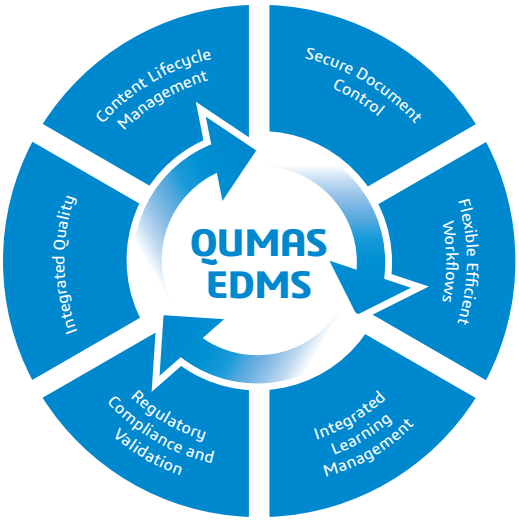
BIOVIA

3DEXPERIENCE®

QUMAS EDMS
ENTERPRISE DOCUMENT MANAGEMENT SYSTEM

Datasheet

DASSAULT SYSTEMES



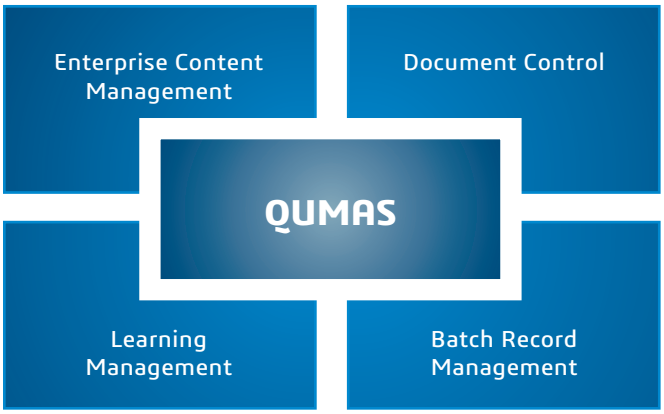
Dassault Systèmes has been developing and delivering best- in-class Electronic Document Management Systems (EDMS) to life sciences firms since 1994. With more than 300 global customer deployments, QUMAS EDMS is a proven and comprehensive cloud-based Content and Document Management solution that ensures that GxP content is being managed in a consistent and compliant manner throughout the organization.

QUMAS EDMS enables organizations to create, manage, and securely store documents, using built in password policies to protect against unauthorized access. The cloud-based off-the-shelf solution contains full support for Electronic Signatures as per 21 CFR Part 11 requirements. Best practice document management workflows ensure that the correct content is created, reviewed, approved, consumed, distributed and retired. It encourages optimal content management through built-in best practices. Flexible configuration enables you to easily mirror your existing organizational structures and practices. All of the rich functionality of QUMAS EDMS is accessed through an intuitive user-friendly interface.

QUMAS' data-centric approach allows organizations to re-use and truly leverage their quality data. Users can easily access documents and data to support typical business use and to support audits and investigations.

KEY MODULES

QUMAS EDMS consists of modules that provide a comprehensive solution for managing regulatory content, Enterprise Content Management, Document Control, Learning Management and Batch Data Management

