BIOVIA QUMAS R&D SOLUTION™

SECURE, EFFICIENT CONTENT AND SUBMISSION LIFECYCLE MANAGEMENT

DATASHEET

R&D STRATEGY OUT OF THE BOX

In an industry shaped by ever-increasing regulation, global competition and market expectations, successful life sciences companies must bring new products to market faster than ever. Preparing for a drug application is a complex and timeconsuming process. Many organizations have insufficient systems for creating and approving responses, which can delay time to market for new drugs and tighten the profit window before patents expire.

Conventional submission management solutions are not enough – they lack the integration to unify document and submission management into one seamless lifecycle.

BIOVIA QUMAS - INTEGRATED SUBMISSION AND CONTENT MANAGEMENT

The **BIOVIA QUMAS R&D Solution™** addresses this gap by linking document creation using content-rich Microsoft Word authoring templates to content gathering;tracking; and submissions compilation for an efficient one-stop shop for submission lifecycle management.

By combining content authoring; content management; real-time collaboration and submission management; we provide one, integrated solution for all functional R&D areas. **This solution includes but, is not limited to, Regulatory Affairs, Clinical, Non-clinical, and Quality. The solution is all inclusive – there is no sourcing, customization or additional integration required to immediately take advantage of a complete R&D strategy out of the box.** And with a full integrated QMS package available for your QA and manufacturing departments, BIOVIA QUMAS solutions can span the enterprise with one consistent platform.

OFF-THE-SHELF REGULATORY CONTENT MANAGEMENT SYSTEM

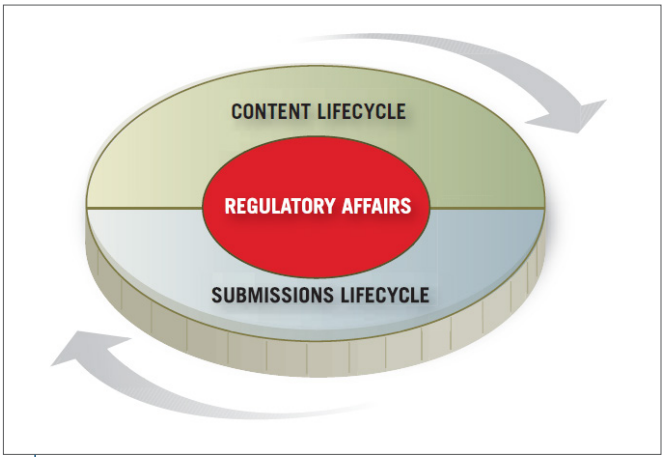
BIOVIA QUMAS for SharePoint is the cornerstone of the BIOVIA QUMAS R&D Solution. As an off-the-shelf regulatory content management system, **BIOVIA QUMAS EDMS** enables your organization to create, manage, and securely store all content, reports, and records. Sophisticated built-in password policies protect against unauthorized access while the system supports the use of electronic signatures at task completion.

Critical features include:

- **Workflow & configuration management** – point and click interface to workflow design and configuration allows users to map their unique business processes to the system without customization
- **Advanced lifecycle management** – convenient access to all document lifecycles with configurable lifecycle states and permissions
- **Automated notification & distribution** – enables effective distribution and rapid notification of document changes and approvals
- **Role-based electronic signatures** – ensures the meaning of electronic signatures match user intent
- **Read & Understood** – provides traceable accountability throughout the organization
- **Comprehensive, independent audit trail** – captures more than 270 auditable events, allowing export or printing for regulatory agency review
- **Full Web services based software development kit for custom interfaces and actions**

OFF-THE-SHELF SUBMISSION MANAGEMENT SYSTEM

The **BIOVIA QUMAS R&D Solution** also incorporates **eCTDmanager™** from **EXTEDO** – a high-quality solution designed for the assembly and compilation of compliant electronic dossiers based on the eCTD standard. The solution supports all current standards of paper-based, hybrid and electronic submissions such as CTD, eCTD, and more. **eCTDmanager** contains a visual structure editor that allows you to compile a dossier step-bystep. Structural elements can be edited, added, or deleted and documents can be scanned, copied, moved, or imported by drag and drop from other dossiers or from the BIOVIA QUMAS content management system. Links, comments, and highlights can be set at anytime during compilation since documents are referenced relative to a structure element. In addition to compilation and publishing, **eCTDmanager** provides complete submission lifecycle management. This means that once an eCTD dossier has been approved by the agency, a post approval maintenance lifecycle automatically starts (new, append, revise, delete) and continues through the life of the submission. Any hyperlinks you have established on a document will be retained through subsequent versions of that document. The integration provides drag and drop access to your document repository and up-versioning of submissionswhen the content changes.



Submissions Lifecycle

COLLABORATIVE REVIEW AND AUTHORING

The **BIOVIA QUMAS R&D Solution** leverages technology from **PleaseTech** to provide a secure, structured and controlled review environment – unique in that the review takes place in the browser – there are no documents to download. This truly collaborative review environment allows everyone to simultaneously comment on the same copy of the document, including MS Word documents, PowerPoint slides, PDFs, images and image collections.

Accordingly, document quality is enhanced and the number of review cycles can be dramatically reduced. This functionality is especially useful in assisting with the review of documents with both internal and external authors. At the completion of the review an optional review report shows you each change made during the review process.

