DASSAULT SYSTEMES

BIOVIA

BIOVIA QUMAS EDMS™

ROBUST REGULATORY CONTENT MANAGEMENT

DATASHEET

OVERVIEW

BIOVIA QUMAS EDMS is an off-the-shelf, web-based regulatory content management system that ensures enterprise-wide consistency and compliance. The solution enables organizations to create, manage, and securely store documents, using built in password policies to protect against unauthorized access. It 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, and the intuitive user-interface ensures ease-of-use for all end users. BIOVIA QUMAS EDMS can be used in conjunction with BIOVIA QUMAS PORTAL to provide access to flexible business process management, learning management, business intelligence and content collaboration.

KEY FUNCTIONALITY

BIOVIA QUMAS EDMS consists of the following main elements:

- Content Management and Advanced Search and Retrieval
- Flexible Process Control and Configurable Reports
- Built-in System Administration
- Secure Audit Trail
- Automated Version Control
- Automated PDF Rendering

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

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

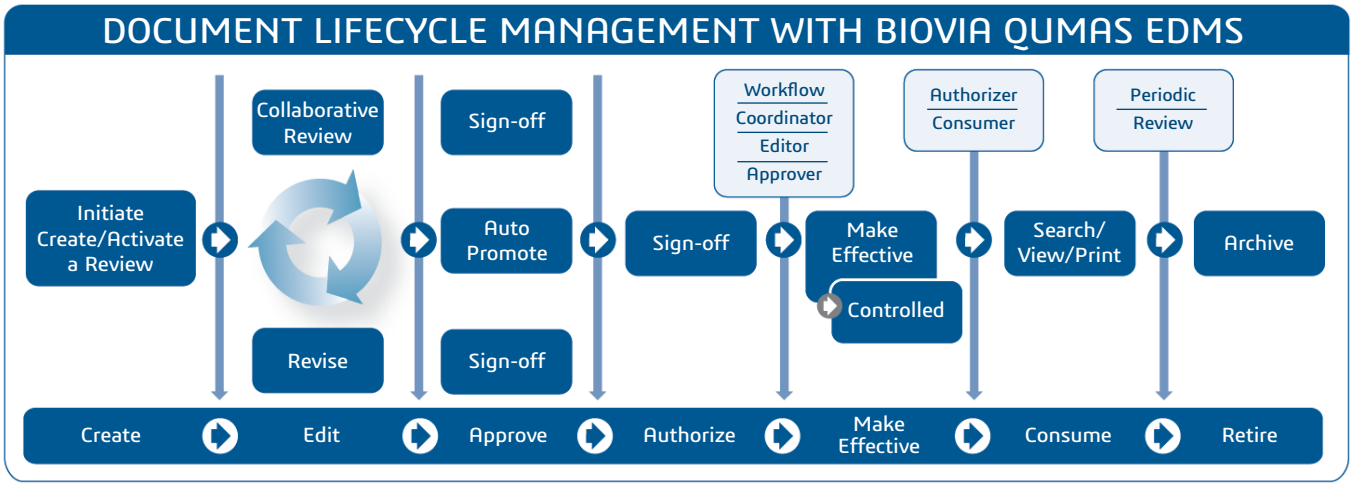
- FDA 21 CFR Parts 11; 210; 820; 600
- ISO standards (9001; 2008)
- GxP practices

A comprehensive audit trail 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.

Closed-Loop Compliance

Product Compliance

Features	Benefits
Complete Electronic Signature Manifestation	Displays all electronic signature components including printed name of signer, time/date stamp and meaning of signature.
FDA 21 CFR Part 11	All approved documents include an electronic signature which demonstrates compliance to 21 CFR Part 11 guidelines.
Role-based Electronic Signatures	Meaning of signatures is synonymous with user role to ensure electronic endorsements match user intent.
Comprehensive, Independent Audit Trail	Independent, secure audit trail capturing 270+ auditable events.
Hardcopy Management	Reports on sensitive documents that need to be destroyed or returned and confirms by electronic signature when the document is actually destroyed.
Automated Version Control	Removes the risk of users accessing outdated versions of documents.
Read & Understood	Accountability throughout the organization by ensuring traceability.



The BIOVIA QUMAS EDMS workflow engine is an intuitive end-to-end workflow solution. The process takes the content from its initial creation either by template or desktop selection and uploads 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 can be archived with retention period applied as per company policy. These documents are removed from the view of the consumer users.

Flexible Workflow Control

Features	Benefits
Workflow and Configuration Management	Flexible business process workflows allow users to easily map their unique business processes to the system without customization.
Flexible Workflow Processing	Enables efficient management of in-process workflows without complication or compromise of regulatory diligence.
Change Request Tracking	Tracks change requests in accordance with GxP and GAMP guidelines.
Controlled Printing and Watermarking	Effectively tracks and controls all printed and hardcopy documentation in accordance with regulatory guidelines.
User-Definable Change Dictionary	Enables users to easily categorize change request rationale for effective tracking and statistical monitoring.
User-Definable Retention Policies & Expiration	Helps users manage document policies in accordance with regulatory requirements.
Advanced Lifecycle Management	Accountability throughout the organization by ensuring traceability.

