

The Aizon GxP AI Platform

Accelerate the Path to Operationalizing Pharma 4.0

Introduction

Pharma is one of the most complex, competitive, and heavily regulated industries internationally. It requires business agility to streamline processes throughout the manufacturing lifecycle — allowing pharmaceutical manufacturers to achieve their KPIs and maintain a competitive edge. To support and positively impact strategic and reactive decision-making, pharmaceutical manufacturers need to develop a more complete understanding of their processes as well as of the direct and indirect factors involved across their Lines of Business (LoB).

Ideally, standardized, static processes and equipment should be the norm; however, variability, caused by operators, equipment, materials, processes, and other external conditions, is the reality. It's this variability, and the complexity brought about by multiple interacting variables, that makes understanding pharma processes and their outcomes especially challenging.

To solve these challenges, Aizon uniquely applies artificial intelligence (AI), and other advanced statistics, to capture insights across the manufacturing process, and then present these findings within a holistic, multivariate view — and within a GxP compliant data environment. The Aizon solution contextualizes data and insights, which in turn, allows pharma enterprise to make, with greater confidence, faster decisions that have a greater value-based impact.

Demands on the pharma industry are greater now than ever. Fortunately, with Aizon, GxP compliant digital transformation for industrialized process optimization is consistently accessible and tunable for your processes.

Core Aizon Attributes

- **Scalable**
GxP AI 'Pilot to Production' in a seamless platform, enabling data integration and contextualization, for any scale on demand
- **Designed for Value Creation**
Accelerating time to insights and lowering total cost of ownership and the risk associated with platform maintenance, scaling, and compliance
- **Sustainable**
Data type, data source, and application agnostic plus real-time enabled to cover a comprehensive set of use cases now and into the future

As Aizon's mission is firmly grounded in pharma, we make it easier for you to optimize your operations and streamline your business to allow you to continue to save and improve lives around the world.

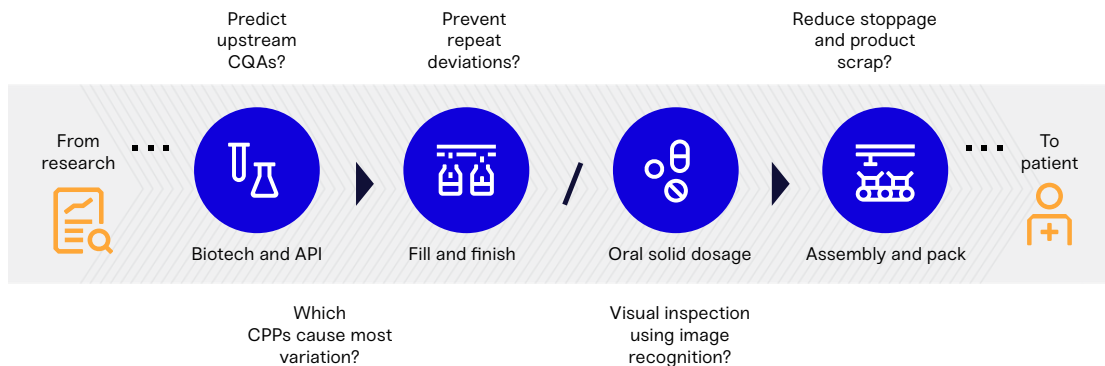


Figure 1: Aizon Serves Across Upstream and Downstream Processes

Use Cases

The highly configurable Aizon GxP AI platform covers a wide range of use cases. For example, pharma manufacturers can use the Aizon Partner Ecosystem and Marketplace to develop proprietary applications. Moreover, Aizon extends to and adapts with your manufacturing department and works in concert with other Lines of Business and operational units. Implementable across multiple sites, our platform is future-ready, extensible, and sustainable.

Data Fabric	<ul style="list-style-type: none"> → CDMO Integration → Technical Transfer Support → Global Process View – Customized Dashboarding
Process Optimization	<ul style="list-style-type: none"> → Raw Material Classifications → CPPs / Yield Optimization → Root Cause Analysis → Golden Batch / Pattern Recognition
Predictive Insights	<ul style="list-style-type: none"> → CPPs / Yield Prediction → Multivariate Anomaly Detection (OOT Detection) → Predictive Maintenance → Digital Twin
Asset Performance Management	<ul style="list-style-type: none"> → Failure Root Cause Analysis → OEE (Overall Equipment Effectiveness) → Condition Based Maintenance → FMEA (Failure Mode and Effects Analysis) → Operations and CMMX Integration
Quality Optimization	<ul style="list-style-type: none"> → Process Performance Qualification → Product Quality Review → PPQ (Process Qualification) → RFT (Right First Time) → Production, QMS & Quality Control Connectivity
CPV Enablement	<ul style="list-style-type: none"> → Continuous Manufacturing Real-time Monitoring Control → Multivariate Anomaly Detection (OOT Detection) → Holistic Process View
Sustainability Initiatives Support	<ul style="list-style-type: none"> → Energy Optimization → Water Consumption Analysis → WFI / Purified Water Process Optimization → Process Waste Management

Table 1: Use Cases

Sustainable and scalable, Aizon can be applied to limitless digital transformation and Pharma 4.0 use cases to serve you today and into the future.

