



PI Automated Intelligence

Revolutionizing Investigations and Process Analysis for Pharmaceutical Companies



THE CHALLENGE

Why Pharmaceutical Companies Need PI Automated Intelligence

The Problem

Investigating Out-of-Specification (OOS) or Out-of-Trend (OOT) results is time-consuming and resource-intensive, impacting product quality and regulatory compliance.

The Solution

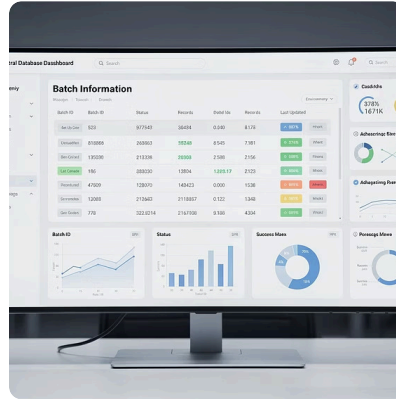
PI Automated Intelligence streamlines initial analysis, centralizes data, provides actionable insights, and supports compliance—transforming complex investigations into efficient processes.

Centralized Data Repository



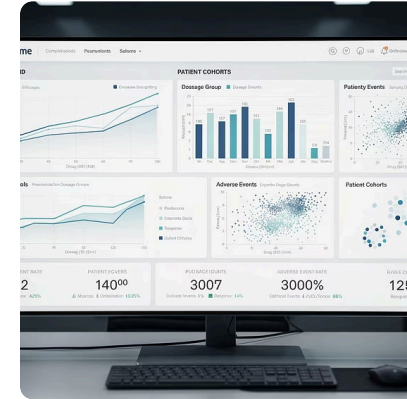
Seamless Integration

Integrates with LIMS, SAP, TrackWise, and EDMS to unify data across multiple sources.



Centralized Access

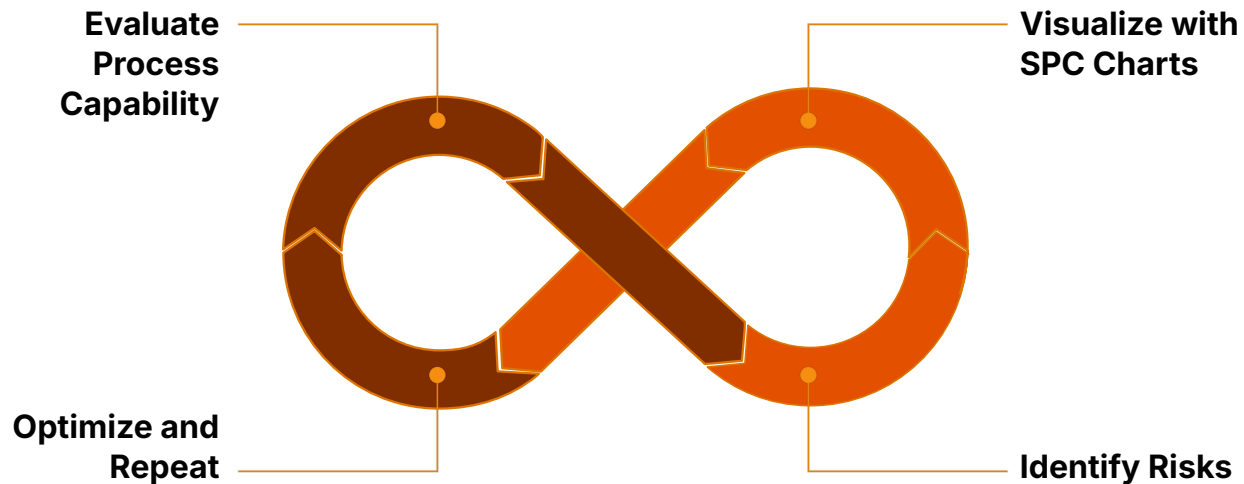
Access batch information, materials, analytical methods, and process data in one place.



Real-Time Visibility

Monitor OOS/OOT trends, deviations, and investigation details as they happen.

Continued Process Monitoring



Continuous assessment of Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs) ensures proactive risk identification and process optimization.

Process Capability

Ongoing evaluation for newly manufactured batches using Ppk and Cpk metrics.

Advanced Visualization

SPC charts, histograms, X-bar/R charts, and capability analysis graphs.

Automated Intelligence Reports

01

Initiate Reports

Start directly from batches with OOS/OOT parameters for immediate analysis.

