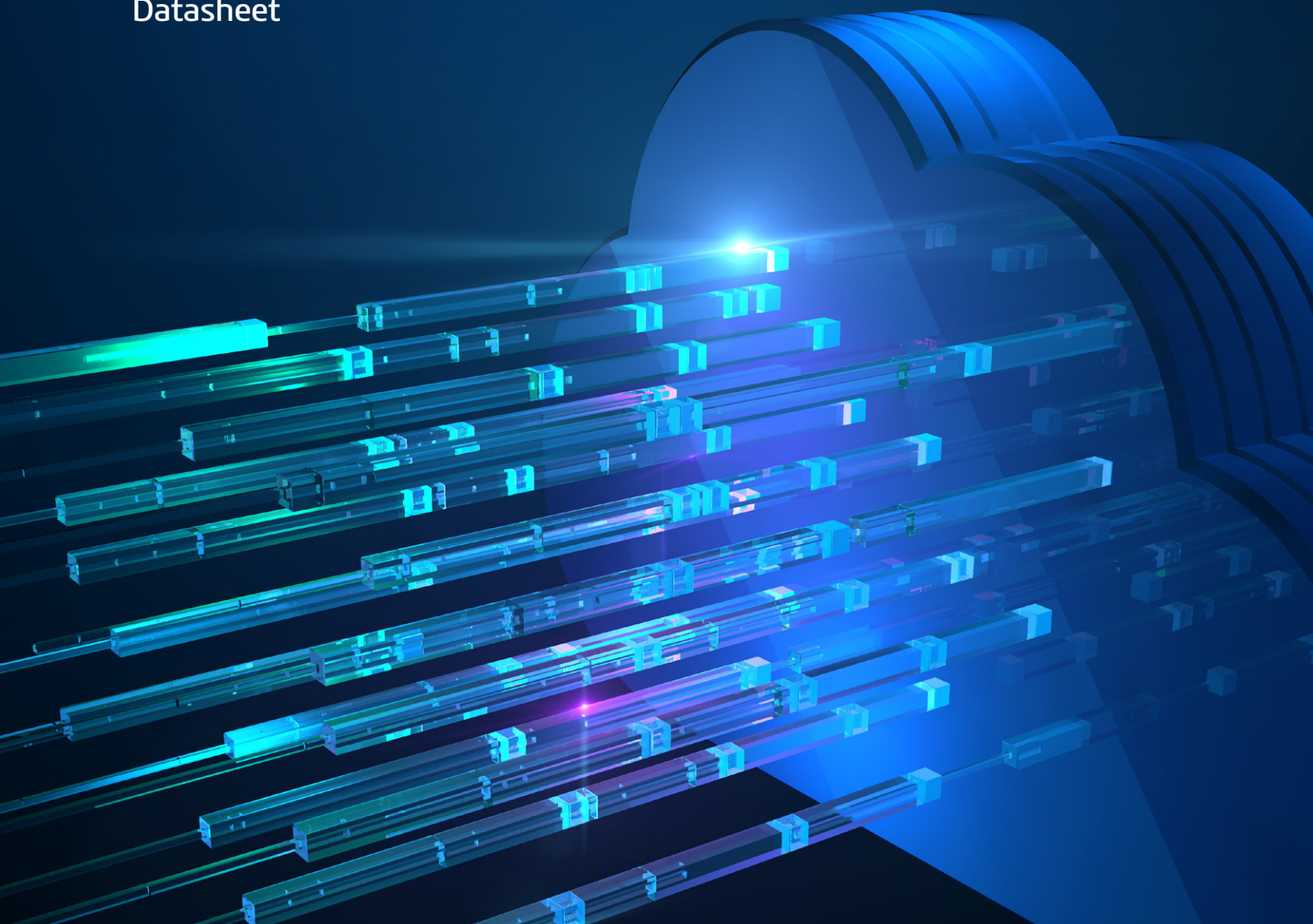
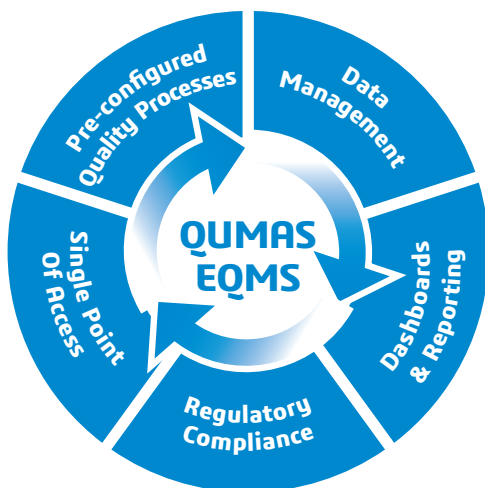




