BIOVIA

3DEXPERIENCE®

BIOVIA QUMAS PACKAGED SOLUTIONS OVERVIEW

Datasheet

DASSAULT SYSTEMES

BIOVIA Services offers a number of QUMAS Packaged Solutions providing pre-defined and pre-tested configurations of Document content management or Process management for specific, common industry problems. Each Package addresses a specific business function and includes all required software, implementation services, training and documentation to support that business function. Customers can combine packages to address multiple areas of the business while maintaining a single, robust compliance system.

BENEFITS OF PACKAGED SOLUTIONS

- Large enterprise application platforms do not enable companies with limited budgets, time and resources to deploy solutions reliably and quickly.
  - **QUMAS Packaged Solutions enable companies to get up and running with working solutions quickly and without long consulting engagements or expensive customizations.**
- Validation of GAMP 5 Category 4 applications pose major problems for companies with very limited time and resources, often impeding the successful implementation of solutions indefinitely.
  - **QUMAS Packaged Solutions meet GAMP 5 Category 3 definitions, making them significantly easier to validate and deploy.**
- It is increasingly difficult to find solution providers who can offer a rapid deployment model on the foundation of a proven regulatory record of accomplishment and a global client community.
  - **QUMAS Packaged Solutions are pre-defined and pretested and are backed with 25+ years of experience in delivering compliance solutions to small and large pharmaceutical, biotechnology and medical device companies.**
- In-house domain expertise is a challenge for many organizations that do not have personnel with regulatory or compliance experience. In many cases, resources are over-burdened with their regular duties and cannot dedicate time to a large IT project.
  - **QUMAS draws upon its years of industry experience in the design of the Packages and leverages its proven Services Methodology to ensure implementation success.**

PACKAGE OUTLINE

Each package offers the appropriate QUMAS software application together with a pre-defined and pre-tested configuration, developed through the experience of BIOVIA Services who have configured and deployed compliance solutions in highly regulated industries for over 25 years. The standard design and artifacts in each Package eliminate the need to change configuration, documentation and test scripts, thereby assuring a fixed price and a fixed scope for a quick and successful deployment.

Each package includes the following key elements:

- **Applicable software**
- **A business function-specific, pre-defined and pre-tested configuration as applicable to the package**
- **Localization support, such as**
  - List of users
  - Group and role memberships for the list of users
  - Client-specific picklist values (such as sites, product names, department names and document functions)
- **Design documentation**
- **Testing and validation scripts (IQ and PQ)**
- **Professional Services to install, test and deploy the system**
- **Training**

QUMAS PACKAGED SOLUTIONS

The available BIOVIA QUMAS packaged solutions are:

QUMAS Quality Assurance Documents Enterprise Package

This package addresses document management requirements pertaining to documents used in Quality Assurance. The pre-defined configuration supports the creation, approval and ongoing lifecycle management of documents such as Standard Operating Procedures (SOPs), Methods, Work Instructions, Validation documents and Specifications.

QUMAS R&D Submission Documents Enterprise Package

This package addresses document management requirements pertaining to documents used in Global Regulatory Submissions, particularly Common Technical Documents (CTDs) 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.

QUMAS CAPA Process Enterprise Package

This package addresses the process management requirements of a Corrective and Preventive Actions (CAPA) Management process. The predefined configuration supports the electronic capture, management and reporting of CAPAs resulting from business events or other business processes such as deviations or audits.

QUMAS Deviation Process Enterprise Package

This package addresses the process management requirements of a deviations management process. The pre-defined configuration supports the electronic capture, management and reporting of deviation occurrences, root cause analysis and follow-up CAPAs, as necessary.

QUMAS Change Control Process Enterprise Package

This package addresses the process management requirements of a change control management process. The pre-defined configuration supports the electronic capture, management and reporting of change control requests, approvals and execution.

