DASSAULT SYSTEMES

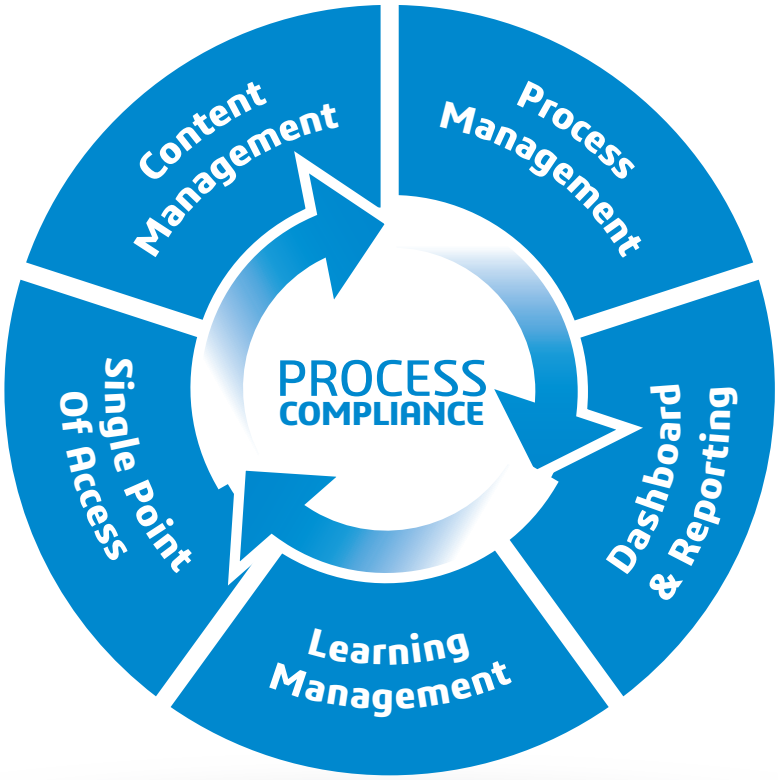
BIOVIA

ProcessCompliance

A COMPREHENSIVE, CLOSED LOOP ENTERPRISE QUALITY MANAGEMENT SOFTWARE (EQMS) SOLUTION

Datasheet

CLOSED LOOP COMPLIANCE



OVERVIEW With increasing pressure on costs and margins across Life Sciences, the industry must move away from point solutions that address specific regulatory challenges – and move towards a solution that offers a consolidated, integrated approach to quality and compliance management.

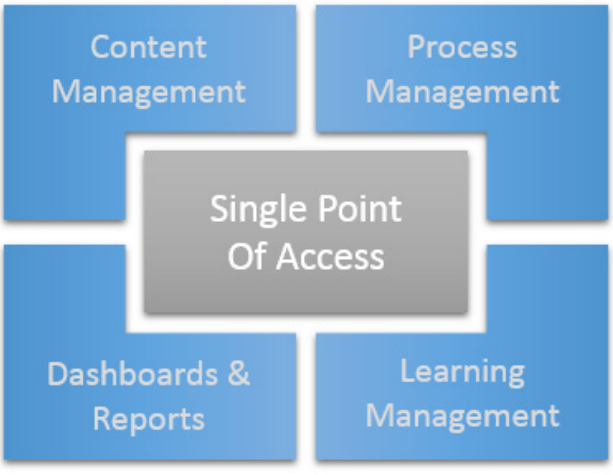
ProcessCompliance provides companies with a comprehensive and harmonized solution that combines all of the elements required for a complete, closed loop Enterprise Quality Management Software (EQMS) solution. The solution is fully configurable and provides an integrated environment to manage all quality activities. The solution enables organizations to drive costs down and reduce cycle times by enabling users to get accurate information and make the right decisions quickly. Advanced web services capabilities enable information from core systems to be synchronized with the EQMS solution. ProcessCompliance incorporates the controls, audit trails, permissions and structures to provide certainty that:

- All incidents and issues are logged and registered
- Reports are generated for all issues and incidents
- If required, a corrective action plan or remediation plan is generated
- Plans, reports and any associated information are delivered to the right people
- All plans, information and issues are reviewed and investigated on a timely basis
- All plans are approved and signed off by the relevant managers with fully compliant electronic signatures
- Tasks are assigned to the appropriate people to remedy incidents and issues
- Reviews are conducted to validate the effectiveness of the action plan or remediation plan
- Once effectiveness of the plan has been validated, the incident or issue is closed

KEY COMPONENTS

ProcessCompliance is comprised of 5 key components that can be joined together in a single, seamless environment. Companies can elect to deploy the entire platform consisting of all the components or start with the foundational Content Management component and add on the Quality and Learning Management components at a later date.

All of the components provide built-in compliance management and support the most stringent requirements such as: 21 CFR Part 11; 210; 820; 600, ISO standards (9000; 1400), Annex 11 and GxP practices.