# **QUMAS EQMS** **ENTERPRISE QUALITY** **MANAGEMENT SYSTEM**

Datasheet





## OVERVIEW

With increasing pressure on costs and time to market across Life Sciences and other regulated industries, organizations must move away from point solutions that only address specific regulatory challenges – and move towards a solution that offers a consolidated, integrated approach to quality and compliance management.

QUMAS EQMS provides companies with a comprehensive integrated cloud-based solution that combines all of the elements required for a complete, closed-loop Enterprise Quality Management-System (EQMS). The solution enables organizations to drive and cycle times enabling users to get accurate information and make the right decisions quickly. The configurable solution provides an integrated environment to manage all quality activities. Advanced capabilities enable data and information from other systems to be synchronized with the EQMS. QUMAS EQMS 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
- Tasks, reports and any associated information are delivered to the right people

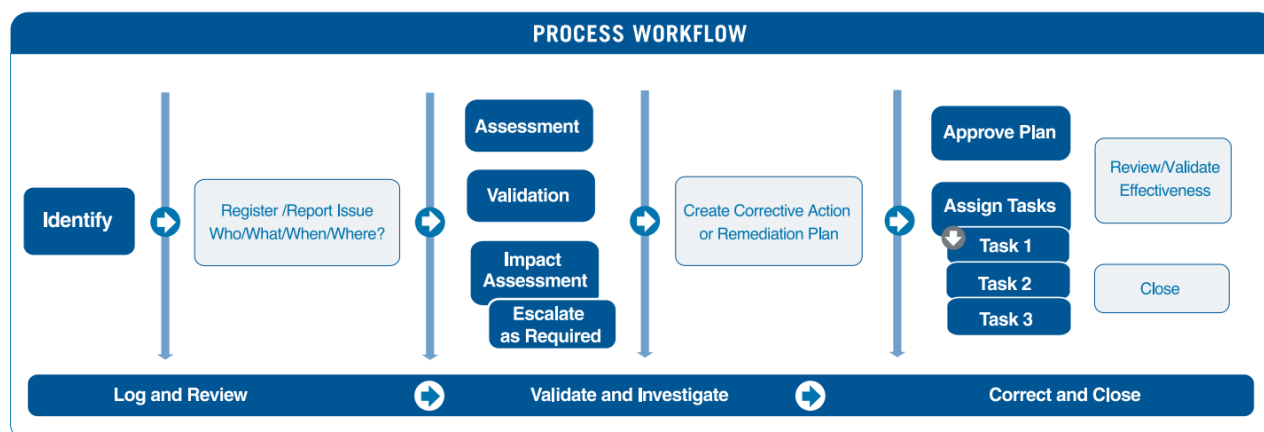
- All investigations and analysis are reviewed and investigated on a timely basis
- All CAPAs and Change Controls are approved and signed off by the relevant managers with fully compliant electronic signatures
- Tasks are assigned to the appropriate people to remedy incidents and complete actions
- Reviews are conducted to validate the effectiveness of the action plan or remediation plan
- Once completion and effectiveness of the plan have been validated, the incident or issue is properly closed

## QUALITY PROCESSES

- QUMAS EQMS includes process management capabilities for the most common 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

QUMAS EQMS can be used to manage a wide variety of quality and enterprise processes, including but are not limited to:

