BIOVIA

3DEXPERIENCE®

QUMAS
INTEGRATED CLOUD-BASED QUALITY AND REGULATORY COMPLIANCE MANAGEMENT

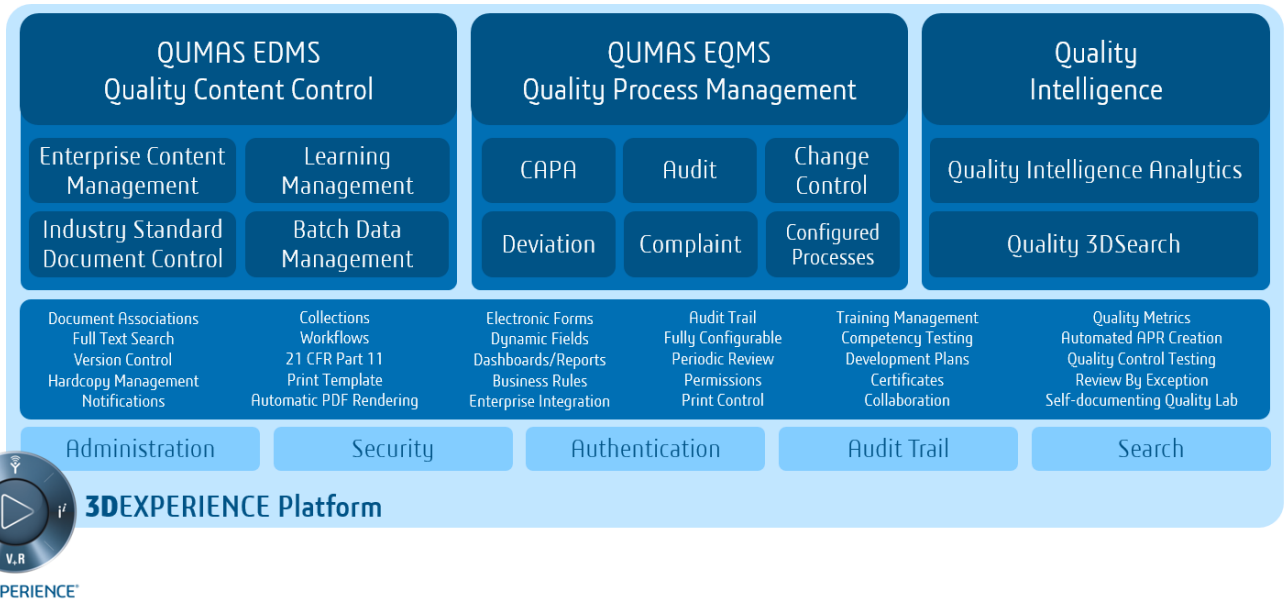
Datasheet

A Quality Management System is the core of any Quality strategy of organizations. It helps organize and document all quality efforts to ensure systems, processes, and products are of utmost quality and meet all regulatory compliance mandates. Quality Systems are relevant to any regulated industry such as Life Science, Consumer Packaged Goods, and Aerospace. Quality is often perceived as a costly burden and compliance is considered as non-value adding. However, compliance and Quality can both be achieved at the same time in a cost effective way. An integrated, easy to use and easy to manage Quality System contains costs and efforts of compliance and results in more efficient and higher quality products and processes.

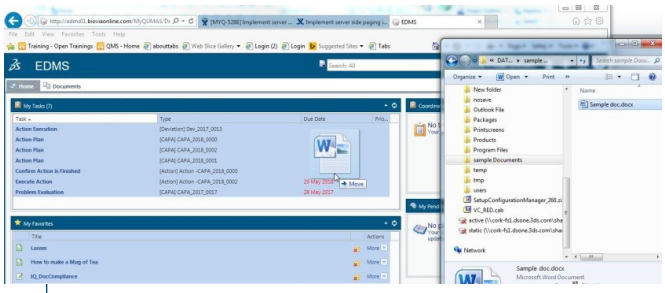
QUMAS, Dassault Systèmes' integrated cloud-based solution for managing quality documentation and processes provides customers with the confidence of a proven comprehensive solution, designed for heavily regulated industries with a modern and agile deployment approach. It connects quality processes, document control, learning management and quality data search and analytics in a single solution and allows connecting to other Quality relevant applications from BIOVIA such as laboratory informatics (BIOVIA ONE Quality Lab) and manufacturing intelligence (BIOVIA Discoverant) as well as to 3rd party applications.

The QUMAS portfolio consists of QUMAS EDMS for Quality Document and Content Management and QUMAS EQMS for Quality Process Management. This integrated solution allows organizations to automate quality processes and manage quality processes across all stakeholders, ensure data integrity, reduce compliance risks and to achieve Quality Excellence. In contrast to traditional document-centric solutions with static unstructured reports and documents, QUMAS is a data-centric solution that allows for easy access to documents as well as data to support typical business use as well as to support audits and investigations. Additional capabilities for Quality Intelligence allow easier and faster GMP-decision making.

