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PI Quality Intelligence

Digitizing Product Quality Monitoring for Pharmaceutical Manufacturing

OVERVIEW

Transforming Quality Management in Pharma

PI Quality Intelligence is a comprehensive software tool designed to monitor and analyze product quality results to aid management reviews and ensure compliance with ICH Q10 guidelines. The platform transforms raw quality data into actionable insights that drive continued improvement across pharmaceutical manufacturing operations.

By centralizing quality monitoring, assessments, and reporting in a single platform, PI Quality Intelligence enables organizations to move from reactive quality management to proactive process optimization. The analysis capabilities built into the system lead to actionable insights that support both regulatory compliance and operational excellence.

Why Choose PI Quality Intelligence?

Traditional Quality Metrics

Track critical quality indicators including:

- Out-of-Specifications (OOS) events
- Customer complaints and trends
- Deviation tracking and analysis
- Batch rejection rates

Advanced Quality Assessments

Perform comprehensive evaluations:

- Product Quality Reviews (PQRs)
- Statistical Process Control Analysis
- Capability Assessments (CPK/PPK)
- Method Evaluation Reports

Seamless System Integration

Connect with existing infrastructure:

- LIMS integration for lab data
- SAP connectivity for enterprise data
- TrackWise integration for quality events
- Centralized data repository

Powerful Visualizations

Make data-driven decisions with:

- Control charts for process monitoring
- Histograms for distribution analysis
- Scatter plots for correlation studies
- Interactive dashboards

With PI Quality Intelligence, organizations can perform quality management using data-driven, efficient, and centralized processes that support both compliance requirements and continuous improvement initiatives.

The PI Quality Intelligence Advantage

PI Quality Intelligence is a compliance-driven automation platform that digitizes and optimizes quality monitoring and review, transforming how pharmaceutical organizations manage product quality.

70%

Reduced Manual Effort

Automation eliminates time-consuming manual data compilation and report generation

85%

Fewer Errors

Automated data integration and validation reduces human error in quality assessments

60%

Faster Reviews

Streamlined workflows accelerate product quality review completion times

100%

Inspection Ready

Built-in compliance features ensure continuous regulatory readiness

☆ KEY FEATURES

Quality Monitoring, Assessments, and Reporting

PI Quality Intelligence supports both summary and in-depth quality assessments with comprehensive features designed to provide actionable insights at every level of your quality management system.

1

Process Capability Analysis

Comprehensive capability metrics including:

- CPK/PPK trends over time to monitor process performance
- Multi-site capability comparisons for global operations
- Historical trending to identify improvement opportunities
- Automated alerts for capability degradation

2

Process Stability Monitoring

Real-time stability assessment through:

- Control charts across all products and processes
- Variation rule triggers for out-of-control conditions
- Trend detection algorithms
- Multi-product stability dashboards

3

Product Assessment Reports (PARs)

Comprehensive product quality insights:

- Retrospective analysis of product quality failures
- Prospective insights for risk mitigation
- Root cause analysis support
- Corrective action effectiveness tracking

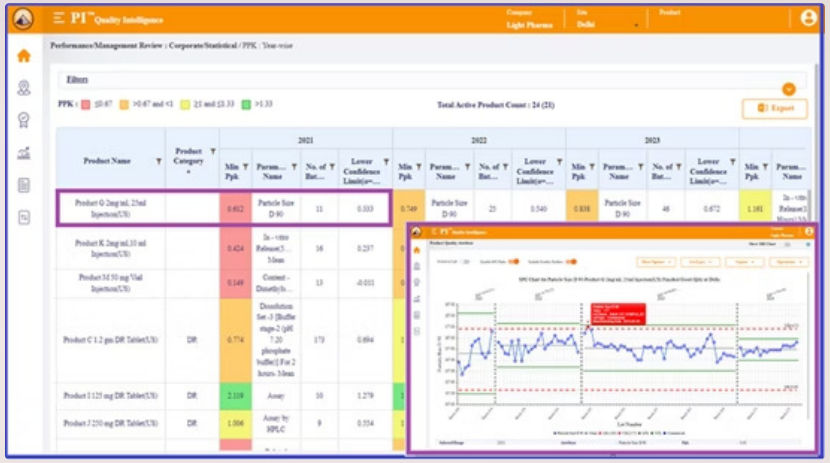
4

Method Evaluation Reports (MERs)

Analytical method performance assessment:

- Method variability analysis and trending
- Precision and accuracy metrics
- Method suitability evaluations
- Comparative method performance studies

These comprehensive insights empower organizations to proactively address quality issues, optimize manufacturing processes, and maintain a state of continuous improvement aligned with ICH Q10 principles.