02

Analyze Historical Data

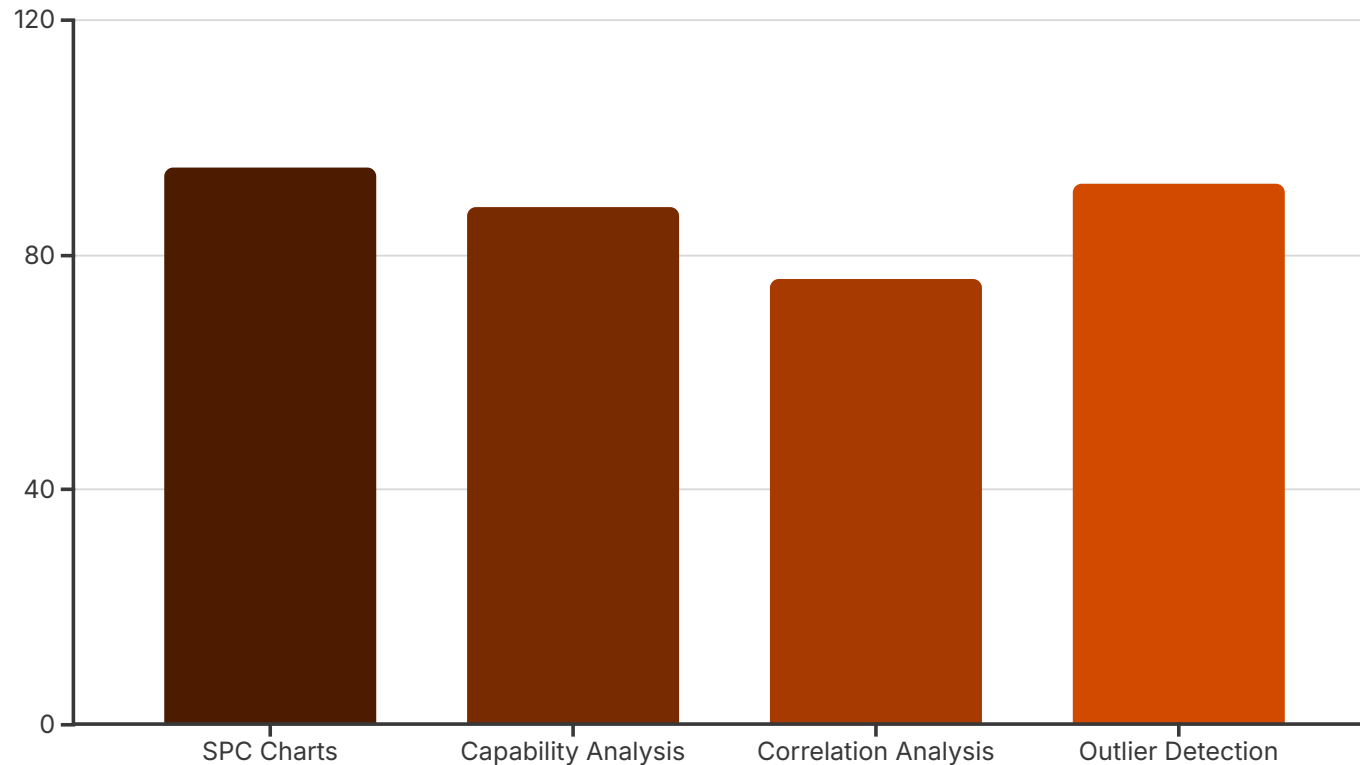
Review last 25 batches to detect trends and anomalies, with flexibility to add earlier batches.

03

Generate Insights

Use Anderson-Darling plots, Grubbs outlier tests, and SPC charts for comprehensive analysis.

Advanced Data Analysis Tools



Comprehensive Statistical Tools

Visualize data trends with SPC outliers, shifts, drifts, and capability analysis graphs. Perform correlation analyses using scatterplots to assess relationships between attributes and identify root causes.

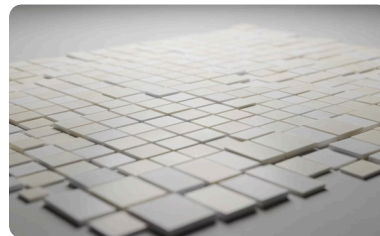
 AI-POWERED

AI-Augmented Summaries and Conclusions



Intelligent Automation

AI-driven summaries and recommendations based on comprehensive data analysis, with human override capabilities for critical decisions.



Advanced Correlation

View correlated attributes and parameters with predefined thresholds. Integrate with heat map tools for attribute-parameter relationships.

Streamlined Workflow and Compliance



Built for Collaboration

Seamless progression from batch selection to report generation with built-in comment capture and transparent tracking.

E-Signatures

21 CFR Part 11 compliant e-signatures at all stages.

Audit Trails

Complete tracking of changes and approvals for inspection readiness.

Data Security

Embedded compliance with CGMP and EU Annex 11 standards.

The PI Automated Intelligence Advantage



Reduce Timelines

Minimize manual effort and accelerate investigation processes.



Enhance Quality

Improve process reliability and product quality through data-driven insights.



Ensure Compliance

Maintain regulatory readiness with embedded compliance features.



Drive Improvement

Gain actionable insights for continuous operational excellence.



Invest in Operational Excellence

PI Automated Intelligence is more than software—it's a compliance-driven automation platform that transforms pharmaceutical investigations. Empower your organization to focus on innovation while ensuring process reliability and product safety.



Operational Excellence



Quality Assurance



Regulatory Compliance