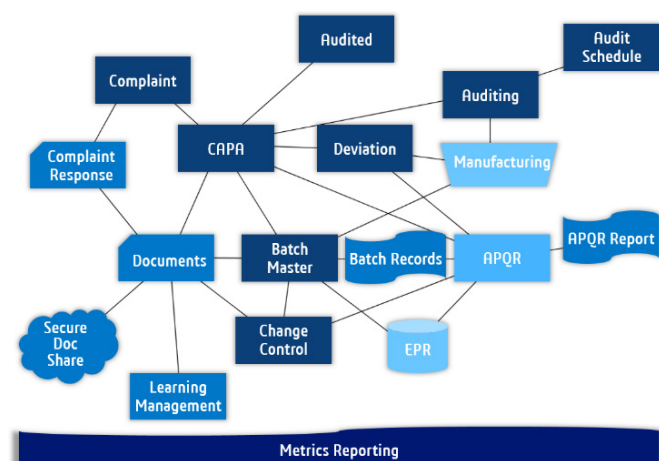
- Event Handling
- Planned and Unplanned Deviations
- CAPA
- Customer Complaints
- Audits (internal and external)
- Quality Check
- Out-of-Specification (OOS)
- Non-conformance



- Change Control
- IT Change Control
- Administration Processes
- Financial Processes
- Legal Processes
- Sales and Marketing Processes

## DATA MANAGEMENT

Quality processes don't exist in isolation, they are linked and the same data is used within different processes, e.g. Deviations and Audits are linked to CAPAs, CAPAs are linked to Change Controls.



Interdependency of quality processes showing the need for a data-centric approach for data-driven decision-making across the enterprise.

Only a data-centric EQMS, tightly integrated with an Electronic Document Management System (EDMS) that at the same time is equally data-centric allows organizations to leverage information across processes efficiently without duplication and errors. QUMAS EQMS integrates all processes minimizing transcription errors, consolidating information and minimizing repeat instances. Its data-centric approach allows users to flexibly manage quality content moving away from static documents. Users can now access and re-use all quality data gaining comprehensive visibility into Quality.

QUMAS EQMS provides interactive forms for recording deviations, corrective actions, change controls, etc. so that users can search, view, report, analyze and prioritize the quality related events and corrective actions.

## COMPLIANCE

QUMAS EQMS supports effective means for achieving quality goals, fast and effective corrective actions and minimizing adverse events. It provides a comprehensive framework to achieve sustainable compliance supporting the most stringent requirements such as:

- FDA 21 CFR Parts 11; 210; 820; 600
- ISO 9000 and 14000 Standards
- EU Annex 11
- cGxP Practices

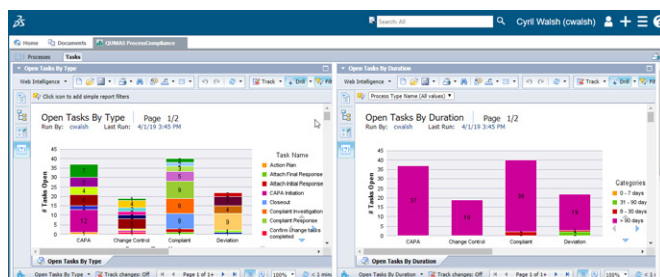
The QUMAS EQMS solution provides full support for Electronic Signatures as per FDA 21 CFR Part 11 requirements.

QUMAS EQMS configurations offer a Risk Analysis table supporting the ISPE GAMP model and Ichikawa based Root Cause Analysis.

## DASHBOARDS & REPORTS

An interactive quality dashboard provides oversight across business areas and quality initiatives. Dashboard reports are available for export, email and scheduling whenever comprehensive overviews are required. It enables Quality Managers to:

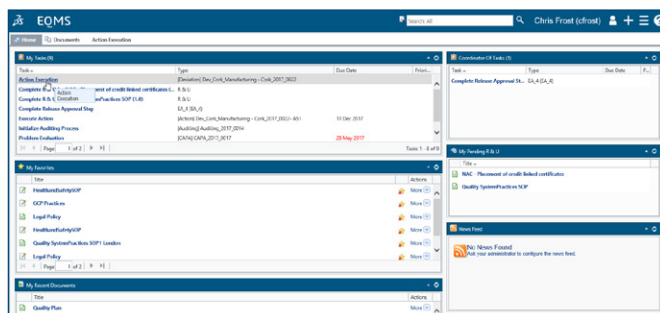
- Tailor an organization-specific view of compliance and quality metrics: analyzed by organizational taxonomy, product, category or location
- Drill-down to actionable quality information for investigation, remediation and planning of proactive compliance initiatives based on real-time data
- Securely access critical compliance and quality data at any time
- Create custom reports that provide specific views across the organization to monitor business objectives
- Develop print-friendly reports that can be delivered on to a configurable schedule



QUMAS EQMS offers a number of out-of-the-box reports and dashboards.