DASSAULT SYSTEMES

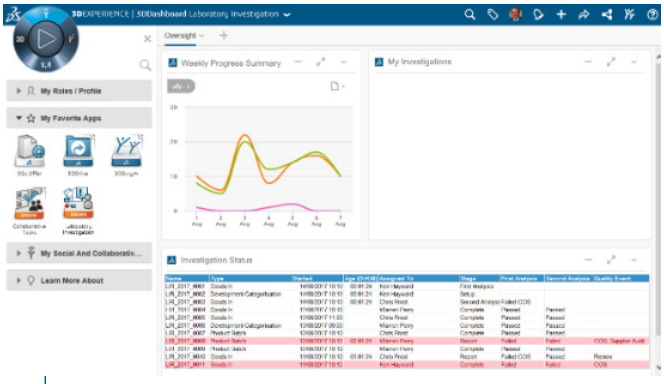


QUMAS solutions are specifically developed for the highly regulated Life Science industry. It provides full security controls and compliance with the US Food & Drug Administration (FDA) 21 CFR Part 11 including Electronic Signatures and Audit Trail and can adapt to any regulatory demand. Its inspection-readiness helps organizations to run smooth inspections and to reduce overall audit times. The modern and intuitive user interface makes user adoption easy and fast. Drag and drop of content like Word documents onto the user interface simplifies Standard Operating Procedure (SOP) creation and reviews. QUMAS Cloud minimizes Total Cost of Ownership (TCO). The system's scalability makes it possible to adapt the solution from small to large enterprise deployments.



Drag and drop for simplified document creation: Content like Word documents can be dropped onto the user interface. The system recognizes if it is an update of an existing document and checks it in accordingly. If it is a new document the Document Creation Wizard appears with auto populated attributes in place allowing for the addition of extended attributes.

The QUMAS portfolio also leverages Quality Intelligence capabilities based on the Dassault Systèmes 3DEXPERIENCE platform. Quality Intelligence provides dedicated search and analytics capabilities for Quality content. This facilitates true end-to-end control and visibility while at the same time providing data integrity and a Single Source of Truth for all Quality data and content. This comprehensive and pro-active approach to Quality is well inline with the FDA's request that organizations move from mere compliance to a Culture of Quality.



Oversee the documents and quality processes being run, generate analytic reports, use pre-defined dashboards or generate new dashboard designs to support organizational requirements

Customers reported:

- 80% reduction of approval times
- 40% time improvement for First-to-File, First-to-Market and Chemistry, Manufacturing and Control (CMC) approval
- 30% cycle time reduction for documentation

QUMAS provides organizations with the most comprehensive solutions of key quality capabilities:

- **QUMAS** is an integrated cloud-based solution for quality management and document control providing a single source of truth.
- **QUMAS** includes an integrated Learning Management System. This enables customers to leverage GxP training related compliance content and documents to assign, track, and manage their corporate as well as GxP training compliance requirements.
- **QUMAS** provides integrated Search and Analytics for your Quality data delivering Quality intelligence for easier and better decision making.

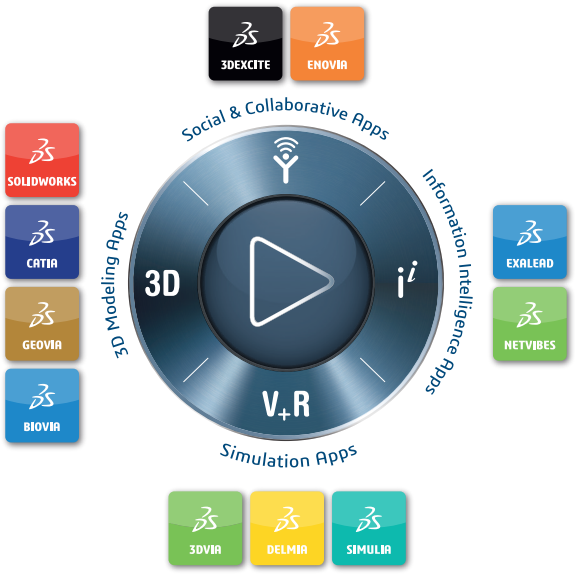
QUMAS is designed and engineered to support compliance, lower the total cost of quality, and deliver true business value:

- **Compliance:**
  Achieve data integrity with electronic signatures and immutable audit trails
- **Single-source-of-Truth:**
  Leverage a single data repository to easily track, monitor, trend and report on quality performance information
- **Reduced inspection time and downtime:**
  Provide immediate access to data and documents with drill down and interactive hyperlinks
- **Efficiency:**
  Automate tasks and standardize controlled processes
- **Deviation tracking:**

  Track actual performance against SOPs, identify deviations and manage related information in a single system
- **Change Control and CAPA:**
  Manage CAPA investigations and conduct root-cause analysis to get accurate information and quickly make correct decisions
- **Low Cost-of-Ownership:**
  Easily configure and deploy the QUMAS cloud-based solution without a heavy IT footprinvt
- **Productivity:**
  Automate and streamline processes for SOP changes and retraining and for regulatory submissions
- **Overview and control:**
  Tailor analytics and dashboards to gain meaningful insights into quality data for impactful decision making
- **Shorter Time-to-Market:**
  Accelerate approval cycles and reduce rework/recall rates
- **Culture of Quality:**
  Adopt a comprehensive, data-centric approach to Quality

Our **3D**EXPERIENCE® Platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3D**EXPERIENCE® Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 210,000 customers of all sizes in all industries in more than 140 countries. For more information, visit **www.3ds.com**.



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