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Brochure

AspenTech Inmation in Pharmaceutical Manufacturing

Introduction

Pharmaceutical manufacturing is undergoing a shift. As the industry moves toward continuous manufacturing, real-time release and AI-driven quality assurance, the need for a unified, reliable data infrastructure has become more urgent. Data is central to every aspect of pharmaceutical operations, from batch execution and deviation investigations to predictive maintenance and regulatory compliance.

AspenTech Inmation provides a GMP-ready **industrial data fabric** that unifies, contextualizes and structures operational technology (OT) data across pharmaceutical operations. It enables pharma and life science manufacturers to move beyond siloed systems and toward an intelligent digital infrastructure.

Data Challenges in Pharmaceutical Manufacturing

Pharmaceutical manufacturers face a unique set of challenges specifically related to their operational data.

- **Fragmented Systems:** Data is often siloed across DCS/PLC systems, LIMS, MES, ERP and standalone lab instruments. These systems typically use different protocols and data models, making direct interoperability difficult without specialized integration.
- **Manual Data Handling:** Operators and quality teams frequently rely on spreadsheets or paper-based logs to bridge gaps between systems, increasing the risk of transcription errors and non-compliance.
- **Lack of Context:** Time-series data lacks contextual metadata and batch context, making root cause analysis and AI model training difficult for batch-oriented operations in the pharma and life science industries.
- **Scalability Issues:** Many digital initiatives stall after pilot phases because the underlying data infrastructure cannot scale across multiple sites or product lines.
- **Regulatory Pressure:** Compliance with GxP, ALCOA+ and 21 CFR Part 11 requirements demands traceability, auditability and secure access control, which are challenging to achieve with legacy systems.

The Role of AspenTech Inmation

AspenTech Inmation addresses pharmaceutical data challenges by serving as a unified data layer across plant and enterprise systems. It connects directly to OT platforms (such as DeltaV, Siemens and Rockwell), lab instruments and IT systems (such as LIMS, MES, ERP), creating a single source of contextualized, structured data.

Beyond OT connectivity, AspenTech Inmation integrates seamlessly with enterprise IT environments. This includes ERP platforms, quality management systems and cloud-based analytics environments. These integrations enable data exchange between manufacturing operations and business processes. By bridging the gap between OT and enterprise systems, AspenTech Inmation empowers pharmaceutical manufacturers with true end-to-end visibility.

Key capabilities of AspenTech Inmation include:

- Real-time data ingestion from control systems, lab devices and edge sensors
- Object-oriented data modeling to reflect the physical and logical structure of the plant
- Contextualization at ingestion, minimizing post-processing and accelerating insights
- Secure, single-port TCP (TLS) communication across network layers, supporting air-gapped and validated environments
- Scalable deployment from a single site to a global network of facilities



Technical Architecture and Capabilities

AspenTech Inmation is built on a distributed microservice architecture designed for scalability, resilience and secure data flow across industrial and enterprise environments. Its components include:

Master Core: This is the central aggregation and orchestration layer. It collects and harmonizes data from multiple sites, enabling enterprise-wide visibility and integration with cloud platforms, data lakes and analytics environments. It is also the central point of configuration for all system components.

Local Cores: These serve as the site-level processing and storage engines. They manage contextualization, execute local data operations and ensure continuity during network disruptions. They also support horizontal and vertical scaling and can operate independently if disconnected from the enterprise network and master core.

Connectors: Deployed close to source systems, these components ingest data using native protocols like OPC UA, MQTT, Modbus, REST and many more. They support local buffering and preprocessing to ensure reliable data capture.

Relays: These optional services securely bridge network zones, facilitating communication between local, master cores and connectors. Like any other component, they minimize exposure by requiring only a single firewall port, supporting validated and air-gapped environments.