## A SINGLE POINT OF ACCESS

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.

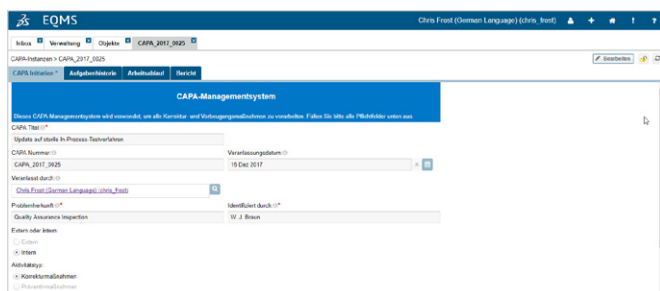


A consolidated interface provides users with a single point of access to manage all their quality -related tasks as well as access information like SOPs and Training Assignments.

## COLLABORATION

QUMAS EQMS enables organizations to collaborate securely with their partner ecosystem and supports compliance of Contract Manufacturing Organizations. Organizations can exchange information securely and operate efficiently and compliantly in the supply chain, delivering easy oversight with cloud-based content.

QUMAS EQMS can be localized to support organizations that operate and collaborate globally.



QUMAS EQMS can be localized to any language.

## COMMON PRACTICE CONFIGURATIONS

QUMAS EQMS offers out-of-the-box configurations for common processes such as Deviations and CAPAs including all the necessary documentation and validation to ensure a rapid deployment. The configurations draw from industry and regulatory guidelines (ISPE, DIA, FDA, ICH).

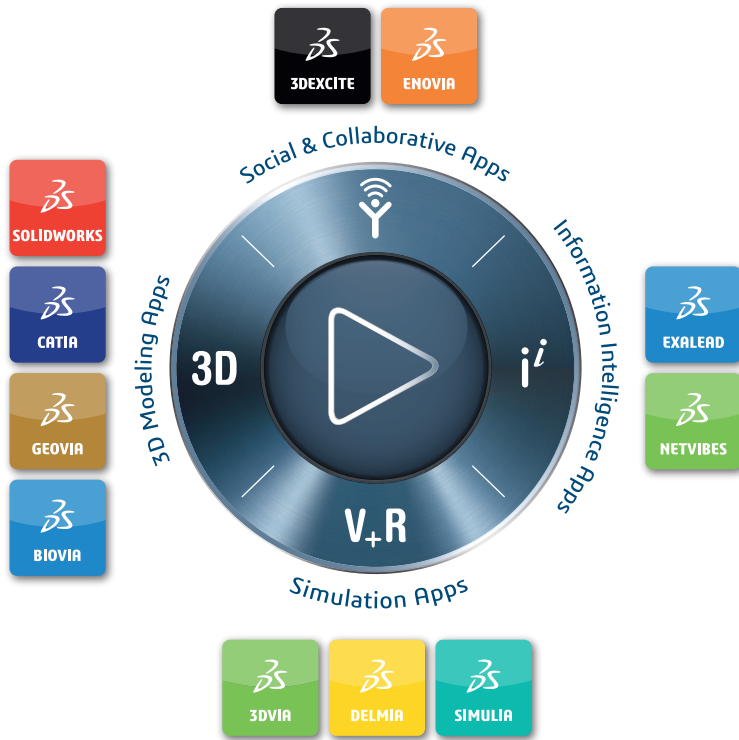


## BENEFITS OF QUMAS EQMS

With QUMAS EQMS companies are able to:

- Minimise non-value-added tasks like manual process tracking, and implement 'Effectiveness Reviews' as part of the CAPA process.
- Standardize and automate regulatory and quality processes, while ensuring all incidents are logged, investigated, and remediated in an accountable and consistent way that drives efficiency and accuracy across all quality functions.
- Ensure regulatory compliance with Electronic Signature functionality (21 CFR Part 11) that is built in, enhancing the value of this regulatory-required capability.
- Reduce the costs of compliance and quality management by ensuring that the information users require is accessible to them through an intuitive user interface, reducing training overheads.
- Expedite regulatory compliance management activities with out-of-the-box common industry practices for quality processes.
  - Simplified end-user experience and training
  - Consistent management of quality workflows
  - Improved productivity and reduced risk of user error
  - Reduced internal support demands and requirements
- 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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