PQMS

Look beyond software.
Go beyond digitization.

PQMS (Process Quality Management Suite) is a comprehensive, modular software platform designed to streamline quality processes, ensure compliance, and drive operational excellence across the pharmaceutical, biotech, food, and cosmetic industries.

The suite consists of five integrated modules that work together seamlessly to cover the full spectrum of quality and compliance needs:

QMS Pro: A comprehensive quality management system that can serve as the backbone of the PQMS suite. QMS Pro provides a centralized platform for managing non-conformances, corrective and preventive actions (CAPAs) and change control. Inbuilt are root cause analysis and risk analysis tools.

ValDoc Pro: Manages and streamlines qualification by providing a paperless framework for creating, executing, and approving protocols. It is also a document management application wherein SOPs can be created and version controlled from the comfort of MS Word on PC.

eProcess Pro: A powerful tool to track your CPP and CQA through PPQ and OPV runs, the software provides powerful data analysis tools. APQR reports can be generated automatically when linked to a QMS system.

eResidue Pro: An end-to-end cleaning validation application that calculates residue limits, and ensures audit readiness by providing qualification status of the equipment and products.

eLog Pro: A digital logbook solution that revolutionizes the way companies capture, store, and retrieve log data. eLogbook replaces traditional paper-based logbooks with a secure, centralized electronic system that enables real-time data entry, search, and collaboration

One of the key advantages of the PQMS suite is that it has been developed by SMEs. The same application therefore will meet the unique requirements of different industry segments. By leveraging the power of digitalization, automation, and data-driven insights, the PQMS software suite empowers companies to optimize their quality processes, reduce costs, and improve overall operational efficiency. With PQMS, companies can focus on what they do best - delivering high-quality products to their customers - while the software takes care of the rest.

In summary, the PQMS software suite is a game-changer for companies seeking to elevate their quality management, validation and record keeping practices and stay ahead in today's competitive landscape.

Quascenta

Record, Investigate, Resolve

Thorough RCA, Robust CAPA

QMS Pro is a comprehensive, cloud-based quality management system that streamlines nonconformance and CAPA processes. Document NCs, investigate root causes, and implement effective actions seamlessly to drive continuous improvement. With powerful analytics and audit-ready documentation, QMS Pro helps you maintain compliance effortlessly.

Record

Centralized Nonconformance Tracking

Maintain a centralized repository to record all non-conformances in a standardized format. Capture relevant details like description, location, date, and personnel involved. Upload supporting documents and assign unique IDs for traceability, ensuring a complete audit trail

Investigate

Thorough Root Cause Analysis

Utilize embedded root cause analysis tools such as 5 Whys, fishbone diagrams, and FTA for thorough investigations. Standardize investigation processes with configurable workflows, ensuring no step is missed and all relevant data is captured.

Resolve

Integrated CAPA Management

Implement corrective and preventive actions based on investigation findings. Assign tasks with deadlines, send automated notifications, and verify the effectiveness of actions taken. Monitor trends to prevent recurrence and ensure compliance with regulatory requirements

Streamline

Automated Workflows and Notifications

Configure automated workflows for routing, escalation, and approvals based on nonconformance type and severity. Send notifications and reminders to ensure timely action. Eliminate manual tracking for efficient resolution

Report

Real-Time Reporting and Analytics

Generate reports on nonconformance metrics like categories, status, aging. Identify trends and high-risk areas. Make data-driven decisions to improve quality performance and drive continuous improvement.

QMS Pro

Streamline, Simplify, Qualify.

Seamless Document & Qualification Management.

ValDoc Pro integrates a robust document management system with asset qualification execution and management capabilities, providing complete insight and control throughout the asset lifecycle. When connected with eProcess Pro and eResidue Pro, ValDoc Pro is the world's only comprehensive digital validation system.

Capture

- Store and manage all master plans, procedures, specifications, work instructions, protocols and reports, drawings/plans, agreements, etc in a secure, centralized location.
- Create and edit documents like Standard Operating Procedures (SOPs) in Microsoft Word format directly from within the software.
- Add comments and see changes highlighted for easy review and understanding.
- Maintain and access previous versions of documents to track changes and ensure accuracy.

Execute

- Perform Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) from within the software.
- Trace User Requirement Specifications (URS) to Functional Specifications (FS) to IQ/OQ, ensuring better compliance.
- Execute script sections in a user-specified order, ensuring the correct sequence and dependencies are maintained.
- Execute script based on script requirement related to user role.

Streamline

- Use of pre-defined, reusable templates ensures that SOPs, protocols, and reports follow the same document format, enhancing consistency and compliance.
- Automate repetitive tasks and workflows, reducing manual effort and the potential for human error.
- Streamline approval processes with electronic signatures and automated notifications.

Integrate

- Integrate with eProcess Pro, eResidue Pro and eLog Pro to get a complete validation and process monitoring platform. Track equipment and product validation status.
- Link to QMS Pro to trigger change control.

ValDoc Pro

Process Management Simplified...™

A game-changing, intelligent, lifecycle-based guided process management platform that understands & speaks your language

Design

- Track Target Product Profile, Raw Material Attributes, Process Parameters & Product Quality Attributes for your new molecules.
- Establish an optimal design space with built-in Design of Experiments (DoE) to understand main and interaction effects.
- Conduct predictive scale-up/scale-down for scale-dependent parameters.
- Perform small-scale PPQ runs in an isolated environment.