Flexible Workflow Control (continued)	
Features	**Benefits**
Automated Notification & Distribution	Enables effective distribution and rapid notification of document changes and approvals.
Formal and Informal Review Process	Allows adaptable business processes based on formal or informal workflow policies.
Cooperative Review	Allows one or more users to approve/disapprove on behalf of a group.
Read and Understood	Enables users to mark information as Read & Understood, and to define distribution and notification lists.
Collaborative Authoring & Reviewing	Allows multiple users to comment on and edit the same document in 'real time' or asynchronously reducing review times and review cycles.
Document Comparison	Full document comparison, enabling users to identify changes between versions of documents.

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 then be exported and printed to be distributed as required.

Advanced Search and Retrieval	
Features	**Benefits**
User-Definable Saved Searches	Facilitates the reuse of user-defined searches to improve efficiency and consistency.
Public and Private Searches	Promotes consistency and security across the organization through sharing of public searches and security for private searches.
Content and Attribute Searches	Enables enhanced regulatory intelligence through attribute and content searches.

BUILT-IN SYSTEM ADMINISTRATION

The BIOVIA QUMAS EDMS administration module allows administrators to manage users, group and roles 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 only have access to 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.

Built-In System Administration	
Features	**Benefits**
User Profile Manager	Establish access and security profile for each user, enabling access and control in compliance with current regulations.
Configurable Security Model	Requires minimal technical experience, facilitating easy deployment.
Multiple Roles/User Support	Enables the configuration of a user with one or more roles. Minimizes administration and configuration burdens.
Controlled Printing and Watermarking	Effectively tracks and controls all printed and hardcopy documentation in accordance with regulatory guidelines.
User-Configurable Parameters	All system administration parameters are configurable such a groups, roles, departments, etc. enabling easy adaptation to your production environment without customization.
User-Definable System Preferences	System preferences may be defined according to regulatory requirements or industry best practices i.e. password expiration.
Configurable Content Types	BIOVIA QUMAS EDMS can be used to manage any type of regulatory document. Each type of document is configurable or content that needs to be controlled
Built-in Best Practices	Promotes and drives the use of best practices to address GxP, 21 CFR Part 11, and other global regulations.
Out-of-Office Settings	Avoids system bottlenecks by allowing users to designate when they are out of the office and to specify role substitutes.
Easily Localized Interface	Easily adaptable to any local system environment.

REPORTING

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

Reporting	
Features	**Benefits**
Active Workflows Report	Delivers a comprehensive summary of all active workflows and controlled processes.
Comprehensive Audit Trail Report	Tracks over 270 auditable events delivering the most comprehensive support for this 21 CFR Part 11 requirement.
Point-in-Time Reporting	Allows business users to build reports on the fly, detailing which versions of policies and procedures were in effect on a particular date (point-in-time) or at the time of an adverse event (without the need for consultants or IT resources).
Table of Contents	Delivers a written taxonomy of your regulatory compliance portal at a glance.
Document Details Report	Summarizes the complete revision history of any document within the system to ensure compliance.
Controlled Copy List	Facilitates efficient hard copy management.
Out–of-Office Report	Delivers an overview of all users that have activated their Out-of-Office settings.
Security Violations Report	Convenient summary report that helps administrators to track security issues.
Read and Understood Report	Delivers a detailed list of all Read and Understood signatures by document or by user.
Permissions Reports	Enables system administrators to capture at-a-glance all group, user and object permissions to maintain security and access requirements.
Integration with SAP BusinessObjects Enterprise	Extensive reporting capabilities are provided through full integration with SAP BusinessObjects Enterprise.

* For configurable reports with analytical and graphical drill-down functionality please refer to the BIOVIA QUMAS Dashboard datasheet.

ABOUT BIOVIA

Dassault Systèmes Biovia Corp. (BIOVIA) provides global, collaborative product lifecycle experiences to transform scientific innovation. Powered by Dassault Systèmes' 3DEXPERIENCE® Platform, BIOVIA solutions create an unmatched scientific management environment that can help science-and process-driven companies create and connect biological, chemical, and material innovations to improve the way we live. The industry-leading BIOVIA portfolio integrates the diversity of science, experimental processes and information requirements across research, development, QA/QC and manufacturing. Capabilities include scientific data management; biological, chemical, and materials modeling and simulation; open collaborative discovery; scientific pipelining; enterprise laboratory management; enterprise quality management; environmental health and safety; and operations intelligence. BIOVIA solutions are used by more than 2,000 companies in the pharmaceutical, biotechnology, energy, chemicals, aerospace, consumer packaged goods and industrial products industries, as well as academic and government entities.

SYSTEM REQUIREMENTS

Platforms

- Available on Documentum 6.7, Oracle 10g, 11g R2 and ORA 12C, and Microsoft SQL Server 2005, 2008 and 2012

Third Party

- IIS 6, Office 2003, Office 2007, Office 2010, XP and Internet Explorer 7, 8 9,10 and 11, and bin 7 and 8; Acrobat Reader and Adobe Acrobat 9 or higher

Reporting

- Integrated with SAP BusinessObjects Enterprise XI v3.1

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Dassault Systèmes Corporate
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