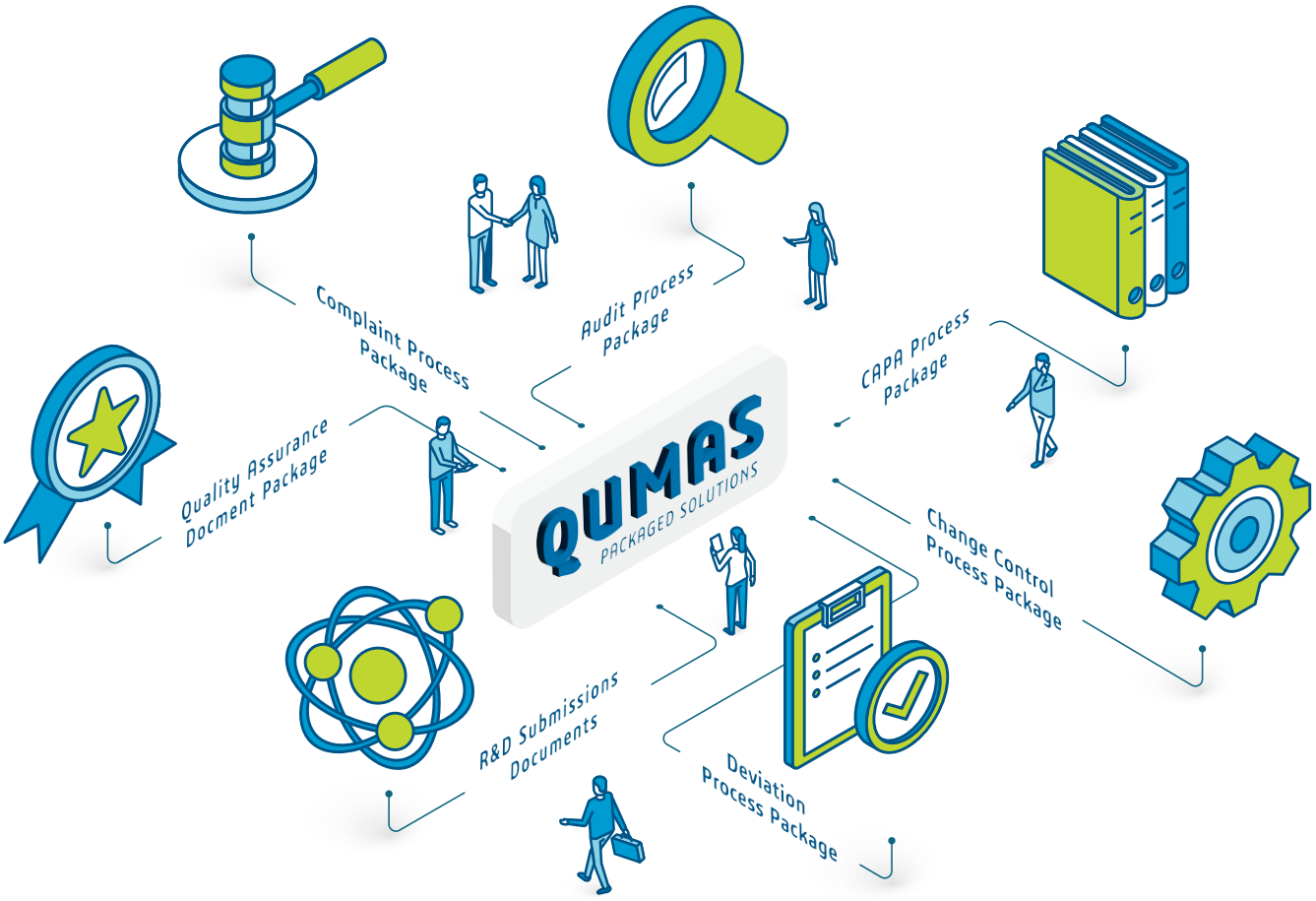
QUMAS Complaint Process Enterprise Package

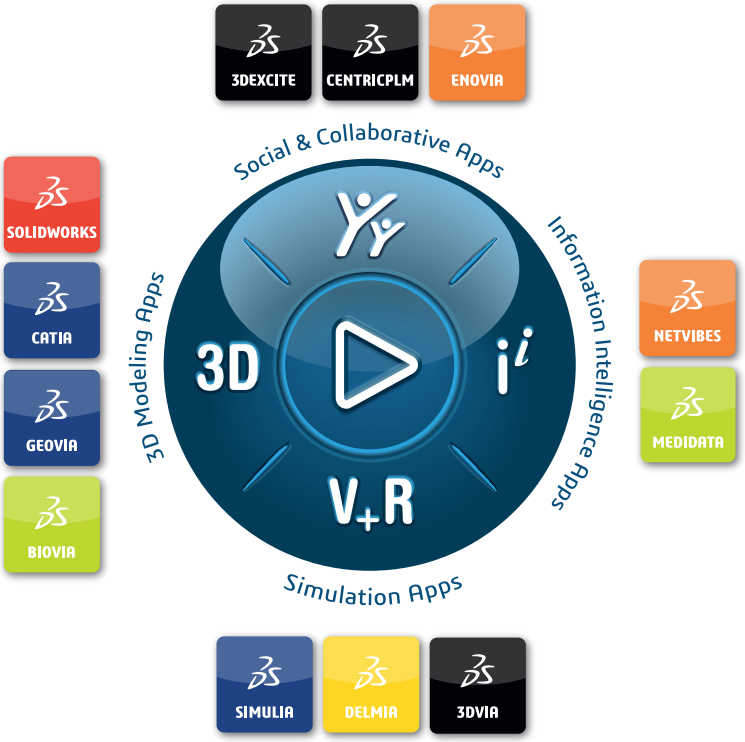
This package addresses the process management requirements of a complaint management process. The pre-defined configuration supports the electronic capture, management and reporting of complaint recording, investigation and remedial actions.

QUMAS Audit Process Enterprise Package

This package addresses the process management requirements of an audit management process. The predefined configuration supports the electronic capture, management and reporting of audit observations, recommendations and follow-up actions.

LEARN MORE





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