BIOVIA

3DEXPERIENCE®

BIOVIA QUMAS
R&D SUBMISSION DOCUMENTS ENTERPRISE PACKAGE

Datasheet

DASSAULT SYSTEMES

BIOVIA Services offers a number of packaged solutions providing pre-defined and pre-tested configurations of document content management or process management for specific, common industry problems. This package addresses document management requirements around documents used in global regulatory submissions, particularly CTD and eCTD submissions. The pre-defined configuration supports the creation, approval and ongoing lifecycle management of documents used in functions such as Clinical, Nonclinical, Quality, Manufacturing, Regulatory Affairs and Safety.

PACKAGE FEATURES

The R&D Submission Documents Package offers the BIOVIA QUMAS EDMS, together with a pre-defined configuration to support development of documentation used in submissions to global regulatory authorities.

This package contains advanced, out-of-the-box QUMAS EDMS functionality including the following features:

- **Audit Trails**
- **Reporting**
- **Workflows**
- **Messaging**
- **Auto-Rendering**
- **Version Control**
- **Lifecycle Management**
- **Full-text Searching**
- **Role-based Security/Permissions**
- **21 CFR Part 11 Electronic Signatures**

This Package also contains the following pre-defined configurations and professional services:

- **EDMS configuration, designed specifically for R&D use, based on business fundamentals following the DIA EDM reference model and CTD standards**
  - 12 pre-defined document types, including the following:
  - Governance and Procedure Documents
  - Submission Archive
  - Clinical Site Documents
  - Clinical Study Documents
  - CMC Drug Product Documents
  - CMC Drug Substance Document
  - Reg General Document
  - Published References
  - Nonclinical Documents
  - Product Information Documents
  - Regional Documents
  - Safety Documents
- 10 pre-defined workflows to ensure best practice content progression and management
- 4 pre-defined collection types: CSR, CTMF, CTD and General Collections
- A taxonomy (cabinet / folder structure) matching the common CTD structure
- Supporting configuration for R&D Submissions
- **Documentation**
  - Design Document detailing the pre-defined configuration
  - Client-specific Picklist values document (to be filled in by client and returned to BIOVIA for inclusion in configuration prior to installation)
  - Validation Pack: IQ, PQ, Functional Specification, Design Specification, and Trace Matrix (OQ not required because this Package contains a pre-defined configuration)
  - End-user training course (PDF Guide)
  - System Access Plan (to be filled in by client and returned to BIOVIA for inclusion)
- **Professional Services including full package installation, delivery of End-user training and Train-the-Trainer training**

PACKAGE BENEFITS

The R&D Submission Documents Package provides:

- Industry standard design mapped to DIA EDM model for document types, attributes and taxonomy
- The ability to store an archive of submissions and correspondence with agencies
- Pre-defined configuration
- Complete documentation, IQ/PQ test scripts and End-user training
- Complete installation and design services documented and performed by BIOVIA
- Fully understood and proven implementation methodology for successful project delivery
- Lifecycle management of Regulatory Submission Source Documents
- Electronic Archiving of Final Submissions and Agency Correspondence

The package design allows authorized users to create a variety of documents intended for drug submission, or to import them from external sources, control access to them by group membership and approve them with 21 CFR Part 11 compliant electronic signatures, if applicable. Documents can be printed, edited and approved, as well as scheduled for automated periodic reviews. The system captures all actions in the audit trail.

BIOVIA Dassault Systèmes offers over 25 years of experience in delivering Compliance Solutions for regulated industries. From this experience, a common, industry standard design has been developed and tested, providing a pre-defined configuration of document types and minimum attribute sets, fully supported by workflows for editing, approving, re-approving and retiring documents, a controlled printing system and all supporting documentation and professional services for installation, testing and training.