The system supports:

- ISA-88 and ISA-95 models for batch and enterprise integration
- Graph and tree-based data structures for flexible modeling
- Structured and unstructured data types, including alarms, events, lab results, PDFs and images
- Integration with cloud platforms like AWS, Azure, GCP and data lakes

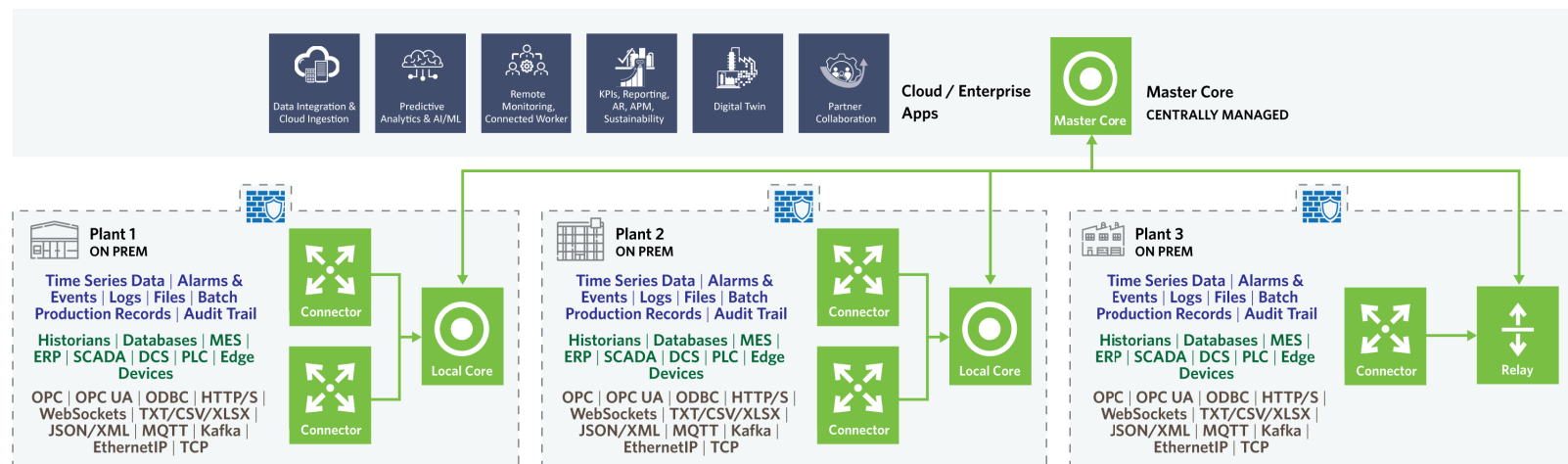


Figure 1: Typical distributed microservice architecture of AspenTech Inmation using Local Cores and central Master Core.



Use Cases in Pharma Operations

Throughout the pharmaceutical industry, customers are continuously developing new applications for AspenTech Inmation tailored to their specific operational goals. AspenTech Inmation's flexible system allows teams to build and scale solutions that meet evolving business and regulatory needs.

Because the platform is designed to be extensible, many organizations are using it as a foundation for innovation by creating custom operational procedures, integrating with emerging technologies and applying AI in ways that weren't previously possible.

This ongoing development is helping pharma manufacturers stay ahead of compliance requirements, improve efficiency and unlock new value from their data. The following use cases represent just a portion of what AspenTech Inmation enables.

Batch Traceability and Review by Exception

AspenTech Inmation captures all relevant batch data, including process parameters, lab results, operator actions and equipment status, in a contextualized format based on production events. This enables automated review-by-exception workflows and reduces batch release times.

SAP Integration for Batch Synchronization

AspenTech Inmation supports integration with SAP to synchronize batch records and align production orders with enterprise resource planning systems. This ensures that manufacturing execution is tightly coupled with business workflows, enabling real-time updates to inventory, quality status and production schedules. This integration reduces manual reconciliation efforts and supports compliance with regulatory documentation requirements.

