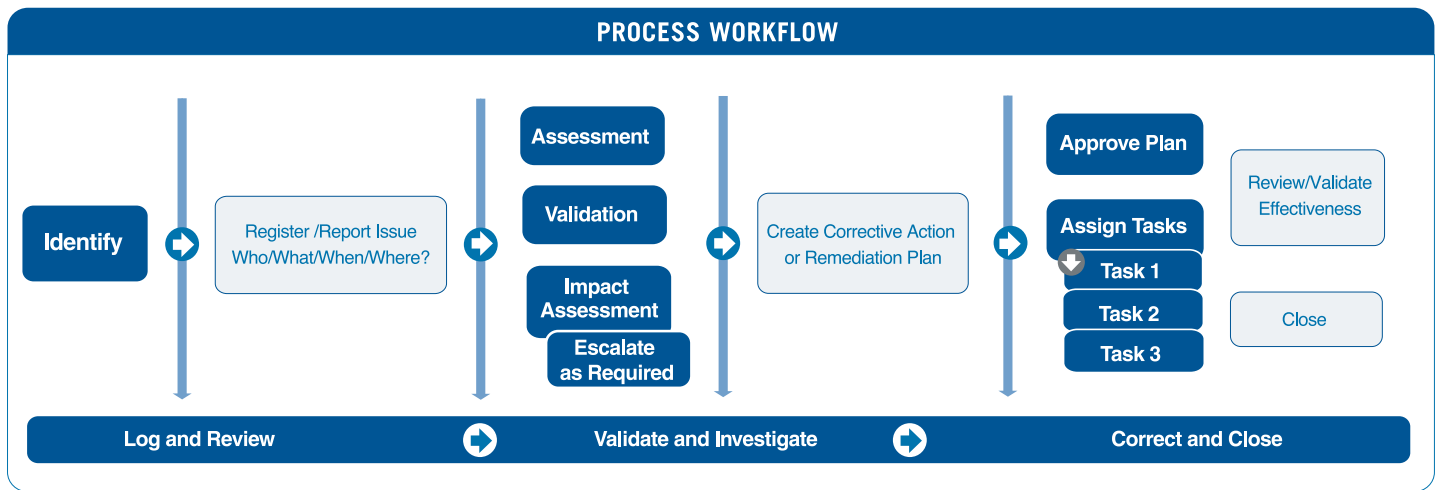


Overview

QUMAS ProcessCompliance™ enables organizations to standardize and automate their business processes that manage the collection, tracking, and analysis of information and the resolution of related issues. ProcessCompliance includes web-based, configurable processes, workflows and forms that can be tailored to meet the needs of the organization. ProcessCompliance integrates with QUMAS DocCompliance™ to provide access to controlled documentation during all phases of process management and with QUMAS ComplianceUnity™ for sophisticated reporting of their business performance. Organizations not only benefit from an increase in efficiency and accuracy of business processes and activities, but also proactively improve their business performance.

MyQUMAS™ provides a single, unified user interface for ProcessCompliance and DocCompliance - see the MyQUMAS datasheet for more information.



Functionality

QUMAS ProcessCompliance consists of the following core components:

- Rules-based Workflow Engine
- Data Dictionary
- Business Rules Engine
- Audit Trail
- Forms Manager
- Advanced Reporting

ProcessCompliance can be used to manage a wide variety of processes, including:

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

If you require prepackaged processes, which include configuration, services and training, please refer to the following datasheets:

- QUMAS CAPA Process Package
- QUMAS Deviation Process Package
- QUMAS Change Control Process Package
- QUMAS Complaint Process Package
- QUMAS Audit Process Package

Compliance

Features	Benefits
<i>Comprehensive Independent, Audit Trail</i>	Independent, secure audit trail capturing all auditable events.
<i>Complete Electronic Signature Manifestation</i>	Displays all electronic signature components including printed name of signer, time/date stamp, and meaning of signature.
<i>Irrefutable E-Record/ E-Signature Link</i>	All electronic records include irrefutable link to electronic signatures to ensure record integrity.
<i>Role-Based Electronic Signatures</i>	Meaning of signature is synonymous with user role to ensure electronic endorsements match user intent.

