BIOVIA

3DEXPERIENCE®

BIOVIA QUMAS
QUALITY ASSURANCE 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 quality/process management for specific, common industry problems. This package addresses document management requirements around documents used in Quality Assurance. The pre-defined configuration supports the creation, approval and ongoing lifecycle management of documents such as standard operating procedures, methods, work instructions, validation documents and specifications.

PACKAGE FEATURES

The QUMAS Quality Assurance Documents Enterprise Package offers the QUMAS Electronic Document Management System (EDMS) along with predefined configuration to support the lifecycle management of Quality Assurance management documentation in highly regulated industries.

This package contains advanced, out-of-the-box 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 QA use, based on business fundamentals widely accepted in industry**
- **26 pre-defined GxP document types, including the following:**
  - Facility Document
  - Facility Record and Certificate
  - General Document
  - Governance and Procedure Documents
  - Manufacture Master
  - Manufacture Record
  - Method - General
  - Method - Material
  - Method - Product
  - Method - Substance
  - Packaging Document
  - Project Documents
  - Quality - Management
  - Quality - Product
  - Quality Substance
  - Records and Certs - Materials
  - Records and Certs - Products
  - Records and Certs - Substance
  - Specification - General
  - Specification - Material
  - Specification - Product
  - Specification - Substance
  - Validation - Equipment
  - Validation - Material
  - Validation - Product Substance
  - Validation System
- **9 pre-defined workflows to ensure best practice content progression and management**
  - Edit Approve
  - Periodic Review
  - Q Collection Edit Approve
  - Q Collection Retire
  - Retire
  - Templates Edit Approve
  - Templates Retire
  - External Approve
  - External Edit Approve
- **Supporting Configuration for Quality Assurance Management**
  - Automated Numbering Systems for each Document Type
  - Automated Location for all Document Types
  - Roles and Meanings of Signature to support the above workflows
  - Groups to grant access and functionality
  - Pre-defined Cabinet / Folder structure
  - 3 Print templates:
  - General print
  - Hardcopy managed print
  - No Watermark Print

- **Documentation**
  - Design Document detailing the pre-defined configuration
  - Client-specific Picklist values document (to be filled in by client and returned to Dassault Systèmes 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 Dassault Systèmes for inclusion)
- **Professional Services including full package installation, delivery of end-user training and train-the-trainer training**

PACKAGE BENEFITS

The QUMAS Quality Assurance Documents Enterprise Package provides:

- Industry standard design mapped to common QA practices for document types, attributes and taxonomy
- The ability to control electronic and printed copies of documents
- Pre-defined configuration
- Complete documentation, IQ/PQ test scripts and end-user training
- Complete installation and design services documented and performed by Dassault Systèmes
- Fully understood and proven implementation methodology for successful project delivery

The package design allows authorized users to create a variety of documents such as SOPs, Policies, Work Instructions, Methods, Specifications and Forms; control their access with role and group based permissions; and manage their review and approval with 21 CFR Part 11 compliant Electronic Signatures. 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 has 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

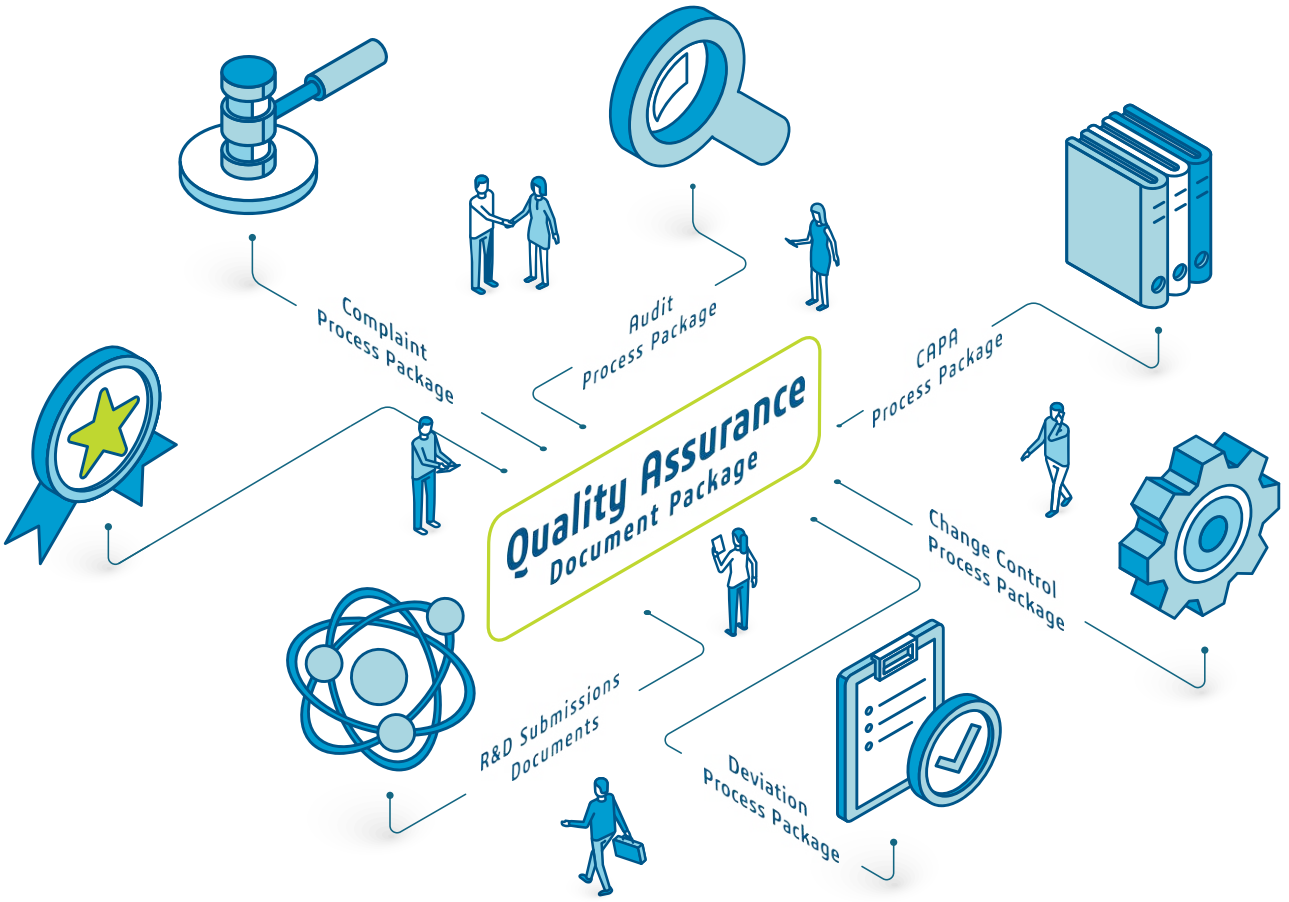
In addition to the out-of-the-box elements of this package, clients have the option to purchase further options such as:

- 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 (Database Server, Application Server, Render Server, Auto-populate Server) for 2 environments (Test environment and Production environment)
- 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 Dassault Systèmes packages

LEARN MORE



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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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