Use your increased process understanding to optimize your operations and control your business
- **Live and Predictive Monitoring:**
Leverage advanced analytics and powerful AI tools for real-time data analysis, deviation and anomaly detection, and yield prediction. Increase yield and save millions through product recovery
- **Root Cause Analysis and Historical Batch Comparison:**
Retrieve, compare and analyze batches for advanced insights and deviation detection. Get to the real root cause faster, respond to audits with efficiency, faster time-to-market (TTM)

Key Benefits

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

- Accelerates time-to-market (TTM); optimizing process understanding and efficiency.
- 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).
- Is developed using 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 compliant cloud data lake.
- Uses advanced AI/ML tools, monitoring capabilities, and multivariate statistical analysis to facilitate real-time release testing (RTRT). In this context, RTRT defines the ability to use process data (for example, measured material attributes, process controls, etc.) to evaluate and guarantee the quality of the manufacturing process and final yield.

Features

The Bioreactor Application Setup Solution

A separate but related component of the Bioreactor Application, the Setup solution is a configuration UI that allows authorized users to adapt the application to individual batch manufacturing processes. Ultimately, the solution's purpose is to enable users to easily configure the application and track its previous modifications.

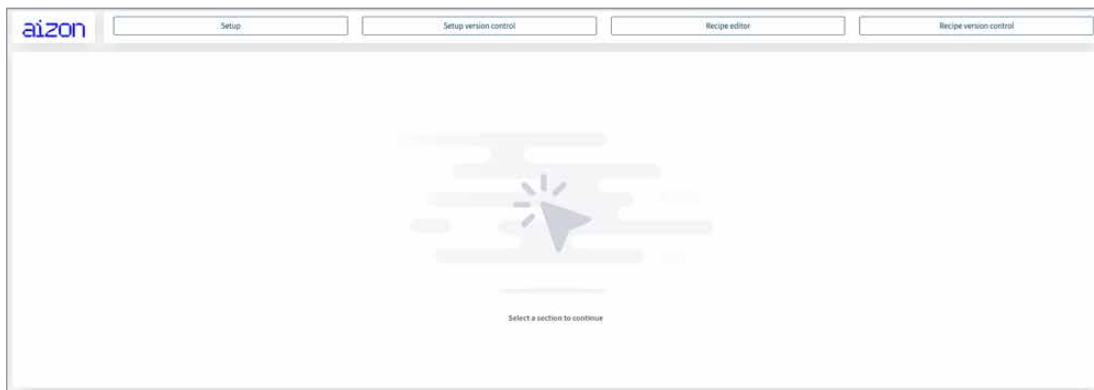


Image 1: The Bioreactor Application Setup Solution Home Screen

The Aizon Bioreactor Application Setup solution features four distinct screens:

- **Setup** – Users can apply active manufacturing process data to the Bioreactor Application (for example, process recipe parameters, and batch, product, and manufacturing phase information). Moreover, users can select and apply contextual information, including the unit procedure and the facility's timezone, and, via user comments, provide reasons for the application's configuration.

- **Setup version control** – Users can view a log of configurations made to the Bioreactor Application over a specific period.
- **Recipe editor** – Users can create, edit, enable or disable manufacturing process recipes, as well as view a list of recipes associated with the different batch manufacturing process products.
- **Recipe version control** – Users can view a log of configurations made to the Bioreactor Application's manufacturing process recipes over a specific period.

The Bioreactor Application

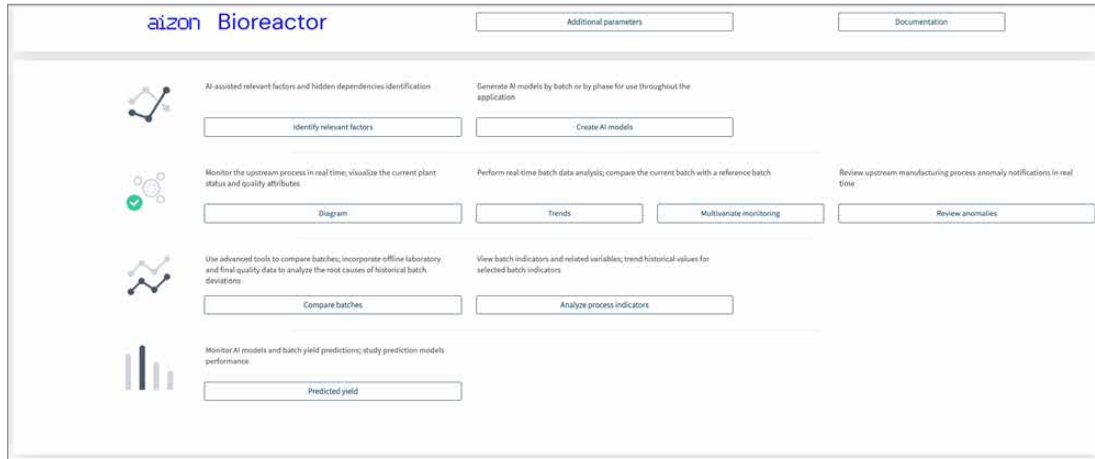


Image 2: The Bioreactor Application Home Screen

Ten screens grouped under four distinct modules are accessible from the Aizon Bioreactor Application's Home screen:

