

QUMAS CAPA Process Package

Package Description

QUMAS offers a number of Packaged Solutions providing pre-defined and pre-tested configurations of content and process management for common industry problems. 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.

Package Features

The CAPA Process Package offers the QUMAS ProcessCompliance application, together with pre-defined configuration to manage corrective and preventive actions in highly regulated industries.

This Package contains advanced, out-of-the-box business process management functionality including the following features:

- Data Dictionary
- Configurable Forms Builder
- Business Rules Engine
- Workflow
- Reporting
- Audit Trails
- Messaging
- Role-based Security / Permissions
- 21 CFR Part 11 Electronic Signatures
- Integrated with QUMAS DocCompliance for document management

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

- ProcessCompliance configuration, designed specifically for change control management, including
 - Workflow of tasks from Initiation through Supervisor Approval, Team Selection, Impact Assessment, Evaluation, Action Approval, Execution and Monitoring of Actions, Effectiveness Review, and QA Follow-up
 - Appropriate user selection from pre-defined roles per task

- Pages of pre-defined mandatory and optional fields to capture the information, analysis and decisions
- Dynamic forms with inline help that guide users to provide the information needed
- 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)
 - 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

CAPA Overview

A Corrective Action / Preventative Action is required to correct something that has either gone wrong - or has been identified as having a potential to go wrong. CAPAs may be identified by any other process - or just 'generated' as needed. These actions are formally recorded to identify why actions are being initiated or proposed.



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The process records the details of the action(s), gaining approval before permitting any activity and evaluating the effectiveness of the solution proposed by completion of the actions.

See Figure. 1 as an example of a CAPA process

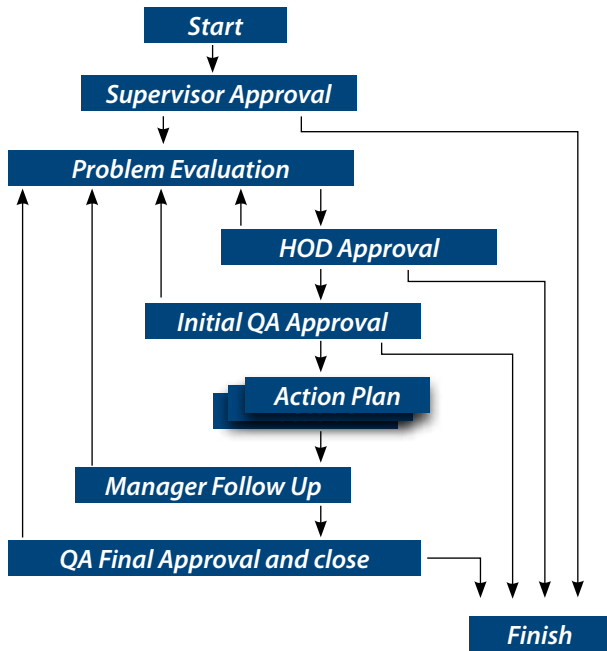


Figure 1.

Package Benefits

The CAPA Process Package provides

- Industry standard design mapped to common CAPA form designs and business workflows
- 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 and contribute to electronic CAPA forms to document the problem, analysis and proposal of resolution actions and manage their review and approval with 21 CFR Part 11 compliant Electronic Signatures. The execution of actions is automatically monitored for effectiveness and routed to QA for approval before closure. All actions are captured in the audit trail.

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
- Custom Reports
- Computer-based training

System Requirements

- 2 servers (Database Server and Application 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

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