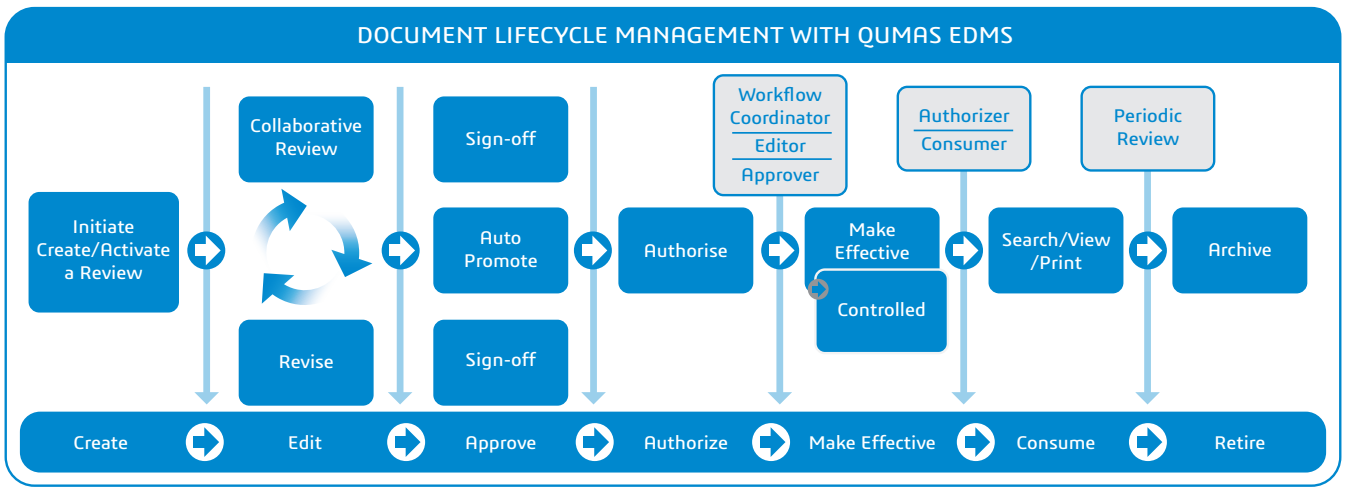


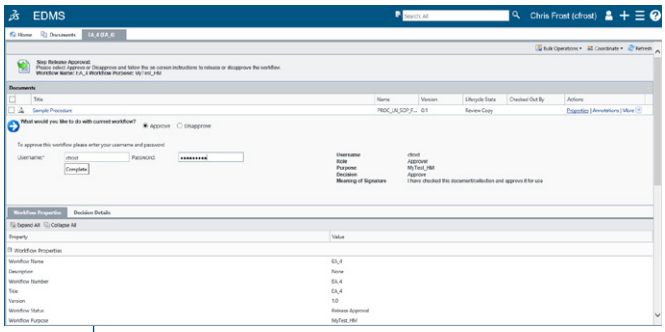
ENTERPRISE CONTENT MANAGEMENT

A key module of QUMAS EDMS is an intuitive end-to-end workflow engine. The workflow engine enables users to select the content for its initial creation either by template or desktop selection and upload it to QUMAS EDMS. Collaborative authoring and review is then completed by multiple authors / reviewers who can simultaneously comment and propose changes to the content in an efficient way.

On completion of the review, the content is routed forward to the approval step in the workflow where electronic signatures are applied in compliance with 21 CFR Part 11 guidelines.

Once the document is authorized and made effective it allows for the users, with the correct permissions to com- plete Read and Understood training, view, search and print the document for the duration of the lifecycle. A periodic review is typically conducted after a configurable period of time, to ensure content accuracy and validity. Ultimately when the document has reached its end of life, it is retired and removed from the view of the users.





Workflow: Flexible business process workflows allow users to easily map their unique business processes to the system without customization.

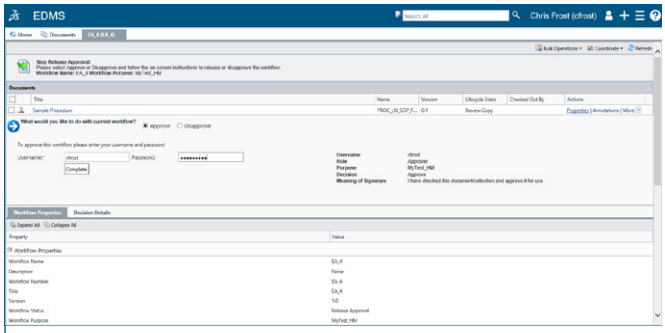
Key capabilities include.

- Collaborative authoring and review
- Automated workflow based on content type
- Advanced document lifecycle management
- Document comparison for ease of review
- Automated PDF rendering
- Automated version control
- Read and Understood notifications and training
- Controlled printing and watermarking
- Hardcopy management and destruction

DOCUMENT CONTROL

QUMAS EDMS allows easy authoring and management of Policies, Standard Operating Procedures (SOPs), work instructions and manuals as well as for eCTD, non-eCTD and Regulatory Submissions for Regulatory Affairs, CMC (Drug Product and Drug Substance), Clinical, Nonclinical, Quality and Manufacturing, Legal Documentation, Sales and Marketing Collateral, HR Policies and Reports including Annual Quality product Reviews (APQRs).