Configuration

- **Additional parameters** – Users can select which Additional Parameters (APs) to apply to the batch manufacturing process, as well as view an active recipe's Critical Process Parameters (CPPs) and Quality Parameters (QPs).

Process Discovery

- **Identify relevant factors** – AI-assisted relevant factors and hidden dependencies discovery allow users to identify and analyze which variables could negatively impact the manufacturing process and, therefore, react in time.
- **Create AI models** – Users can create AI models (Principal Component Analysis, Outlier Detection, Causality Detection, Dependence Test) by batch or by process phase for use throughout the application, as well as tailor and apply date and time ranges to specific AI models.

Live and Predictive Monitoring

- **Diagram** – Users can monitor the upstream manufacturing process in real-time to detect process anomalies and deviations, analyze Quality Parameters (QPs), and view the facility's status.
- **Trends** – Leverages classic univariate Critical Process Parameter (CPP) trends and Out of Specification (OOS) alarms to allow users to perform real-time data analysis of an entire batch.
- **Multivariate monitoring** – Users can use a Principal Component Analysis (PCA) model to monitor and compare the trajectory of the current batch against a predefined reference batch.
- **Review anomalies** – Users can review real-time batch manufacturing process anomaly and deviation alerts, warnings, and alarms.
- **Predicted yield** – Users can monitor and compare the current yield against the predicted yield. On detecting poor yield, users can leverage root cause analysis (RCA) tools to discover the causes.

Root Cause Analysis and Historical Data Analysis

- **Compare batches** – Users can leverage advanced filtering tools and incorporate offline laboratory and final quality data to analyze continuous process data from multiple batches.
- **Analyze process indicators** – Allows users to view batch process indicators and related variables, as well as trend historical values for selected batch indicators.

The Multiple Bioreactor Dashboard

A stand-alone solution, the Multiple Bioreactor Dashboard (MBD) serves as an extension to a Bioreactor Application and allows its users to monitor multiple bioreactor assets simultaneously. Using Aizon platform capabilities, the MBD optimizes bioreactor site efficiency and productivity by providing high-level views of real-time and historical process indicators and predictions, as well as detailed concurrent analysis of bioreactor process performance.



Image 3: The Multiple Bioreactor Dashboard Home Screen

The Multiple Bioreactor Dashboard features five screens:

- **Configure a bioreactor** – Users can customize the existing MBD dictionary (a selection of bioreactor assets) by configuring and adding, modifying, or removing bioreactor assets. Users can also create and store a new MBD dictionary.
- **Select bioreactors** – Users can select which bioreactor assets to monitor on the MBD's Real-time view, Indicator history, and Compare bioreactors screens.
- **Real-time view** – Users can simultaneously monitor the real-time manufacturing process status of multiple bioreactor assets and assess and compare process performance indicators and predictions. Users can also access individual bioreactor applications for a detailed overview of the bioreactor asset fermentation process data.
- **Indicator history** – Users can analyze current and past critical process indicators performance, as well as compare performance indicator data across different bioreactor assets.
- **Compare bioreactors** – Users can compare how bioreactor assets perform by analyzing the aggregated values of their KPIs for a specified period.

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

Process Discovery

Identify relevant factors

- 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.

