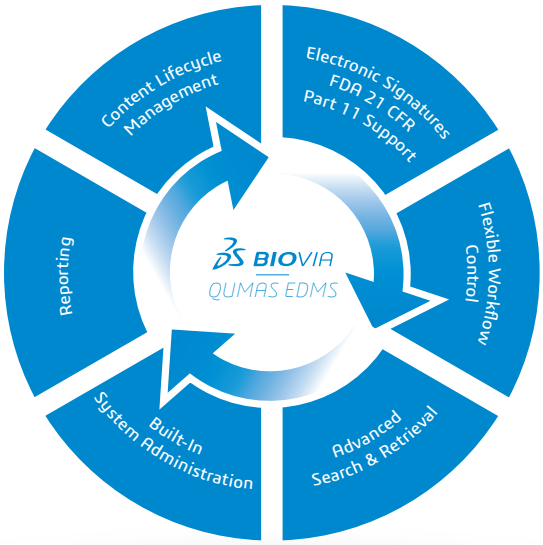
BIOVIA QUMAS EDMS

ROBUST REGULATORY CONTENT MANAGEMENT

DATASHEET



BIOVIA QUMAS 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, BIOVIA QUMAS EDMS is a proven and comprehensive solution that ensures that regulatory content is being managed in a consistent and compliant manner throughout the organization.

BIOVIA QUMAS EDMS enables organizations to create, manage, and securely store documents, using built in password policies to protect against unauthorized access. The off-the-shelf solution contains full support for Electronic Signatures as per FDA 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 optimum 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 BIOVIA QUMAS EDMS is accessed through the BIOVIA QUMAS Portal, an intuitive user-friendly interface.

BIOVIA QUMAS EDMS can be used to manage a wide variety of controlled content, including: Policies, Procedures, Standard Operating Procedures (SOPs), Work Instructions, R&D Documentation (Clinical, Regulatory, Manufacturing), Legal Documentation, Sales and Marketing Collateral, HR Policies and Reports including CIAs.

COMPLIANCE FRAMEWORK

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

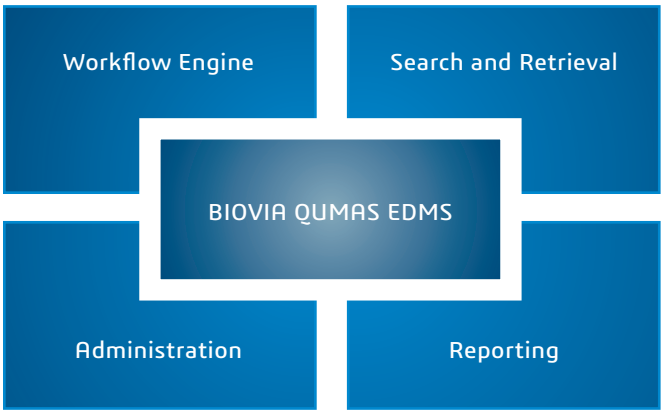
- FDA 21 CFR Parts 11; 210; 820; 600
- ISO Standards (9000; 1400)
- Annex 11
- GxP Practices

Key Compliance Features Include:

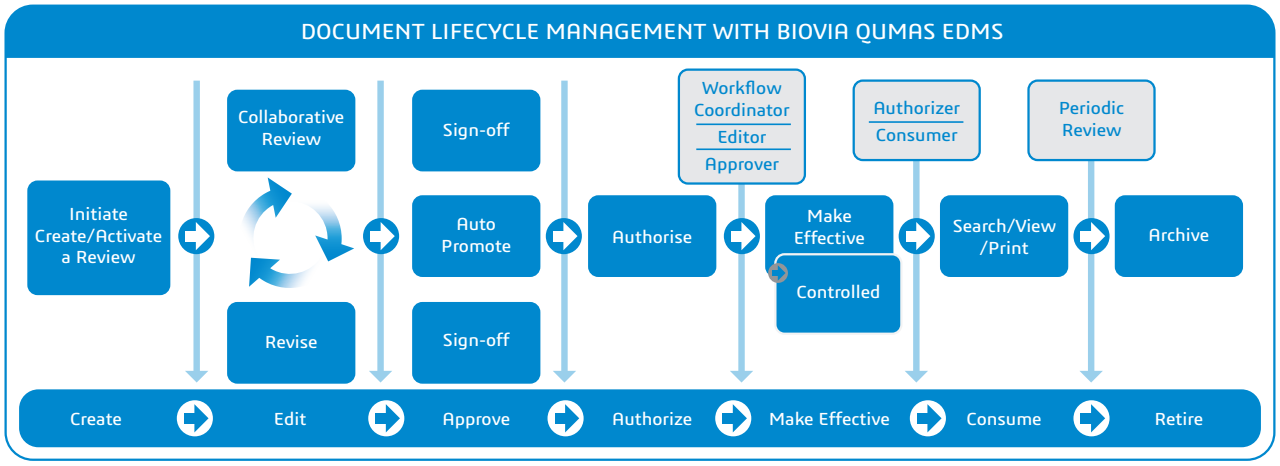
- Automated version control
- Support for electronic signatures that demonstrates compliance to 21 CFR Part 11 guidelines
- Automated PDF Rendering
- Comprehensive and secure audit trail capturing over 270 auditable events
- Controlled printing and watermarking
- Hardcopy management and destruction
-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

KEY MODULES

BIOVIA QUMAS EDMS consists of 4 tightly integrated modules that provide a comprehensive solution for managing regulatory content. The 4 modules are depicted in the diagram below.