Its reporting module provides access to over 20 preconfigured reports providing business critical information in relation to compliance requirements.



Document Management: 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.

BATCH RECORD MANAGEMENT

QUMAS makes the handling of large quantities of documents easy and efficient with dedicated capabilities:

QUMAS Enterprise Scanner

The automated scanning solution for converting paper archives to electronic documents stored in the EDMS Repository as well as for creating cover pages or printing batches of forms to be reconciled (and archived).

QUMAS Document Transfer

It provides an automated batch load of multiple documents from different originating applications through the definition of meta-data. Users can 'drag and drop' a set of files from the file system.

QUMAS Content Cache

The storage of a local cache of frequently used documents for widely dispersed global deployments allows for significant performance improvement.

LEARNING MANAGEMENT

Powered by our technology partner NetDimensions, the system provides a module for compliance training and management or launching, tracking and managing interactive corporate compliance training. Also eLearning modules, instructor led training, and QUMAS EDMS content can be easily browsed and converted into effective and measurable training. Industry standard SCORM compliant content can also be launched and tracked within the application, dramatically reducing the time needed to create and deliver critical training. Support is included for:

- Online Courses, Classroom/Instructor-Led Training, External Learning Events
- Learner, Instructor, Supervisor, Administrator roles
- Exams, surveys, and competency testing
- Recording of External Training, Attendance Lists, and Results
- Certificates
- Self-Registration
- Controlled Content, PDF, Word, SCORM, AICC with bulk load capabilities
- Default Reports
- Configurable Reporting

KEY CAPABILITIES

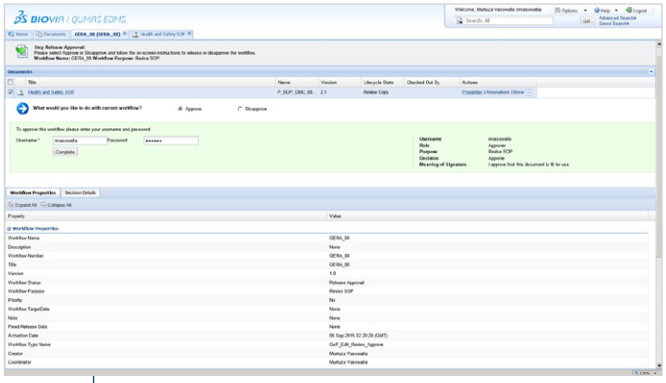
COMPLIANCE

QUMAS EDMS provides a comprehensive framework to achieve sustainable compliance supporting the most stringent requirements such as:

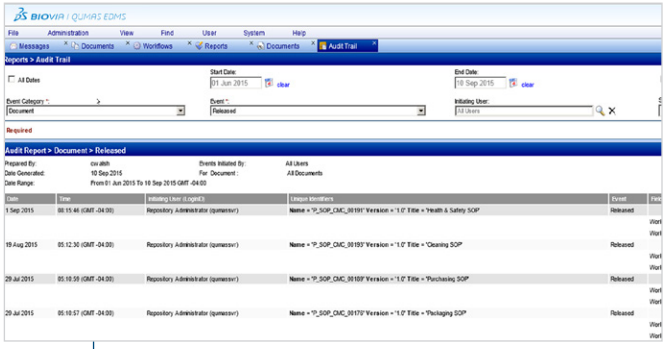
- 21 CFR Parts 11; 210; 820; 600
- ISO Standards (9000; 1400)
- EU Annex 11
- cGxP Practices

Key compliance features include:

- Automated version control
- Support for electronic signatures that demonstrates compliance to 21 CFR Part 11 guidelines
- Automated PDF Rendering
- Comprehensive and secure audit trail capturing over 270 auditable events
- Controlled printing and watermarking
- Hardcopy management and destruction
- Read and Understood notifications



Compliance: QUMAS EDMS provides full support for Electronic Signatures as per FDA 21 CFR Part 11 requirements.



Control: Business users can create audit trail reports that detail which versions of policies and procedures were released on a particular date, or between particular dates (point-in-time).