Advanced Analytics and AI Enablement

AspenTech Inmation provides the structured, contextualized data foundation required to support advanced analytics and AI applications in pharmaceutical manufacturing. By aggregating real-time and historical data across process systems, lab instruments and enterprise platforms, it enables the development of predictive models for QA, yield optimization, energy efficiency and more.

The platform's compatibility with cloud-based analytics tools and data science applications allows teams to deploy machine learning models and generate actionable insights while maintaining compliance with data integrity standards.

Deviation Investigation

When a deviation occurs, quality teams can quickly access a complete timeline of events, including alarms, process trends and maintenance logs. This shortens investigation cycles and improves root cause accuracy.

Predictive Maintenance

By combining real-time equipment data with historical trends and maintenance records, AspenTech Inmation supports predictive models that help reduce unplanned downtime and extend GMP-critical asset life.

Digital Twin Enablement

AspenTech Inmation provides the structured, real-time data needed to support digital twins for process optimization, energy efficiency and quality prediction.

Production Loss Analysis (PLA) & OEE

AspenTech Inmation offers a systematic process for identifying, quantifying and understanding the factors that lead to a reduction in output or efficiency during the manufacturing process and builds OEE matrices.

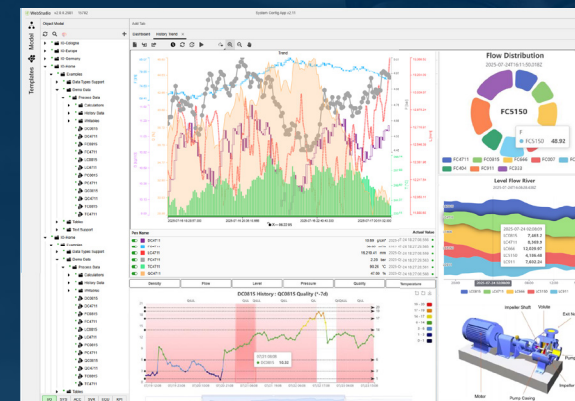
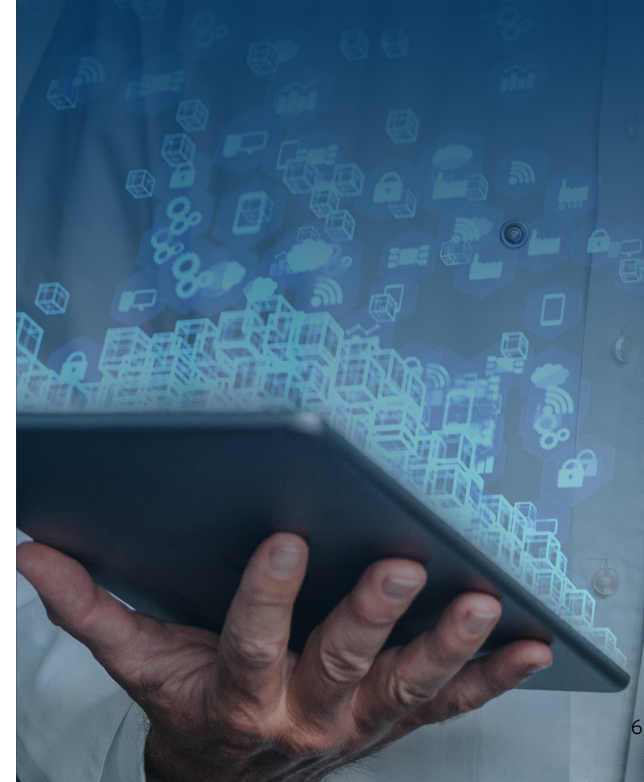


Figure 2: AspenTech Inmation WebStudio is designed to be a secure and singular interface to access your entire data source network.