Additional Options

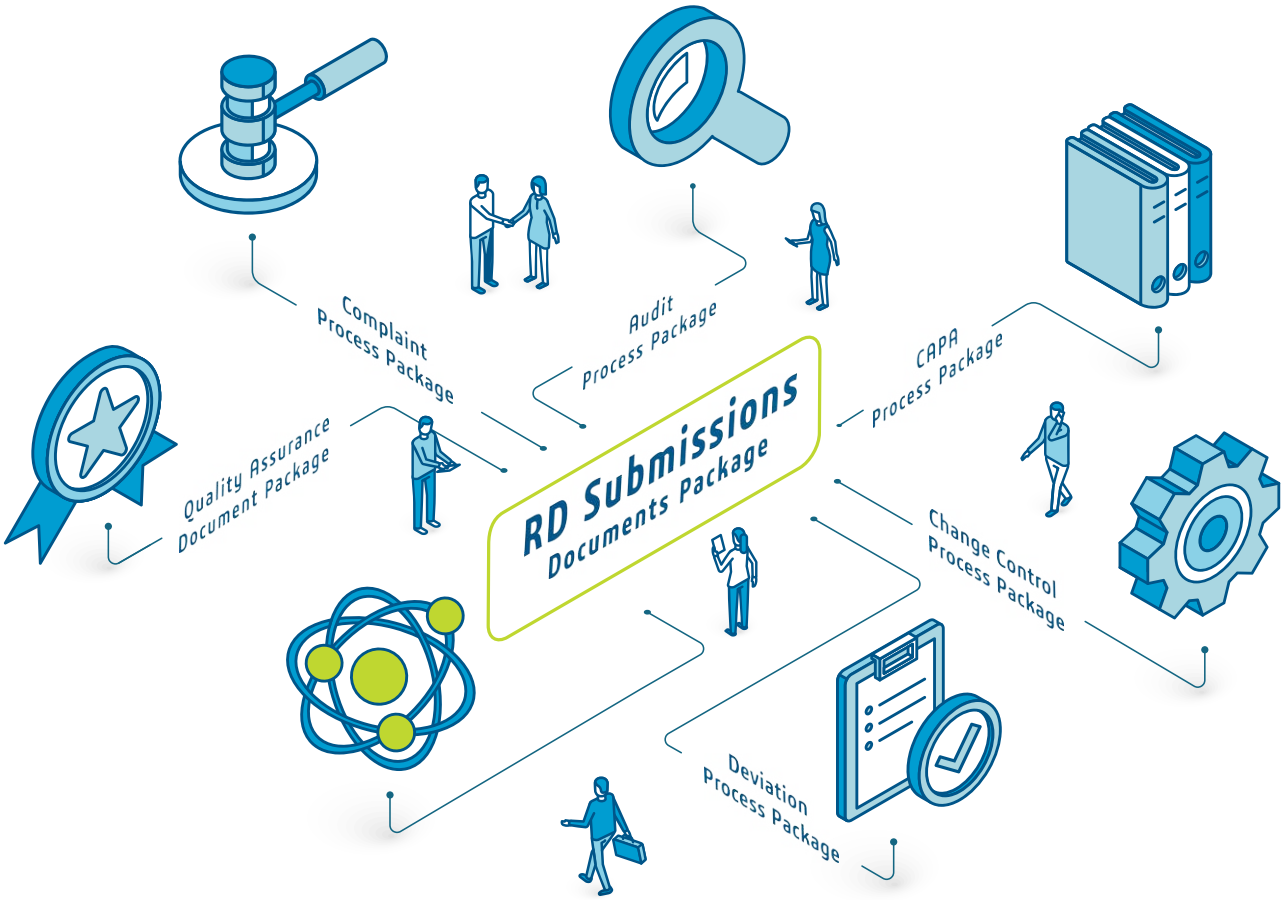
In addition to the out-of-the-box elements of this package, clients have the option to purchase further options such as:

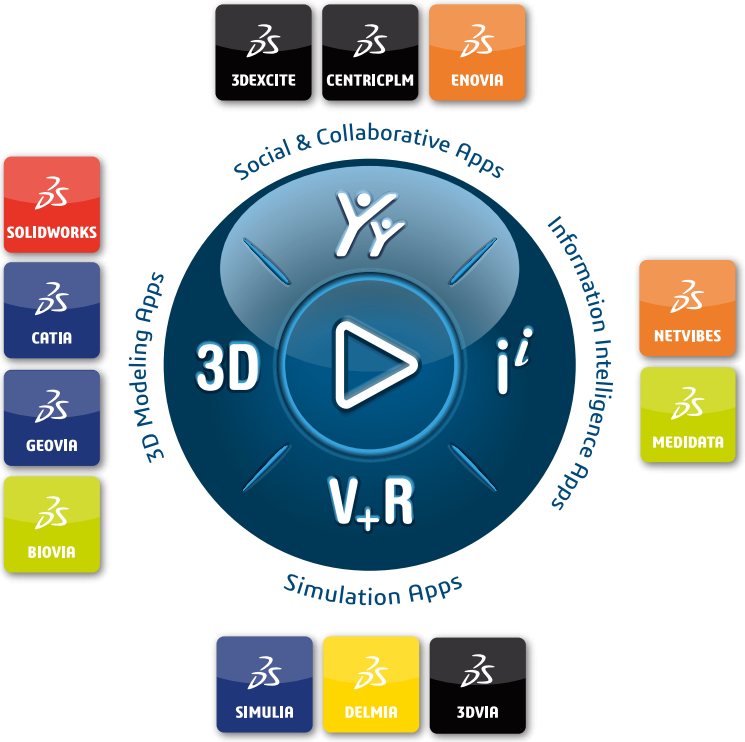
- Additional training days (End User and/or System Administrator)
- Additional specific configuration (together with the required documentation, tests and training)
- Integrations to other systems (e.g., Learning Management System)
- Custom Reports
- Import application for batch import of documents
- Dashboard Reporting tool

SYSTEM REQUIREMENTS

- 4 Servers for each of 2 environments (validation and production)
  - Database Server
  - Web Server
  - Render Server
  - Auto-populate
- Servers can either be physical or virtual hardware
- Detailed guidance on system specifications is available
- ScienceCloud option also available
- Servers can be shared for multiple BIOVIA Packages

LEARN MORE





Our **3D**EXPERIENCE® platform powers our brand applications, serving 11 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3D**EXPERIENCE Company, is a catalyst for human progress. We provide business and people with collaborative virtual environments to imagine sustainable innovations. By creating 'virtual experience twins' of the real world with our **3D**EXPERIENCE platform and applications, our customers push the boundaries of innovation, learning and production.

Dassault Systèmes' 20,000 employees are bringing value to more than 270,000 customers of all sizes, in all industries, in more than 140 countries. For more information, visit **www.3ds.com**.

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