Aizon GxP AI Platform

Serving you with equal power, efficiency, and ease, Aizon's GxP-compliant technology is layered to help you sustainably and consistently achieve your goals.

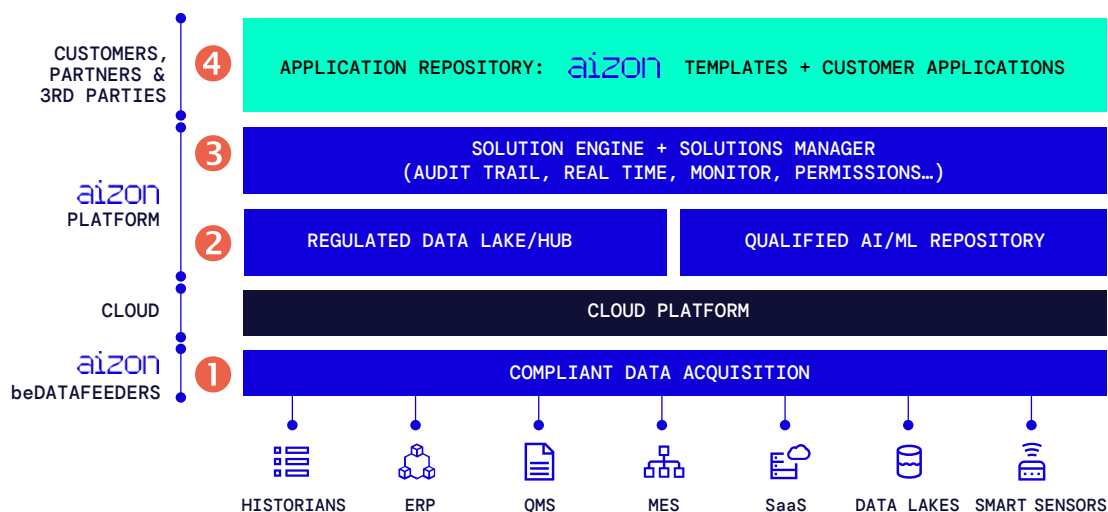


Figure 2: Overview of Aizon GxP AI Platform

Complete with Cloud Security: ISO 27017; Developed and maintained according to GAMP 5 best practices for Category 4 (Custom Applications); Takes into account regulatory requirements for computerized systems; 21 CFR Part 11; EU cGMP Annex 11; Data Integrity and Compliance with CGMP Guidance for Industry (FDA); Audit-ready and compliant; Lowers the risk of audits; Quality Management System (QMS): ISO 9001

- 1 The Aizon platform **captures real-time data** from disparate sources and, leveraging predictive models, exploits this data to optimize pharma manufacturing processes. Our platform is data type, data source, and application agnostic and, for real-time or batch analyses, is compatible with structured and unstructured data obtained from a limitless number of variables.
- 2 Data is ingested into a cloud-based, **GxP compliant data lake** where the creation, verification, and maintenance of **qualified AI/ML** models also takes place. Data silos, which previously hindered full process knowledge, are now integrated to realize the data's full value.
- 3 To create an Aizon solution, customers, partners, or Aizon can **configure applications and templates** within the GxP platform and optionally leverage qualified AI algorithms. AI models can also be uploaded or newly created within the environment. Fundamental Aizon platform functionality includes a complete audit trail, end-to-end data integrity, granular permissions settings, and tailored dashboarding.
- 4 **Customer and Partner applications**, like the Aizon Bioreactor Application, that make up the Application repository, and that are configured on the Aizon platform, are fully secure in transit and at rest.

The Aizon SaaS platform eliminates the costly overheads of building and maintaining IT infrastructure for dynamic challenges that necessitate rigorous compliance requirements. There are 3 Aizon platform options: **Unify, Predict, and Enterprise**.