Regulatory Alignment and Data Integrity

AspenTech Inmation is designed with regulatory compliance in mind. It supports:

Access Enforcement

- **Authentication:** AspenTech Inmation integrates with Windows Active Directory (AD), enabling centralized user authentication and alignment with enterprise identity management policies.
- **Authorization:** The platform supports role-based access control down to the lowest object level, ensuring that users can only access data and functions appropriate to their responsibilities. This granular control is essential for maintaining compliance and minimizing risk.

Built-in Security

- **Encryption:** All data is protected in motion and at rest using built-in encryption mechanisms. This includes encrypted endpoints and secure intercomponent connections, ensuring confidentiality and integrity across the data lifecycle.
- **Network Security:** AspenTech Inmation's built-in security architecture provides robust protection against unauthorized access and cyber threats, enabling safe deployment in regulated and validated environments. All communication within the system—including between components and across network zones—is designed to operate through a single open port, simplifying firewall configurations and IT validation. This firewall-friendly design minimizes exposure and supports deployment in highly restricted environments, ensuring seamless communication without compromising security.

Data Governance

- **Event Logging:** All system activities, including user actions and system events, are automatically logged, providing a complete record for compliance and operational review.
- **Audit Trail:** AspenTech Inmation maintains a comprehensive audit trail for all data access and configuration changes, supporting traceability and accountability.
- **Dedicated Auditor Role:** The platform includes a built-in role specifically designed for auditors, enabling secure, read-only access to relevant data and logs without compromising system integrity.

These capabilities ensure that pharmaceutical manufacturers can maintain data integrity in alignment with ALCOA+ (attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring and available) principles while minimizing the burden on IT and QA teams.

Conclusion: The Future Is Fabric

Pharmaceutical manufacturing is evolving toward more connected, data-driven operations. AspenTech Inmation provides the infrastructure to support that evolution. By unifying data across systems, contextualizing it in real time and making it accessible across the enterprise, AspenTech Inmation helps pharma companies improve efficiency, ensure compliance and prepare for the future of digital manufacturing.

AspenTech Inmation Success Stories



AspenTech Inmation forms the “digital glue” required to integrate any equipment, automation system, MES and other operational data sources. It acts as a single, real-time data platform for the entire business unit. Bayer has seen a reduction of downtime, waste and other inefficiencies.



AspenTech Inmation provides the technological backbone to support the smart manufacturing initiative for all of Boehringer Ingelheim’s worldwide operations. AspenTech Inmation is guaranteed to enhance its product according to the challenging requirements of GxP in the regulated environment of pharmaceutical production.



TotalEnergies is deploying AspenTech Inmation across its industrial operations worldwide to aggregate and centralize millions of real-time data points into a single, secure platform. By unlocking unified access to operational data, TotalEnergies is accelerating the integration of AI into industrial processes, enhancing operational safety and performance, optimizing energy efficiency, and reducing CO₂ emissions.



AspenTech Inmation securely streams real-time data from hundreds of connected interfaces into a centrally managed cluster. Endpoints provide pre-cleaned and contextualized data to various analytics and visualization tools empowering many value-added use cases, such as predictive maintenance, asset effectiveness, reliability center and augmented reality.



Takeda standardized its global operations with AspenTech Inmation, enabling seamless integration from shop floor to MES, ERP and cloud. The platform provides a single point of access to contextualized operations data across hundreds of plant historians, supporting enterprise-wide analytics and automation.



AspenTech Inmation facilitates full integration of all of Philips’ manufacturing equipment for shaver head production. The historian provides the highest performance and throughput capabilities to enable in-and-out of process analytics of high-volume discrete manufacturing data (involving sub-second and even sub-millisecond sensor data).



About AspenTech

Aspen Technology, now part of Emerson, is a global software leader helping industries at the forefront of the world's dual challenge meet the increasing demand for resources from a rapidly growing population in a profitable and sustainable manner. AspenTech solutions address complex environments where it is critical to optimize the asset design, operation and maintenance lifecycle. Through our unique combination of deep domain expertise and innovation, customers in asset-intensive industries can run their assets safer, greener, longer and faster to improve their operational excellence.

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