Flexible Workflow Control

Features	Benefits
<i>Workflow & Configuration Management</i>	Flexible business process workflows allow users to easily map their unique business processes to the system without costly customization.
<i>Flexible Workflow Processing</i>	Enables efficient management of in-process workflows without complication or compromise of regulatory diligence.
<i>Advanced Workflow Management</i>	Management of complex or simple processes and workflows at your fingertips, including workflow relationships.
<i>User-Definable Scheduling</i>	Helps users manage process scheduling of proactive tasks as well as reactive tasks, event notifications of overdue tasks and workflows.
<i>Configurable Triggers and Escalation</i>	Enables triggers to be set that automatically notify management or escalate critical issues.
<i>Graphical Rendering</i>	Produce graphical representation of the entire workflow process type

Forms Creation and Management

Features	Benefits
<i>User-Definable Fields</i>	Allows users to configure the display of data in fields in a way that is familiar throughout the organization, using text entry, drop down lists and radio button selections.
<i>User-Definable Layout</i>	Users can define the layout of forms, including fields, sections and pages.
<i>Simple GUI Wizard</i>	Easy-to-use Forms Wizard facilitates the creation of forms on an as-needed basis.
<i>Forms Security</i>	Enables users to control security on objects.
<i>User-Definable Look and Feel</i>	Style sheets can be used to apply the company's corporate image to the user interface, including colors, logos and layout.

Integrations

Features	Benefits
<i>Web Services API</i>	SDK to link external third party applications with ProcessCompliance
<i>Event Queue Support</i>	Provides messaging queues for integrated applications

Search

Features	Benefits
<i>User-Definable Saved Searches</i>	Facilitates the reuse of user-defined searches to improve efficiency and consistency.
<i>Public and Private Searches</i>	Promotes consistency and security across the organization through sharing of public searches and security for private searches.
<i>Attribute Searches</i>	Enables enhanced regulatory intelligence through attribute and searches.

Business Rule Engine

Features	Benefits
<i>Advanced Business Rules Engine</i>	Allows users to create rules around activities and fields in the system, and to set tolerances.
<i>Easy-To-Configure</i>	Simple GUI interface to Business Rules enables user to create business rules on an as-needed basis.

