

# QUMAS Packaged Solutions Overview

## Description

QUMAS 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. Each Package is designed to address a specific business function and includes all required software, implementation services, training, and documentation to support that business function. Packages may be combined and built upon over time to address multiple areas of the business while maintaining a single, robust compliance platform.

## 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 fixed price, fixed schedule, rapid deployment model on the foundation of a proven regulatory track record and a global client community
  - **QUMAS Packaged Solutions are pre-defined and pre-tested and are backed with 15+ 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 the personnel with regulatory or compliance experience. In many cases, the 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. QUMAS Customers participate in an active User Community and meet frequently at events such as QUMAS Connect, the annual Worldwide User Conference**

## Package Outline

Each Package offers the appropriate QUMAS software application together with a pre-defined and pre-tested configuration, developed through the experience of QUMAS Professional Services, who have configured and deployed compliance solutions in highly regulated industries for over 15 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
- Localisation Support, such as
  - List of Users
  - Group and Role memberships for the list of users
  - Client-specific picklist values (such as product names, department names, and document functions)
- Design Documentation
- Testing and Validation Scripts (IQ and PQ)
- Professional Services to install, test, and deploy
- Training
- A Professional Services Review once the system has been in production use for at least 3 months



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## QUMAS Packaged Solutions

Please review the following list of available Packaged Solutions. To request additional information on each solution email [info@qumas.com](mailto:info@qumas.com)

### QUMAS Quality Assurance Documents Package

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, and Specifications.

### QUMAS R&D Submission Documents Package

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.

### QUMAS CRO Documents Package

This Package addresses document management requirements around documents specific to the business of a CRO. The pre-defined configuration supports the creation, approval, and ongoing lifecycle management of documents such as Clinical, Nonclinical, Library, SOPs, and Correspondence.

### QUMAS CMO Documents Package

This Package addresses document management requirements around documents specific to the business of a CMO. The pre-defined configuration supports the creation, approval, and ongoing lifecycle management of documents such as CMC, SOPs, Methods, Specifications, and Correspondence.

### QUMAS CAPA Process Package

This Package addresses the business process management requirements of a CAPA Management process. The pre-defined 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 Package

This Package addresses the business 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 Package

This Package addresses the business 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 Package

This Package addresses the business 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 Package

This Package addresses the business process management requirements of an Audit Management process. The pre-defined configuration supports the electronic capture, management, and reporting of Audit observations, recommendations, and follow up actions.

### QUMAS Out-of-Specification Process Package

This Package addresses the business process management requirements of an Out-of-Specification Management process. The pre-defined configuration supports the electronic capture, management, and reporting of Out-of-Specification testing results, investigations and remedial actions or CAPAs, as necessary.

### QUMAS Medical Device Documents Package

This Package addresses document management requirements around documents used for Medical Devices. The pre-defined configuration supports the creation, approval, and ongoing lifecycle management of documents such as Engineering Drawings, Bill of Materials (BOM), Design History Files (DHF), and Device Master Records (DMR).

## Contact Us for More Information

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