Overview

With increasing pressure on costs and margins across Life Sciences, the Industry must move away from tackling regulatory compliance with point solutions that address specific, individual regulatory challenges - point solutions that are not integrated and do not provide consolidated quality and compliance management across the entire organization.

The QUMAS Compliance Platform is a closed-loop compliance solution that combines all of the elements of a cohesive and comprehensive regulatory compliance program, on one platform. It delivers traditional capabilities around document and process management, but also presents these through a unified user interface, with just-in-time learning management, and consolidated reporting and dashboarding, all driving regulatory compliance and ultimately delivering better business performance.

Combined with regulatory domain expertise gained from providing closed-loop compliance solutions to regulated industries for almost two decades, the QUMAS Compliance Platform standardizes the entire range of enterprise compliance and governance components into a comprehensive framework that eliminates the cost of managing disparate and isolated applications (see Figure 1). With the QUMAS Compliance Platform, companies can:

- make informed compliance decisions
- accelerate delivery of new products
- achieve and prove regulatory compliance across the enterprise
- avoid costly system duplication and ongoing validation costs
- ensure consistency of information and processes
- quickly respond to new regulations and legislative demands without having to rethink the entire approach

Life Sciences companies recognize the criticality of having confidence in the information and products they produce. This requires certainty and assurance in people, processes and systems. Organizations need to be certain that the annual report, press release, drug, website and other branded deliverables reflect the company in a truthful and accurate way. In essence, they are looking for integrity, certainty, truth and guarantees. The QUMAS Compliance Platform incorporates the controls, audit trails, permissions and structures to provide certainty that:

- Each piece of information is delivered to the right people
- All incidents are logged
- All information and issues are
  - Reviewed or investigated on a timely basis
  - Approved and signed off by the relevant managers
  - Certified read and understood by the appropriate audience
  - Have fully compliant and meaningful electronic signatures
- All data is ultimately defensible against ongoing scrutiny, both internal and external

Figure 1: QUMAS Closed-Loop Compliance
The QUMAS Compliance Platform offers unique best practice compliance configurations, to provide a seamless combination of best practices for addressing specific business requirements. These configurations include, but are not limited to:

**Core Capabilities Snapshot**

- 21 CFR Part 11 compliance for electronic signatures (native capability, not third party integrated capability) and audit trail
- Full lifecycle state management, controlling documents through their lifecycle of create, review, edit, approve, release and distribute
- Controlled content creation based on configurable document templates with workflow automation, auto-naming and metadata support.
- Full traceability and accountability – including who viewed, reviewed and approved documents, key decision points and sign-off on compliance processes
- PDF renditions, including watermarking and overlays, providing permissions-based access to relevant formats of content for viewing and printing
- Electronic forms for automation and processing of regulatory events such as CAPAs and Deviations
- Configurable Segregation of Duties to ensure that only the appropriate users can access certain information and carry out particular compliance tasks
- Compliance Process Visualizations ensure end-users can fully leverage best-practice compliance configuration
- Automated Notifications via Microsoft Outlook, as well as in the Task List, to ensure critical tasks are addressed in real time
- Architected and Designed for large-scale, enterprise-level usage

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**Figure 2: QUMAS Compliance Platform**
Key Components

There are a number of key components within the QUMAS Compliance Platform, each providing proven functionality in traditional regulatory compliance categories:

Compliance Management
Built in compliance management for all components, supporting the most stringent requirements such as 21 CFR Part 11; 210; 820; 600, ISO standards (9000; 14000) & GxP practice, which include:

• A comprehensive, independent audit trail (auditing over 300 events throughout the system) allows users to complete point-in-time reporting for the purposes of regulatory audits and investigations, returning the appropriate information to the investigator in an efficient manner
• A complete electronic signature manifestation displays all electronic signature components including printed name of signer, time/date stamp and meaning of signature (see Figure 3)
• Role based electronic signatures in which the Meaning of Signatures is synonymous with user role to ensure electronic endorsements match user intent

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. This includes:

• Document templates (mandatory or elective)
• Collaborative authoring and review
• Automated workflow for content based on 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 QUMAS DocCompliance datasheet.

Figure 3: Electronic Signature with Meaning of Signature
Process and 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.

- 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
- Advanced and configurable reporting

The QUMAS Compliance Platform can be used to manage a wide variety of processes, that include but are not limited to:

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

For more information on process and workflow management, please refer to the QUMAS ProcessCompliance datasheet.

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 SCORM compliant content can be launched and tracked within the application, all dramatically reducing the time needed to create and deliver critical training.

- Online Courses, Classroom/Instructor-Led Training, External Learning Events
- Learner, Instructor, Supervisor, Administrator roles
- Highly Flexible Assessment Module for exams, surveys, and competency testing
- Recording of External Training, Attendance Lists, Results and so on
- Certificate Support and Recording
- Learning Catalog, with support for Self-Registration
- Controlled Content, PDF, Word, SCORM, AICC, and so on, with bulk load capabilities
- In-Built Reporting Module with Default Reports and Configurable Reporting

For more information on e-learning and learning management, please refer to the QUMAS ComplianceLMS datasheet.

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

- Graphical compliance dashboard providing oversight across business areas and compliance projects
- Tailored company-specific view of compliance: analyze by your organizational taxonomy - product, category, location, etc.
- Drill-down to actionable compliance data for investigation, remediation and planning of proactive compliance initiatives based on real-time data
- Secure, role-based access to your dashboard from a web-browser, providing 24/7 access to your critical compliance data
- Simple to create custom reporting provides specific views across your organization, as well as out-of-the box reports

For more information on reporting and business intelligence, please refer to the QUMAS ComplianceUnity datasheet.
A Single Point of Access to Your Compliance Content

All of these core compliance capabilities are accessed in one, user-friendly interface: MyQUMAS 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 management initiatives, uniquely combining views and tasks related to documents, processes, training and reporting in a single view.

MyQUMAS 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

For more information on MyQUMAS, please refer to the MyQUMAS datasheet.

Figure 4. MyQUMAS Homepage, combining documents, processes, training and reporting in one view.
Implementing a compliance platform helps to reduce complexity while improving the effectiveness of the overall solution. By putting your compliance program on one platform, you can provide consistent direction across the organization and improve overall business performance. Compared to implementing separate solutions, the QUMAS Compliance Platform helps to dramatically lower your TCO, as well as your validation and implementation efforts.

Tieme Stoutjesdijk, Information Services Manager, Synthon BV
QUMAS Compliance Platform Features

- Configurability
- Extendibility
- Secure Collaboration
- Innovative UI
- Enterprise Scalability
- Lowering TCO

About QUMAS

QUMAS is the leader in Enterprise Compliance Management with more than 250 global customer deployments and 20 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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