Built-In System Administration

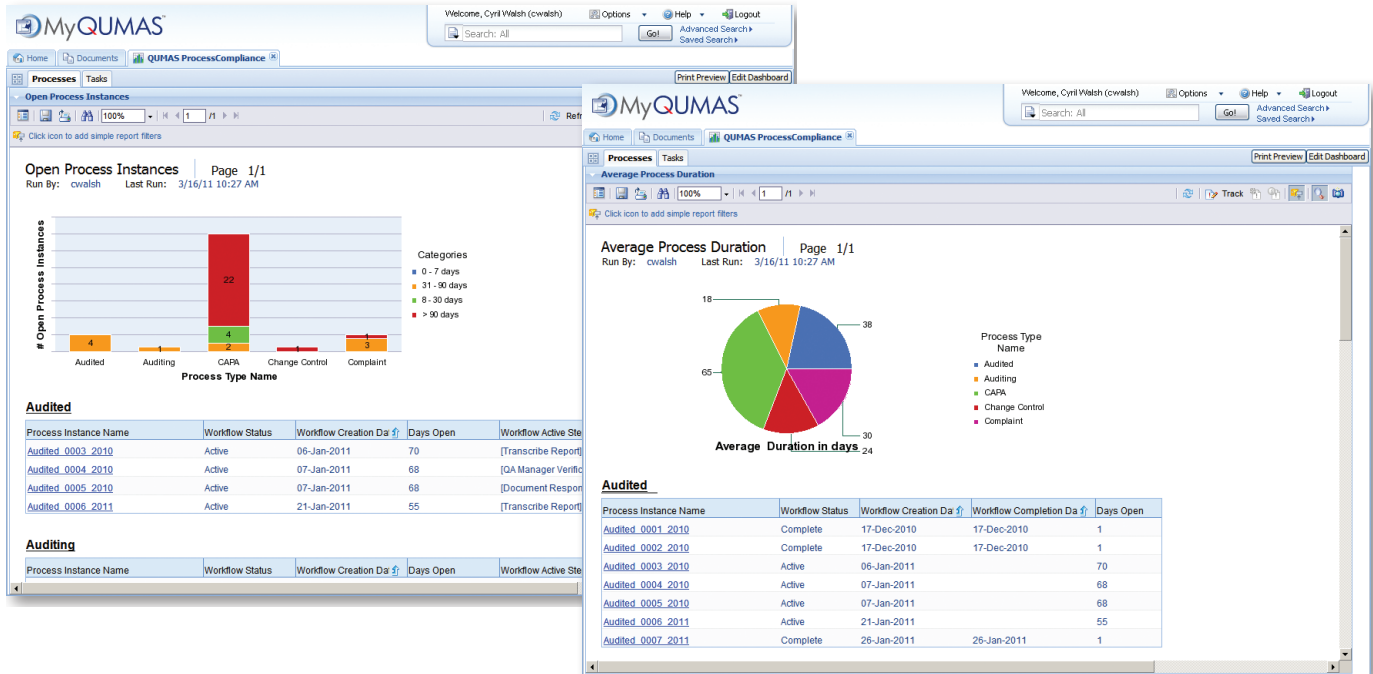
Features	Benefits
<i>User Profile Manager</i>	Establish access and security profile for each role enabling access and control in compliance with current regulations.
<i>Configurable Security Model</i>	Requires minimal technical experience thus facilitating easy deployment.
<i>Multiple Roles/User Support</i>	Enables the configuration of a user with one or more roles. Minimizes administration and configuration burdens.
<i>User Configurable Parameters</i>	All system administration parameters are configurable, enabling easy adaptation to your production environment without customization.
<i>User-Definable System Preferences</i>	System preferences may be defined according to regulatory requirements or industry best practices.
<i>Built-in Best Practices</i>	Includes built-in best practices in accordance with global regulations.
<i>Workflow Configuration Rendering</i>	As the workflow process is being configured, administrators can render it into a flow diagram to view steps and rules branching graphically. This diagram can be printed or e-mailed for discussion.

Configurable Reports

Features	Benefits
<i>Standard Reports</i>	A variety of standard process-related reports are built into the system to facilitate the easy retrieval of commonly accessed information.
<i>User-Friendly Reports</i>	Provides clear and instant access for users to the reports interface.
<i>Integration with SAP BusinessObjects Enterprise</i>	Extensive reporting capabilities are provided through full integration with SAP BusinessObjects Enterprise.

Additional configurable reports are available through integration with QUMAS ComplianceUnity. For more detail please refer to the ComplianceUnity datasheet.

ProcessCompliance Reports via ComplianceUnity



System Requirements

- Oracle 10g and 11i / SQL Server 2005 and 2008
- Tomcat 6
- Java 6
- SAP BusinessObjects Edge XI v3.1

About QUMAS

QUMAS is the leader in Enterprise Compliance Management with more than 250 global customer deployments and over 17 years experience within the Life Sciences sector. QUMAS provides a closed-loop Compliance Platform that enables you to integrate the common elements of compliance, including content, processes, people and systems, across your organization. QUMAS Solutions and Packages for document, quality and incident management, submission management and regulatory approval enable you to accelerate your time to market, decrease compliance risks, improve operational efficiencies and reduce overall quality costs.

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