- Reviewers can see each other's comments and changes and can reply in real-time
- Authors can decide which comments and changes to accept
- Authors get a single document with consolidated comments and changes
- Simple "point and click" browser environment

ECTD AUTHORING TEMPLATES

With more than 200 content templates available, you'll be able to simplify the formatting process so you can focus more on writing and content. Innovative technology from **ISI**, integrated within the solution, allows you to easily create guidance-compliant documents specific to your needs. Each template was designed for a specific regulatory document by a team of medical writers and preset with required headings, sections, instructional text, and formatting. Simply enter the information without having to worry about formatting for compliance. You're also able to enter frequently used information only once. Enter the information and it's repeated throughout the entire document. The same goes for section headings, page headers, footers, numbering, and outline and text formatting. Instructional texts written by medical writers guide you every step of the way, eliminating errors and the potential for omitted information. Content templates are also updated automatically to meet changes in regulatory guidance so you'll always be creating an up-to-date document.

BIOVIA QUMAS R&D SOLUTION INCLUDES:

- Off-the-shelf Regulatory Content Management System
- Off-the-shelf Submission Management System
- Browser-based Collaborative Review and Authoring
- eCTD Authoring Templates
- Document Loading Document Loading

As anyone in the life sciences industry well knows, time is money in the drug development market. Gartner estimates that bringing a drug to market 20 days faster can net an additional $5M in a $100M market; $25M in a $500M market. Gartner estimates that bringing a drug to market 20 days faster can net an additional $5M in a $100M market; $25M in a $500M market.

DOCUMENT LOADING

The **BIOVIA QUMAS R&D Solution** includes an advanced import/export tool to move large collections of documents and/or file folders from a file system and duplicate within **BIOVIA QUMAS EDMS**.

In addition to importing documents, users can specify metadata such as document type, name, title, description, extended attributes and permissions for files and folders imported. Security is transparent to the user so that users can only import/create content to locations and document types for which they have permissions. The import/export tool lets you migrate thousands of documents while leveraging your existing equipment and systems with minimal complexity and training. As an end user solution, this can provide an easy to use environment for non-clinical document loading or a way to exchange information quickly between you and your partners.

Delivering Lower Total Cost of Ownership With dossiers up to or exceeding a million pages – multiple copies of which are normally required – you need a solution that will save you money rather than add to your costs. The **BIOVIA QUMAS R&D Solution** is easily configurable and deploys without a heavy IT footprint. The integration of key content and submissions capabilities is complete so they are optimized to work together. There are no outside consultants or additional customization required. Using one solution to format and submit dossiers in electronic and print formats further reduces costs and simplifies your process.

OFF-THE-SHELF SOFTWARE VALIDATION

In addition, BIOVIA QUMAS provides a complete set of validation templates and scripts that greatly reduce the total time and cost investment necessary for validation. Because FDA-regulated companies must be compliant through each subsequent release of a product, this means that for each hotfix, service pack, and major/minor upgrade, the portion of the system that has changed must be revalidated – often at considerable expense to the regulated organization.

BIOVIA QUMAS significantly reduces these costs with its validation scripts created to satisfy GAMP4 and FDA guidelines. The templates eliminate the need for the clients to write their own while facilitating test and trace requirements. BIOVIA QUMAS support ranges from delivery of the templates and test protocols (many clients prefer to do the PQ piece themselves) to onsite support and management of the validation process. Support is flexible to meet the diverse needs of BIOVIA QUMAS clients.

DELIVERING LOWER TOTAL COST OF OWNERSHIP

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ACCELERATE BRINGING NEW DRUGS TO MARKET

As anyone in the life sciences industry well knows, time is money in the drug development market. Gartner estimates that bringing a drug to market 20 days faster can net an additional $5M in a $100M market; $25M in a $500M market. Adoption of eCTD is forcing life sciences companies to rethink their submission management strategy. One of the biggest tasks is prepping the documents involved in submissions, especially given the exponential nature of many of the regulatory docs needed. Further complicating matters, an eCTD can have thousands of lifecycles, often confusing the regulatory group as to which documents to replace and which version is correct. Good lifecycle management reduces the risk of product recalls and liability suits – visibility that can avert damage to a company's reputation, brand, and market cap. A successful eCTD must capture all lifecycle documents, including responses to questions, variations/amendments, renewals, annual reports, and other materials. The **BIOVIA QUMAS R&D Solution** enables organizations to bring new drugs to market sooner and increase ROI and overall profitability.

BENEFITS:

- Single platform provides one-stop shop for R&D requirements
- Fast start from project inception to completion with a fully integrated complete solution
- Full out of the box compliance with 21 CFR Part 11
- Enables faster time to market through improved regulatory submission assembly, review and approval processes
- Allows you to quickly identify and assemble the relevant documents to support critical submissions
- Shortens review and approval cycles by up to 40%
- Allows for higher quality submissions with fewer iterations, enhancing chances for success
- Delivers automatic compliance with global eCTD standards
- Authoring templates allow authors to focus more on content and less on format.
- Enables you to adapt quickly to regulator or internal changes with flexible configuration capabilities

- Reduces IT costs with flexible, out of the box system complete with validation test scripts to accelerate deployments
- Enhances maturity of submissions and document lifecycle processes to mitigate the risk of future compliance mandates, shifting business priorities and industry consolidation
- Ideal for biotechs who require fixed cost solutions and pre-defined configurations

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.

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 170,000 customers of all sizes in all industries in more than 140 countries. For more information, visit **www.3ds.com**.

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