Validate

- Get a complete picture of your products including its validation status.
- Guide setup of sampling plans to obtain accurate and meaningful results.
- Simplify PPQ/OPV protocol and report generation. Integrate with eBMR, elogbook and LIMS to automate PPQ report generation.
- Track PPQ/OPV runs through sample collection and test results entry.

Monitor

- Optimize your OPV program by applying risk based sampling. Monitor process changes to trigger actions to close the loop.
- Utilize powerful data analysis tools to contextualise data collected, enhances process understanding and decision making.
- Generate APQR report from a single platform that assimilates disparate data sources across multiple systems, i.e. eResidue Pro , QMS Pro.

Process Pro

Cleaning Validation Simplified...™

Establish an Intelligent Cleaning Validation Program

Proven, Compliant & Robust

- Mature application with a stellar track record over 20 years.
- Only cleaning validation application that has passed multiple FDA, MHRA, ANVISA & other regulatory inspections.
- Complies with Part 11 and Annex 11 requirements.
- Address both chemical & microbial residues in alignment with ISPE Cleaning Validation Guide and PDA Technical Report 29.
- A robust calculation engine with validated formulae capable of handling as many as 500 products in 1 calculation.

More than Just Paperless Validation

- Designed by Destin LeBlanc, eResidue Pro is specific to cleaning validation that allows application of knowledge-based, scientific principles to build process understanding as a precursor to validation.
- Built-in AI ensures proper setup and maintenance of an audit ready cleaning validation program.
- Utilize Quascenta resources/expertise in cleaning validation to design future-ready process.

Improve Efficiency

- Capture multiple siloed information, i.e., Equipment and Product Information, Analytical & Microbial methods, etc., in eResidue Pro allowing better visibility. Create an integrated data repository with links to LIMS, SAP, etc.
- Automatically generate protocols and collate associated data from within the application. Build in QbD to develop a robust, well-documented, risk assessed and compliant cleaning process.
- Apply predictive analytics to contextualise data and look for patterns and trends.

eResidue Pro

Digitalizing Logbooks, to enable comprehensive insights.

Pharmaceutical facilities traditionally use paper-based log records for essential GMP activities, which must then be securely stored for regulatory inspections. This resource-intensive activity limits data availability making analysis challenging. Quascenta's eLog Pro offers a streamlined software solution, capturing log data directly and efficiently, facilitating immediate analysis and compliance.

Return

Quick return on investment (ROI)

Adopting Quascenta's eLog Pro eliminates expenses linked to printing and storing records, while boosting productivity. Cost saving eliminates re-work, enabling timely data entry and capturing events with a click of a button.

Visibility

Full Visibility

Information is now readily accessible on-site, with multi-user entry and mobile device support, thus improving coordination among personnel by facilitating contribution to data access.

Analysis

Enhanced Data Analysis and Proactive Decision-Making

Data collected can be leveraged for insightful analysis and informed decision-making. This allows for the identification of patterns, such as the frequency of equipment malfunctions, enabling selective scrutiny. Such data-driven insights empower teams to conduct thorough investigations beyond the software to uncover root causes, leading to more effective maintenance strategies and operational enhancements.

Deployment

Quick Deployment

Deploy quickly and get teams to speed up production in 2-3 weeks, with an electronic logbook that meets your sites demands.

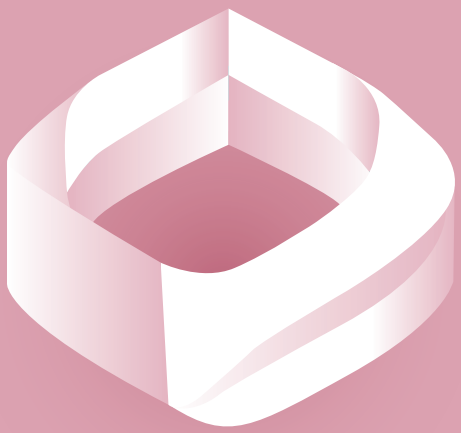
Data

Data always secure

Automated backups on the cloud ensure data never gets lost.

eLog Pro

Organize, Respond, Succeed.



Seamless audit and response management

AuditPro is a comprehensive inspection management application that helps pharmaceutical and life sciences companies navigate and manage regulatory inspections, customer audits, and other compliance assessments with precision and control. It acts as a central command center during audits to coordinate requests, documents, and responses securely. AuditPro then tracks observations and gaps through response, remediation, and closure.

Prepare

- Centralize inspection readiness activities across sites and functions.
- Map regulations and past findings to current inspection focus areas.
- Pre-build response templates and evidence packages for common queries.
- Align roles, responsibilities, and escalation paths before inspectors arrive.

Command

- Run a dedicated physical or virtual war room during inspections.
- Control who sees what, ensuring only vetted documents are released.
- Route inspector requests to the right SMEs with clear ownership.
- Track every question, response, and document shared in real time.

Respond

- Build, review, and approve responses through guided workflows.
- Attach supporting evidence directly to each request or observation.
- Maintain version history for responses and documents for full traceability.
- Ensure consistent, accurate, and timely communication with inspectors.

Track

- Log every observation and commitment with clear owners and due dates.
- Monitor CAPA status from initiation to effectiveness verification.
- Visualize inspection progress, risks, and bottlenecks in dashboards.
- Maintain a complete history of inspections for future readiness.

Improve

- Analyze inspection data to identify recurring issues and weak controls.
- Feed learnings into training, procedures, and preventive actions.
- Benchmark inspection outcomes across sites, products, or agencies.
- Demonstrate continuous improvement to regulators and leadership.

Audit Pro

Discover the power of seamless integration with PQMS

Contact us to experience the difference first-hand

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