PI APQR

Digitizing Product Quality Review for Pharmaceutical Companies

PI APQR is a cutting-edge automation platform that digitizes the entire Annual Product Quality Review lifecycle. It transforms APQR from a resource-intensive task into a seamless, efficient process through role-based management, smart scheduling, streamlined data integration, advanced analytics, and regulatory compliance.

50+%
Time Saved
Accelerated APQR completion timelines

100%
Compliance
Fully aligned with CGMP, 21 CFR Part 11, EU Annex 11

20+
Key Features
Comprehensive capabilities from workflow to AI insights

Core Capabilities

Structured Workflow
Built-in e-signature support, comment capture, and status visibility across cross-functional teams for seamless collaboration.

Smart Scheduling
Dedicated APQR Calendar with country-specific support, auto-generation of APQR numbers, and management reports.

Centralized Data
Integrates with LIMS, SAP, TrackWise, EDMS, and more to unify data from multiple sources.

Streamlined Generation
Generate draft APQR reports with predefined sections, intelligent data population, and configurable validation rules.

Advanced Analytics & Intelligence

PI APQR includes powerful statistical tools to strengthen quality management and enable preventive actions:

1. Product cabability as measured by CPK, PPK
2. Monitoring product consistency with control charts(including Nelson Rules).
3. Comparison before and after changes or specified dates using ANNOVA.
4. Stability and shelf-life predictive analysis.
5. Comparison capabilities across review periods and product strengths

Security & Compliance by Design

Role Management
Assign specific privileges to view, edit, approve, and export APQR reports with controlled access to sensitive data.

Regulatory Compliance
Fully compliant with CGMP, 21 CFR Part 11, EU Annex 11, and global regulatory guidelines.

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Audit Trails
Secure, time-stamped tracking of all user activities, data changes, approvals, and e-signatures.

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E-Signatures
Embedded electronic signatures ensure security and integrity throughout the APQR lifecycle.

Customization & Flexibility

1 **Customizable Templates**
Generate APQRs tailored to organizational needs. Export in Word or PDF formats for single or multiple product strengths and markets.

2 **User-Level Configuration**
User-level configuration allows adjustments to specifications and control charts without coding expertise.

3 **Admin-Level Customization**
Admin level configuration for template customization.

APQR Data Integration Systems

Our comprehensive integration framework connects seamlessly with your existing quality infrastructure, providing flexible options to suit your operational needs.

LIMS
Direct connection to Laboratory Information Management Systems for real-time testing data and analytical results.

Dashboard
Seamless integration with your Lab Performance Dashboard to capture process monitoring metrics and trending data.

TrackWise
Automatic pull of deviation, CAPA, and change control records for comprehensive quality event tracking.

SAP
Enterprise resource planning connectivity for batch records, material data, and production information.

Import from Handwritten Paper Documents
Option to import the data and analystial results from BMR directly using AI document intelligence.

Standardized Excel Import
Upload data using pre-formatted templates when direct system integration isn't available or preferred.

Data Integration
API-based connections, file transfers, or manual uploads feed directly into the centralized system.

APQR Database
Secure, validated repository where all quality data is stored, normalized, and prepared for review.

Continuous Updates
Automated processes ensure the latest data is available in near real-time for ongoing compliance.

☑ **Integration Flexibility:** Choose from API-based real-time synchronization, scheduled file-based imports, or manual data entry—all feeding into a unified database for comprehensive product quality reviews.

AI-Powered Intelligence in PI APQR Software

Transforming pharmaceutical quality review through advanced artificial intelligence capabilities that streamline data extraction, analysis, and decision-making processes.

Intelligent Data Extraction
Advanced OCR and machine learning algorithms automatically extract quality attributes and process parameters from handwritten Batch Manufacturing Records (BMR) and Batch Production Records (BPR), eliminating manual data entry errors.

Predictive Analytics
AI-driven historical trend analysis detects data anomalies and patterns across batches, enabling proactive identification of potential quality issues before they impact production or compliance.

Accelerated Review Cycles
Automated workflows and intelligent data processing significantly reduce review cycle times and approval periods, allowing quality teams to focus on strategic decision-making rather than administrative tasks.

Smart Summarization
Natural language processing generates comprehensive summaries for each APQR section, synthesizing complex data into clear, actionable conclusions that support regulatory submissions and management reviews.

Root Cause Intelligence
Machine learning models analyze quality deviations to identify root causes and recommend immediate corrective actions, supported by historical data patterns and industry best practices for faster resolution.

Streamlined APQR Export Process

The PI APQR system revolutionizes regulatory documentation with seamless, one-click export functionality that transforms complex quality data into professional reports.

Flexible Format Options
Export your APQR as either Microsoft Word or PDF documents with a single click, providing flexibility for internal review, regulatory submissions, and archival requirements.

Template-Driven Generation
Automated document creation based on pre-configured templates ensures consistency, compliance, and adherence to regulatory standards across all product quality reviews.

Multi-Strength Capability
Generate comprehensive APQRs for multiple product strengths simultaneously, significantly reducing preparation time and ensuring uniform quality assessment across your product portfolio.

The PI APQR Advantage

PI APQR is more than just an APQR generator—it is a compliance-driven automation platform that digitizes and simplifies every stage of APQR.

Minimize Manual Effort
Reduce errors and accelerate completion timelines

Ensure Regulatory Readiness
Embedded compliance features for audit preparedness

Gain Actionable Insights
Improve product quality and performance

Focus on Excellence
Empower innovation in pharmaceutical manufacturing

Transform Your APQR Process

Investing in PI APQR is an investment in operational excellence, quality assurance, and compliance. Transform your APQR process and empower your organization to focus on innovation and excellence in pharmaceutical manufacturing.