FLEXIBLE WORKFLOW CONTROL



A key module of BIOVIA QUMAS EDMS is an intuitive end-to-end workflow engine. The workflow engine enables users to take the content from its initial creation either by template or desktop selection and upload it to BIOVIA QUMAS EDMS. Collaborative authoring and review is then completed whereby multiple Authors/Reviewers can simultaneously comment and propose changes to the content in an efficient fashion.

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

Once the document is authorized and made effective it allows for the consumer users, with the correct permissions to complete 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 consumer users.

ADVANCED SEARCH AND RETRIEVAL

The BIOVIA 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 in addition client specific attributes 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.

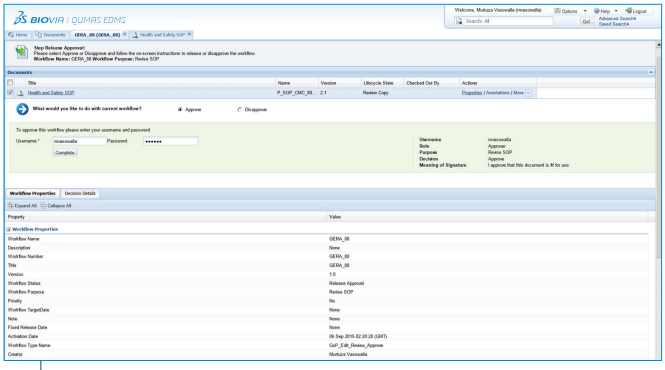
BUILT-IN SYSTEM ADMINISTRATION

The BIOVIA QUMAS EDMS administration module 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 components 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.

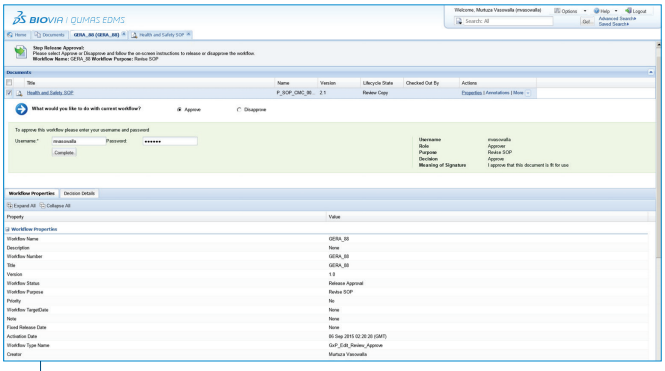
REPORTING

The BIOVIA QUMAS EDMS reporting module provides the user with access to over 20 preconfigured reports providing them with business critical information in relation to their compliance needs.

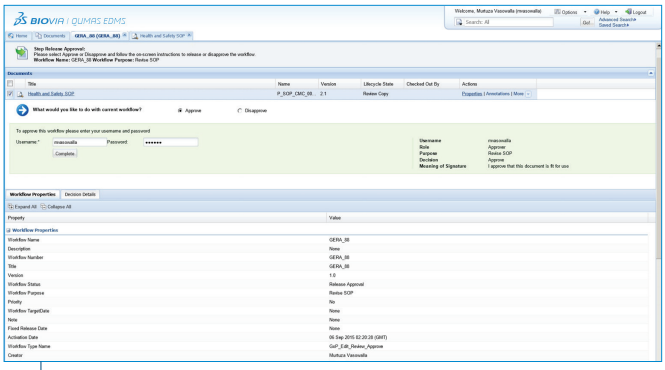
KEY CAPABILITIES



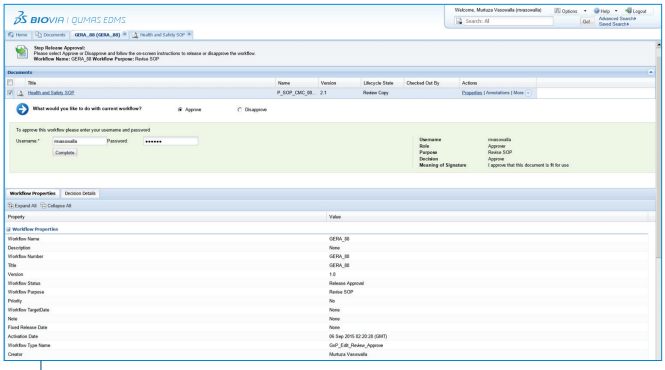
BIOVIA QUMAS EDMS provides full support for Electronic Signatures as per FDA 21 CFR Part 11 requirements.



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



Access and security profiles can be established for each user.



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

OFF-THE-SHELF VALIDATION READY SOFTWARE SOLUTIONS

We have developed several off-the-shelf packaged solutions built around BIOVIA 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 support team can even assist you through the entire validation process.

BIOVIA QUMAS EDMS PACKAGED SOLUTIONS

Insert diagram with just R&D Submission Documents and Quality Assurance Documents rectangles.

ABOUT BIOVIA

BIOVIA from Dassault Systèmes provides a scientific collaborative environment for advanced biological, chemical and materials experiences. The sophisticated enterprise system of modeling, simulation, laboratory, and quality management enables innovation for science-based industries. For Regulatory, Quality, and Compliance Management, BIOVIA QUMAS provides an integrated solution for all quality process and content activities from lab to commercialization, maintaining regulatory compliance with global mandates.

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

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Dassault Systèmes
175 Wyman Street
Waltham, Massachusetts
02451-1223
USA

BIOVIA Corporate Americas
BIOVIA
5005 Wateridge Vista Drive,
San Diego, CA
92121
USA

BIOVIA Corporate Europe
BIOVIA
334 Cambridge Science Park,
Cambridge CB4 0WN
England