QUMAS Quality Assurance Documents Package

Package 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. 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.

Package Features

The Quality Assurance Documents Package offers the QUMAS DocCompliance application, together with pre-defined 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:

- DocCompliance configuration, designed specifically for QA use, based on business fundamentals widely accepted in industry
  - 5 pre-defined GxP document types, including the following:
    - Procedures
    - Methods
    - Specifications
    - Regulatory
    - General

- 5 pre-defined workflows to ensure best practice content progression and management
  - Edit, review and approval
  - Import
  - Import with edit
  - Periodic Review
  - Retire
- Supporting Configuration for Quality Assurance Management
  - Automated Numbering Systems for each Document Type
  - Automated Location for all Document Types except 'General'
  - Roles and Meanings of Signature to support the above workflows
  - Groups to grant access and functionality
  - Pre-defined Cabinet / Folder structure
  - 2 Print templates:
    - General print
    - Hardcopy managed print
- Documentation
  - Design Document detailing the pre-defined configuration
  - Client-specific Picklist values document (to be filled in by client and returned to QUMAS 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) plus 90-days access to QUMAS' Computer-based Training (CBT) Series
  - System Access Plan (to be filled in by client and returned to QUMAS for inclusion)
- Professional Services including full Package installation, delivery of End-user training and Train-the-Trainer training
- A Professional Services Review once the system has been in production use for at least 3 months

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Package Benefits

The Quality Assurance Documents 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 QUMAS
- 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. All actions are captured in the audit trail.

QUMAS has over 15 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
- Computer-based Training (CBT)
- Import application for batch import of documents
- Computer-based training

System Requirements

- 4 servers (Database Server, Application Server Render Server, Autopopulate Server,) for 2 environments (Test environment and Production environment)
- Servers can either be physical or virtual hardware
- Detailed guidance on system specifications is available
- Servers can be shared for multiple QUMAS Packages

Contact Us for More Information

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