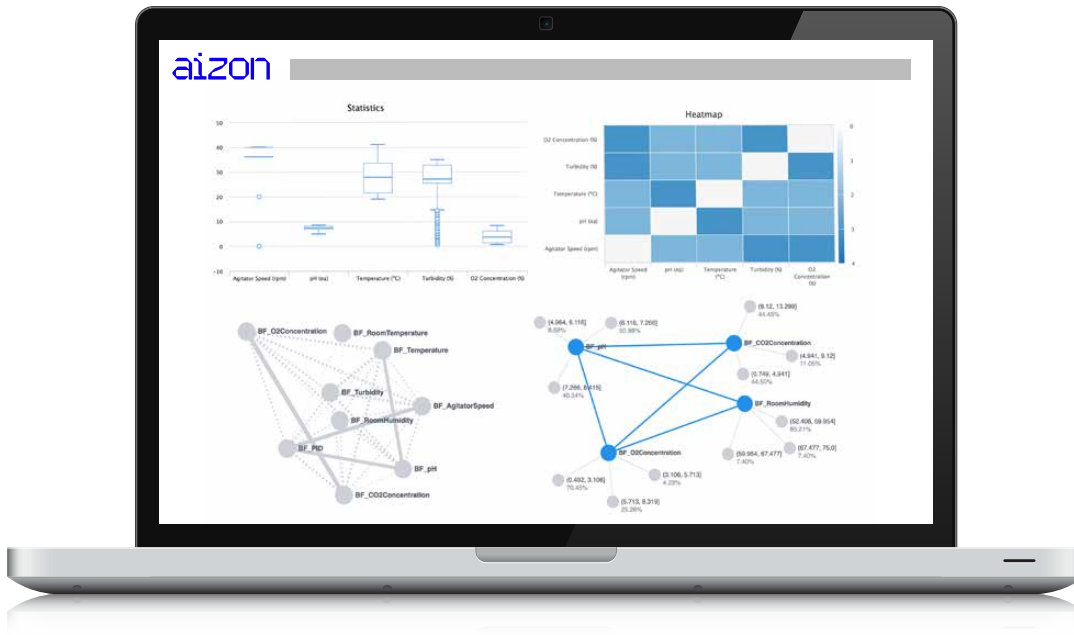


Figure 3: Aizon Dashboard

Aizon dashboards and data visualizations are configurable for your enterprise by persona; providing a single pane of glass across multiple processes, Lines of Business, and site locations.

Customer-Centric Aizon Consulting Services (ACS)

The pharma industry landscape is complex; therefore, digital initiatives require far more than a vision and a transaction. In fact, they necessitate a partnership that involves SMEs on either side, an industrialized platform with compliance at its core, and expert knowledge of data science to make the complex insightful and actionable.

Partner with Aizon Consulting Services (ACS) to deliver data-driven solutions and insights that help you achieve maximum value and success. Starting with your goals, we help you to outperform where you are today while maintaining a keen focus on your areas of core innovation.

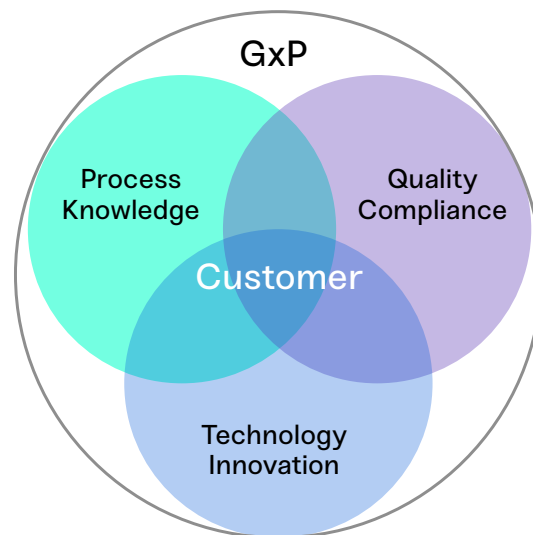


Figure 4: Aizon is Centered on Customer Success

With Customer Success at its core, Aizon uniquely combines process knowledge, technological innovation, and quality and compliance expertise to serve pharma and other regulated industry customers at the highest level.



Figure 5: Certifications, Standards, and Regulations

Aizon partners with life sciences organizations and regulatory bodies to establish new standards for regulated industries that use AI.

Aizon Innovation Lab

Aizon instituted its Innovation Lab to accelerate the adoption of Pharma 4.0 across the industry. The Aizon Innovation Lab allows us to embrace our customers, our industry, and our technology partners by incorporating their input into the direction that our products take. This input allows us to contribute to advancements in initiatives like the Continued Process Verification (CPV) of the Future, AI Algorithm Qualification, AI Standards, and so on.

For more information about Aizon's platform options, our applications, our new Aizon Bioreactor Application, as well as the latest from the Aizon Innovation Lab, and more, please email us at info@aizon.ai.

Let's discuss your digital journey towards process optimization and Pharma 4.0 today.

Learn more: <https://www.aizon.ai>