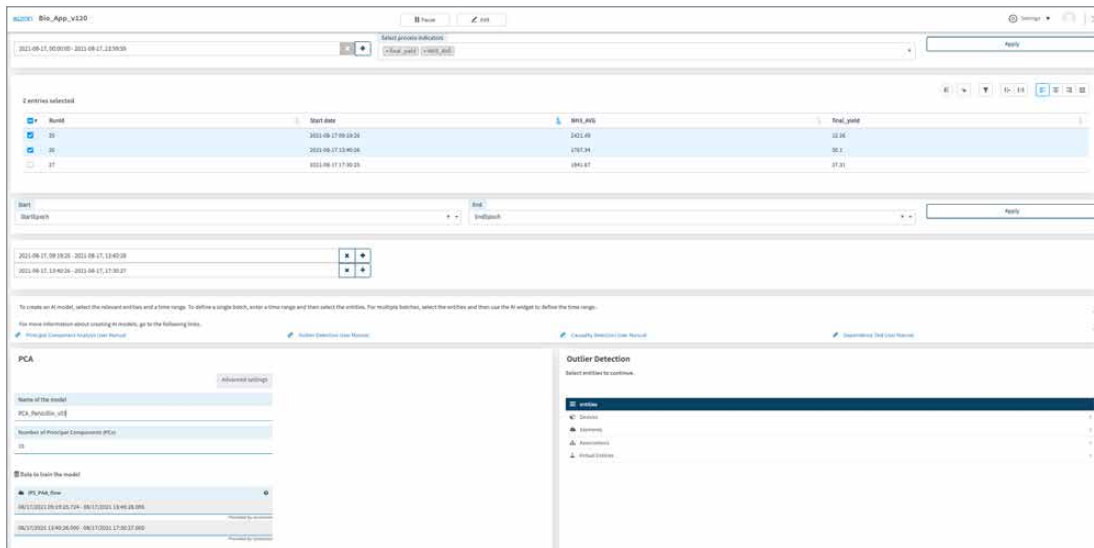


Image 4: Create AI Models

Easily create an AI model, in this instance, using 2 distinct batch time ranges.

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, that in turn, allow the resolution or improvement of anomalies or deviations that arise during the manufacturing process. As a result, the chances of batch failure during the process reduces considerably.
- Saves users from having to access separate systems to perform advanced monitoring.
- Provides the potential to graph data from multiple facility monitoring systems and, subsequently, breaks down data silos.

Basic trending of real-time processes

- The application's Trends screen allows users to select and to monitor additional advanced feature information (multivariate and OOS alerts, CPP deviation trends, etc.) on top of classic univariate trends.

Automated current batch process deviation detection

- Triggers alerts and alarms on the early detection of deviations that surface during the upstream manufacturing process.
- Provides the tools that offer additional process insights, and that subsequently help users resolve process deviations that fall outside known classical conditions, and before known indicators can trigger an alert. The anomaly detection tool helps significantly reduce poor performance outcomes.
- Actively pushes deviation notifications to facility personnel; therefore, reduces the effort required for monitoring the manufacturing process.

- Provides users with the option to monitor data from multiple facility monitoring systems (for example, room light, external vibrations, etc.) and, as a result, break down 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 5: Predictive Monitoring

A monitoring screen displays a chart showing CPP trends, yield prediction, the latest outlier detected, and conventional OOS alarms.

Root Cause and Historical Data Analysis

Batch retrieval and comparison

- Provides AI/ML tools for quick visual data insights into individual batch CPPs.
- Allows users to filter, group, and then navigate between batches that are based on predefined, user-created criteria (for example, high or low batch yields). These predefined criteria are usable throughout the application (for example, on the Create AI models and Compare batches 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 (that is, univariate) alarms.
- Easily integrates data from multiple sources (for example, 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 such as 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.

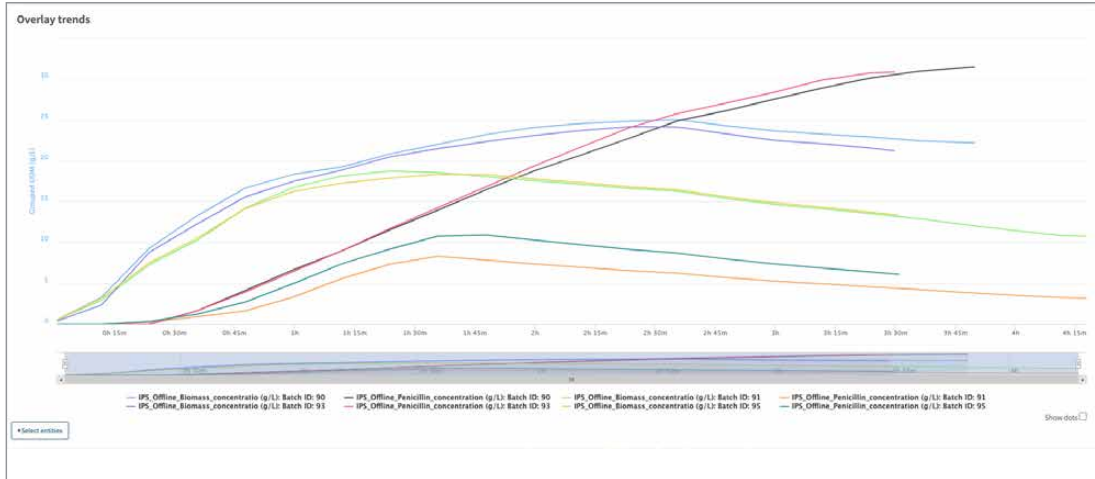


Image 6: Compare Batches

Comparison of penicillin and biomass concentration for 4 penicillin fermentation 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](#)