QUMAS Deviation 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 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.

Package Features

The Deviation Process Package offers the QUMAS ProcessCompliance application, together with pre-defined configuration to manage deviations 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 Deviation 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

Deviation Overview

A Deviation must be recorded if anything out of the ordinary occurs during a regulated process. The essential information regarding the deviation (including effected batches of product where relevant) is recorded, and is verified before an analysis of the cause is initiated. The resolution actions and disposition of the effected batch(es) are approved before any action takes place. Deviations are often linked to CAPAs (for correction).
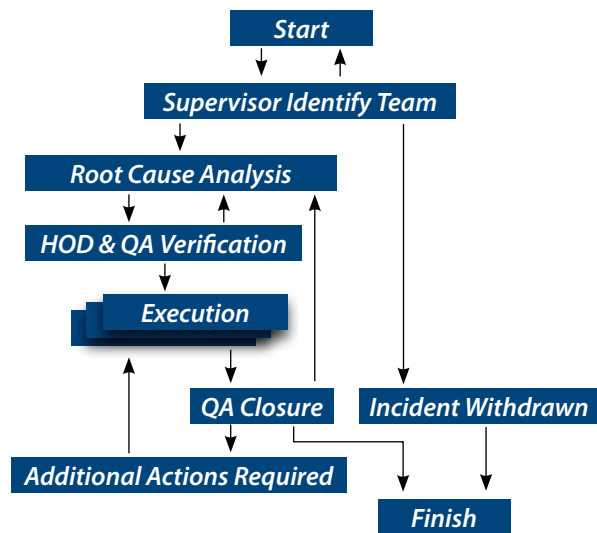*See Figure. 1 as an example of a Deviation process*

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Figure 1.

Package Benefits

The Deviation Process Package provides

- Industry standard design mapped to common Deviation 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 Deviation forms to document the problem, root cause 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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