

# QUMAS Change Control Process 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 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.

## Package Features

The Change Control Process Package offers the QUMAS ProcessCompliance application, together with pre-defined configuration to manage change controls 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

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

## Change Control Overview

A change control process is required when any change is required in the business - Documents, Suppliers, Equipment, Software, Buildings, Supply of utilities and so on. The process requires that the necessary information is recorded and analyzed. It ensures that the required approvals are given before any action occurs and that the effect of the change is recorded. A change control may be generated due to the findings of a CAPA or Audit investigation.

*See Figure. 1 as an example of a change control process.*



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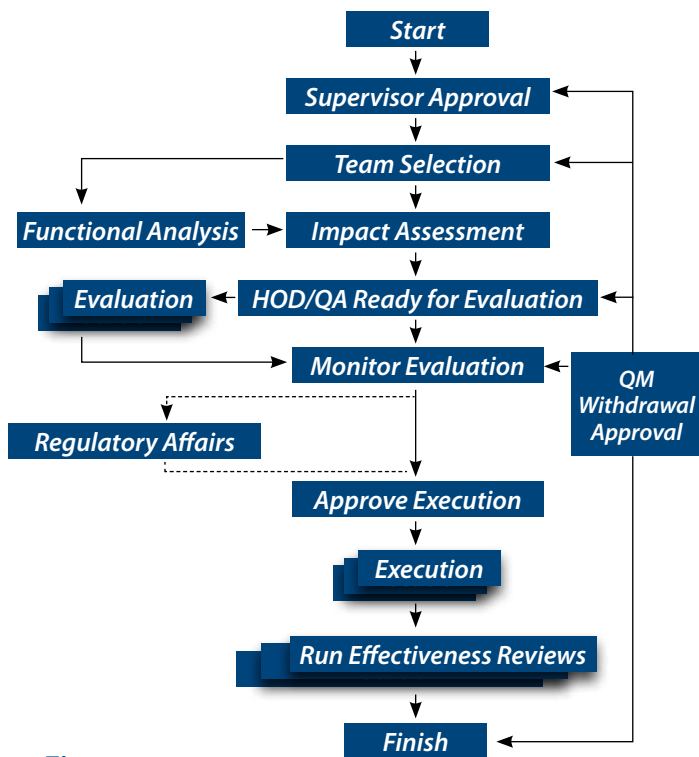


Figure 1.

## Package Benefits

The Change Control Process Package provides

- Industry standard design mapped to common change control 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 Change Control forms to document the change request, justification, impact analysis and proposal of actions and manage their review and approval with 21 CFR Part 11 compliant Electronic Signatures. The execution of the change control 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

## Contact Us for More Information

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