CONTENT MANAGEMENT

Content management for all document formats is managed from creation through distribution and training in one location for all users including: authors, reviewers, editors, approvers, trainers and document consumers. Content management capabilities include:

- Consumer templates (mandatory or elective)
- Collaborative authoring and review
- Automated workflow based on content type
- Advanced document lifecycle management
- Document comparison for ease of review
- Automated PDF rendering
- Automated version control
- Read and Understood notifications and training
- Advanced search and retrieval
- Controlled printing and watermarking
- Hardcopy management and destruction
- Built-in best practices for regulatory compliance

For more information on electronic document management capabilities, please refer to the DocCompliance datasheet.

PROCESS MANAGEMENT

Process Management for all quality activities including: CAPAs, Deviations, Change Controls, Customer Complaints and Audit Management. Workflows for each of these and additional processes can be created, reviewed, processed and approved through this interface. Process management capabilities include:

- Configurable, Rules-based Workflow Engine, including automated triggers and escalations
- Business Rules Engine that allows users to create rules around activities and fields in the system, and to set tolerances
- Forms manager for creation and management of forms
- Two-way integration with other systems (e.g. ERP)
- Advanced and configurable reporting

ProcessCompliance can be used to manage a wide variety of processes, including but are not limited to:

- Event Handling
- Planned and Unplanned Deviations
- CAPA
- Customer Complaints
- Audits (internal and external)
- Quality Check
- Change Control
- IT Change Control
- Administration Processes
- Financial Processes
- Legal Processes
- Sales and Marketing Processes

LEARNING MANAGEMENT

eLearning modules, instructor led training, and ProcessCompliance content can be easily browsed and converted into effective and measurable training. Industry standard SCORM compliant content can also be launched and tracked within the application, all dramatically reducing the time needed to create and deliver critical training. Support is included for:

- Online Courses, Classroom/Instructor-Led Training, External Learning Events
- Learner, Instructor, Supervisor, Administrator roles
- Exams, surveys, and competency testing
- Recording of External Training, Attendance Lists, and Results
- Certificates
- Self-Registration
- Controlled Content, PDF, Word, SCORM, AICC with bulk load capabilities
- Default Reports
- Configurable Reporting

DASHBOARDS & REPORTS

A graphical compliance dashboard provides oversight across business areas and quality initiatives. The dashboard enables users to:

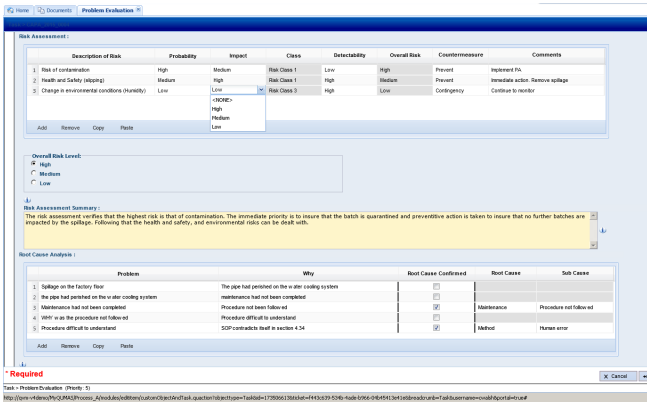
- Tailor a company-specific view of compliance and quality: analyze by your organizational taxonomy - product, category, location, etc.
- Drill-down to actionable quality data for investigation, remediation and planning of proactive compliance initiatives based on real-time data
- Securely access critical compliance and quality data on a 24/7 basis from a web-browser
- Create custom reports that provide specific views across your organization

Users can also develop printable reports that can be emailed to a configurable schedule.

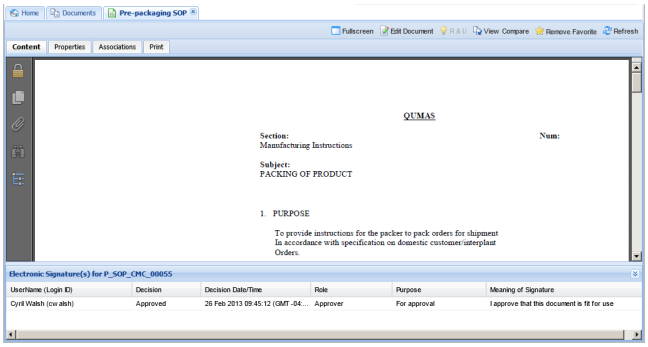
A SINGLE POINT OF ACCESS TO YOUR COMPLIANCE CONTENT

All of these core quality and compliance capabilities are accessed in one, user-friendly interface. This allows users to easily connect and collaborate on compliance content, processes, tasks, training and reporting from one central location. It provides a unified interface into all compliance and quality management initiatives, uniquely combining views and tasks related to documents, processes, training and reporting in a single view.