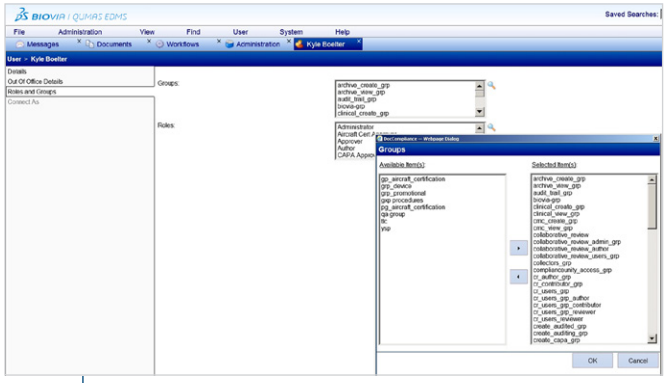
SEARCH AND RETRIEVAL

The QUMAS EDMS advanced search and retrieval module allows the user to generate searches on documents and workflows. The searches can be filtered on key criteria such as: core system attributes, document title, name, author, creation date etc., but also client specific attributes. These can be searched against to further filter the data, for example, product name, disposition, supplier, dosage, etc.

The advanced search module ensures that the user is presented with the current version of the document in an efficient manner from one centrally located database. The search results can be exported, printed and distributed as required.

ADMINISTRATION

The built-in system administration allows administrators to manage users, group and role profiles in conjunction with the core components such as document types and workflow types. The use of groups and roles ensures that best practice security parameters are in place, and that users have access to only the data and functions of the system that they have permissions over. Configuration wizards allow for easy administration of the system to scale as the organization grows over time.



Administration: Access and security profiles can easily be established for each u user, group and role.

VALIDATION PACKAGES

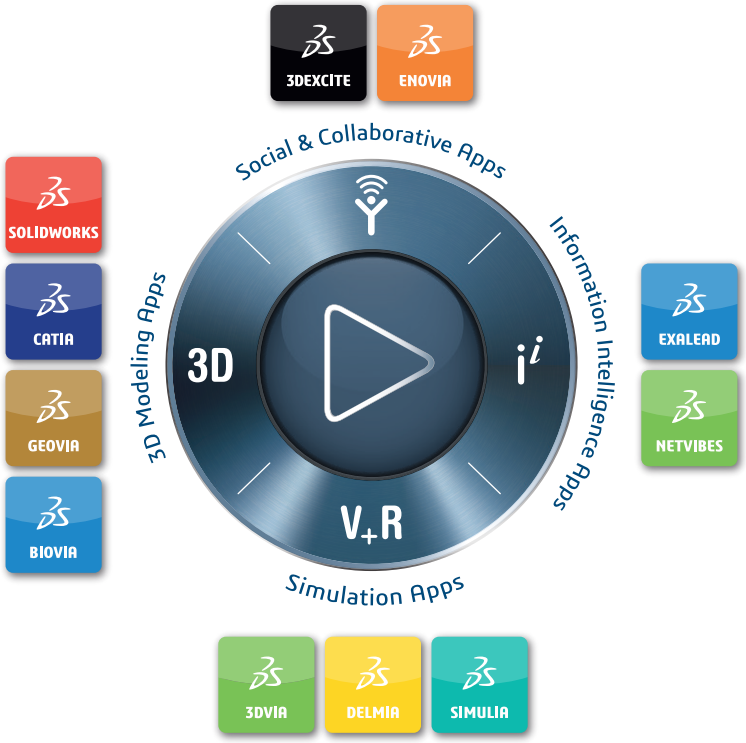
We provide several off-the-shelf packaged solutions for QUMAS EDMS that adhere to the GAMP (Good Automated Manufacturing Practice) guidelines and ISO standards. These pre-packaged solutions are validation ready. Each package comes with a complete project plan and all the required documentation and test scripts to enable you to get up and running quickly with a fully validated solution. If required, our experienced Professional Services team can assist you through the entire validation process.

INTEGRATED QUALITY

QUMAS EDMS can be leveraged as a standalone Quality Document Management solution as well as part of a closed-loop approach with Quality Process Management (QUMAS EQMS) Learning Management (LMS) and Quality Intelligence for advanced usage of your quality data. For an even more comprehensive Quality strategy BIOVIA provides integration with more Quality relevant capabilities such as for the laboratory (BIOVIA ONE Lab) and Quality Metrics (BIOVIA Discoverant).

To learn more please visit:

www.3DSbiovia.com



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