Process Capability Visualization

Figure 1: Minimum PPK Attribute of Each Product for a Manufacturing Site with an Associated Statistical Process Control Chart

The visualization demonstrates how PI Quality Intelligence presents process capability data alongside statistical process control charts. This integrated view enables quality professionals to:

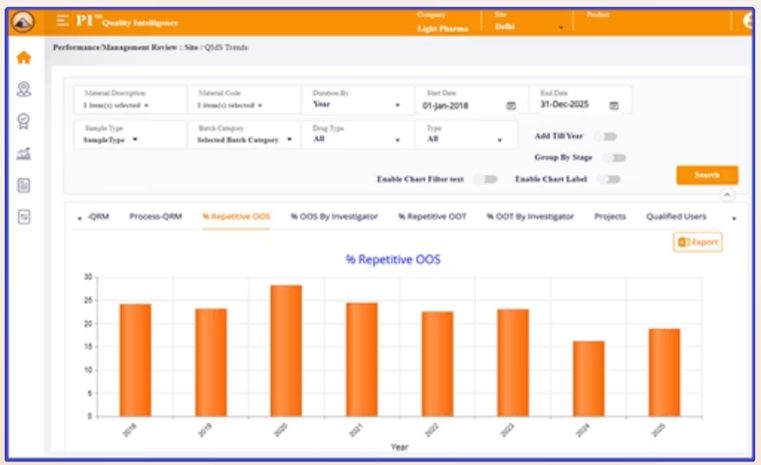
- Monitor minimum PPK values across multiple products simultaneously
- Identify products approaching capability thresholds
- Detect trends in process performance over time
- Correlate capability metrics with control chart patterns
- Make data-driven decisions about process improvements

Key Insight: The combination of capability indices and control charts provides a comprehensive view of both process capability and stability, enabling proactive quality management.

QMS EXCELLENCE

Quality Management System Trends and Analysis

PI Quality Intelligence can advance your Quality Management System (QMS) by utilizing a structured trend analysis program to monitor key quality metrics over defined time periods including monthly, quarterly, and annual reviews.



Conformance Metrics

Critical operational quality indicators:

- Batch rejection rate tracking
- Out-of-specification (OOS) results per batch
- Right First Time (RFT) performance metrics
- Recurring deviation rate analysis
- CAPA initiation and closure rate monitoring
- Stability failure rate trending
- Invalidated test percentage tracking

Customer & Product Metrics

External quality performance indicators:

- Customer complaint rate analysis
- Complaint trending by product and category
- Recall frequency monitoring
- Market feedback integration
- Product quality perception metrics

SECURITY

Role-Based Access Control

PI Quality Intelligence helps secure operations through comprehensive access management and data protection features designed to maintain data integrity while enabling efficient collaboration.

Role-Based Access

Granular permission controls enable organizations to define specific access levels for viewing, editing, or exporting quality reports. Users only see data relevant to their role and responsibilities, ensuring appropriate information access across the organization.

Defined Privileges

Sensitive data and quality event management are protected through defined privilege levels. Administrative functions, data modification rights, and report approval workflows are restricted to authorized personnel only.

Data Segregation

Multi-site organizations benefit from data segregation capabilities that ensure users access only information relevant to their site, product line, or functional area while maintaining enterprise-wide visibility for authorized stakeholders.

Compliance-Ready Features

PI Quality Intelligence is fully compliance-ready and consistent with global regulatory frameworks, providing built-in features that support inspection readiness and regulatory requirements.

ICH Q10 Alignment

Platform design supports Pharmaceutical Quality System requirements:

- Process performance monitoring
- Product quality review capabilities
- CAPA management integration
- Change control documentation
- Management review support

21 CFR Part 11 Compliance

Electronic records and signatures meet FDA requirements:

- Secure audit trails tracking all changes and approvals
- Embedded e-signatures for data integrity
- User authentication and access controls
- Time-stamped activity logs
- Data backup and recovery procedures

EU Annex 11 Requirements

Computerized system validation and controls:

- Exportable change histories for inspection readiness
- System validation documentation
- Data integrity controls (ALCOA+ principles)
- Disaster recovery capabilities
- Periodic review procedures

Transform Your Quality Management

With PI Quality Intelligence, pharmaceutical companies can achieve operational excellence and regulatory compliance simultaneously:

Reduce Manual Effort and Associated Errors

Eliminate time-consuming manual data compilation, spreadsheet management, and report generation. Automated data integration from LIMS, SAP, and TrackWise systems ensures accuracy while freeing quality professionals to focus on analysis and decision-making rather than data collection.

Enhance Product Quality and Process Reliability

Real-time monitoring, statistical process control, and capability analysis enable proactive quality management. Identify process variations before they impact product quality, implement timely corrective actions, and maintain consistent manufacturing performance across all sites.

Increase Regulatory Readiness

Embedded compliance features including secure audit trails, electronic signatures, and exportable change histories ensure continuous inspection readiness. Meet ICH Q10, 21 CFR Part 11, and EU Annex 11 requirements without additional manual documentation efforts.

Utilize Statistical Insights to Drive Continued Improvement

Advanced analytics, trending capabilities, and visualization tools transform quality data into actionable insights. Support data-driven decision-making, verify CAPA effectiveness, and demonstrate continuous improvement aligned with pharmaceutical quality system principles.

Ready to Digitize Your Quality Management?

PI Quality Intelligence represents the future of pharmaceutical quality management—a comprehensive, compliance-driven platform that transforms quality monitoring from a reactive burden into a proactive competitive advantage.

Key Takeaways:

- Centralized quality data from multiple systems
- Automated monitoring and trending of critical quality metrics
- Advanced statistical analysis and visualization tools
- Built-in regulatory compliance features
- Role-based security and access control
- Inspection-ready documentation and audit trails

Transform your quality management system with PI Quality Intelligence and join leading pharmaceutical manufacturers in the digital quality revolution.