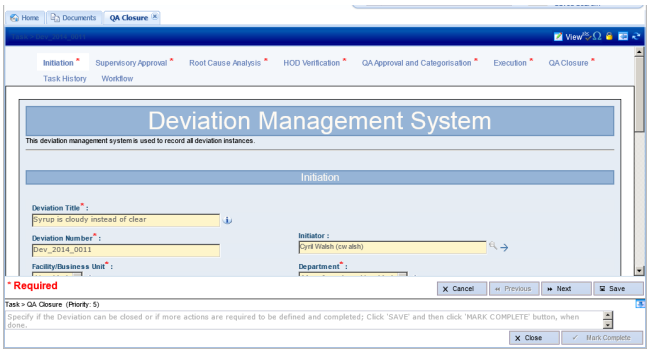
KEY CAPABILITIES



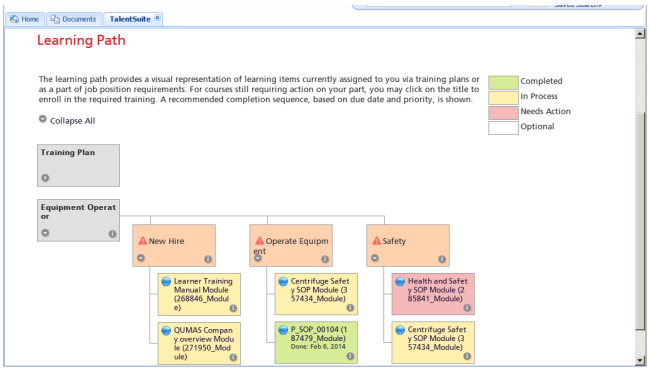
ProcessCompliance packages offer a Risk Analysis table supporting the ISPE GAMP model and Ichikawa based Root Cause Analysis.



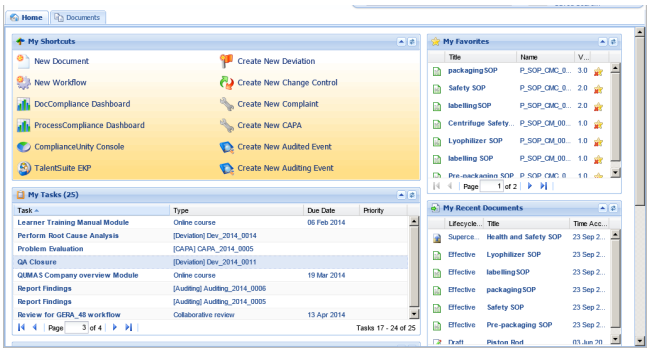
The ProcessCompliance solution provides full support for Electronic Signatures as per FDA 21 CFR Part 11 requirements.



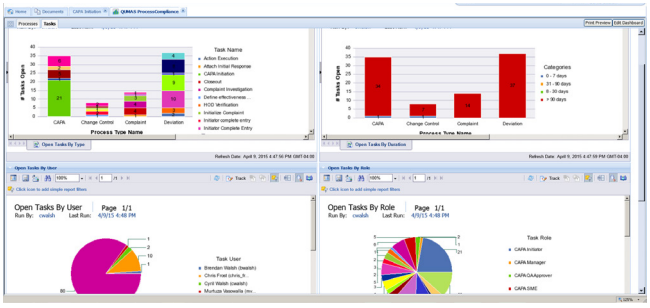
ProcessCompliance provides a standard format for recording deviations, corrective actions, change controls, etc. so that you can search, view, report, analyze and prioritize the commitments that are outstanding from one location.



The ProcessCompliance solution provides a configurable environment for users to launch, manage, and track all of their compliance training requirements.



A consolidated interface provides users with a single point of access to manage all their quality management activities.



Status reporting is surfaced to an integrated dashboard and reporting system that provides users with up-to-date information that identifies areas that need attention and can be targeted and addressed appropriately.

BEST PRACTICE CONFIGURATIONS

ProcessCompliance offer packages of configurations of our standard products including all the necessary documentation and validation to ensure a rapid deployment. The configurations come from industry and regulator guidelines (ISPE, DIA, FDA, ICH).

BENEFITS OF ProcessCompliance

With ProcessCompliance companies will be able to:

- Standardize and automate regulatory and quality processes, while ensuring all incidents are logged, investigated, and remediated in an accountable way that drives efficiency and accuracy across all related activities
- Ensure regulatory compliance with Read and Understood and Electronic Signature functionality (21 CFR Part 11) that is built in, not plugged in, enhancing the usability of this regulatory-required capability
- Reduce the costs of compliance and quality management by ensuring that only the information users require is accessible to them through an intuitive user interface, reducing training overheads and maintenance requirements in the full document management lifecycle
- Reduce the expense and resource burden involved in ensuring that the workforce is current on all relevant training and immediately attain the certification and training standards that are required by regulators and by best business performance practices
- Expedite regulatory compliance management activities with easier and more intuitive access to your compliance content, resulting in:
  - Simplified end-user training
  - Greater end-user satisfaction
  - Improved user productivity and reduced risk of user error
  - Reduced internal support demands and requirements
- Realize optimum content management practices in accordance with global regulatory requirements from agencies such as the US FDA & EMA, driving enterprise-wide consistency and compliance for creating, managing and securely storing documents electronically
- Scale the solution as the organization grows, easily and efficiently accommodating new users and sites
- Accurately and consistently report on and measure the success of quality initiatives, while decreasing risk

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