



MyQUMAS™

The Single Point of Access to your
QUMAS Compliance Platform



Overview

MyQUMAS is a user friendly solution that provides access to all QUMAS Compliance Platform capabilities in one view. It allows people to easily connect and collaborate on compliance content, processes, tasks, training and reporting from one central location.

MyQUMAS enables users to access the following core capabilities of the QUMAS Compliance Platform:

Policy and Procedure Management

Content management for all formats of documents from creation through distribution and training in one location for all users including; authors, reviewers, editors, approvers, trainers and consumers.

Quality Management

Quality process management including CAPA, Deviation, Change Control, Customer Complaints and Audit management. Workflows for each of these and additional processes can be created, reviewed, processed and approved through this interface.

Learning Management

Learning management capabilities for eLearning modules, instructor led training and also for QUMAS content which can be easily browsed and converted into effective and measurable training. Industry standard SCROM compliant content can be launched and tracked within the application, all dramatically reducing the time needed to create and deliver critical training.

Dashboard Reporting

Compliance dashboards, grouping all reporting across your compliance initiatives including content, processes, training and people in one integrated view.

MyQUMAS provides a unified interface into all of these compliance management initiatives, for the first time combining views and tasks related to documents, processes, training and reporting in a single view.

The screenshot displays the MyQUMAS homepage interface. At the top, there is a navigation bar with the MyQUMAS logo, a search bar, and user options like 'Options', 'Help', and 'Logout'. Below the navigation bar, the dashboard is divided into several sections:

- My Shortcuts:** A grid of icons and links for quick access to various functions such as 'Browse the Repository', 'Executive Dashboard', 'New CAPA', 'ComplianceLMS', 'New Deviation', 'New Change Control', 'New Workflow', 'New Complaint', 'New Document', and 'Coordinator of Workflows'.
- My Favorites:** A table listing favorite documents with columns for 'Title', 'Version', and a star icon. The list includes items like 'Documentation Best practiced for ...', 'Foundation GMP Training', 'GMP Refresher for Senior Staff', 'Hazardous Materials Safety & Trai...', 'Master Clinical Trial Agreement_1...', and 'Clinical Trial Registration_4007'.
- My Tasks (14):** A table showing a list of tasks with columns for 'Task', 'Type', and 'Due Date'. Tasks include 'CAPA Initiation', 'Impact Assessment', 'Complete Editing Step', 'Read & Understood', 'Complete Release Approval Step', 'Complete Workflow Approval Step', and 'Route Cause Analysis'.
- My Recent Documents:** A table listing recently accessed documents with columns for 'Name' and 'Version'. Documents include 'TA with ABCPharma for Manufac...', 'Procedure for Archiving and Stor...', 'Implementation of Global Quality...', and 'SOP Preparation of Product Spec...'.
- My Pending R & U:** A section at the bottom for pending reviews and updates.

Figure 1. MyQUMAS Homepage, combining documents, processes, training and reporting in one view.

Core Capabilities

- MyQUMAS is a consolidated interface enabling users to collaborate, communicate and search from a single web-based interface, users can perform all document, process, training and reporting activities in one unified interface
- MyQUMAS users can create and perform tasks across CAPAs, Deviations, Audits, Change Control and Customer Complaints from incident logging through investigation to approval and remediation
- MyQUMAS users can manage all regulatory content through the lifecycles of create, review, edit, approve and distribution, in compliance with regulatory requirements for document management
- Consumer users can view their homepage, browse, view, mark documents as read and understood, print and search
- Contributor users can perform all of the consumer tasks, and can also create new documents and workflows and participate in the full document management lifecycle
- Users can collaborate on documents in real time, working simultaneously on content ensuring faster review cycles and streamlined editing
- Coordinator users can create new documents and workflows, and manage the coordination of the workflows through the MyQUMAS interface
- All Users can access eLearning, QUMAS training and register instructor led training directly from MyQUMAS
- Reporting across all compliance initiatives can be performed and viewed within MyQUMAS and can also be exported to other applications

Step Release Approval:
Please select Approve or Disapprove and follow the on-screen instructions to release or disapprove the workflow.
Workflow Name: Review_Edit_Approve_GXP_1109 Workflow Purpose: Procedure for disaster recovery

Title	Name	Version	Lifecycle State	Checked Out By	Actions
Procedure for disaster recovery	SOP_788	0.1	Review Copy		Properties More

What would you like to do with current workflow?
 Approve Disapprove

To approve this workflow please enter your username and password

Username: cwahsh Password: [REDACTED]

Complete

Username	cwahsh
Role	Administrator
Purpose	To review and approve Procedure for disaster recovery
Decision	Approve
Meaning of Signature	As an approver I have reviewed the workflow and approve the documents.

Workflow Properties | **Decision Details**

Expand All | Collapse All

Step: Release Approval

Order: 1		Cooperative: All			
User	Role	Decision	Reason	Age (Days)	Decision Date
Cyril Walsh (cwahsh)	QA Manager	Pending		7	

Figure 2. MyQUMAS Electronic Signature in accordance with FDA 21 CFR Part 11

Benefits

- Reduce the costs of regulatory compliance 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
- Ensure regulatory compliance with Read and Understood and Electronic Signature functionality (21 CFR Part 11) that is built into all views, enhancing the usability of this regulatory-required capability
- Realize optimum content management practices in accordance with global regulatory requirements from agencies such as the US FDA, driving enterprise-wide consistency and compliance for creating, managing and securely storing documents electronically
- Standardize and automate regulatory and business processes, while ensuring all incidents are logged, investigated, and remediated in an accountable way that drives efficiency and accuracy across all related activities
- Scale as your organization grows, easily and efficiently accommodating new users and sites
- Accurately and consistently report on and measure the success of compliance initiatives, while decreasing regulatory and quality risks

System Requirements

Platforms

Windows 2003, 2007, Oracle 11g, SQL Server 2008 and Documentum 6.5

Third Party

IIS 6, Office 2003 and 2007, Internet Explorer 8, Firefox 3.5.x or greater (incl. Apple Mac OS X), Adobe Acrobat 9

About QUMAS

QUMAS is the leader in Enterprise Compliance Management with more than 250 global customer deployments and almost 20 years experience in highly regulated industries. 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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