

# QUMAS Audit 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. The QUMAS Audit Package addresses the business process management requirements for Audit Management. The pre-defined configuration supports the electronic capture, management, and reporting of Audits, root cause analysis, and follow up CAPAs, as necessary.

## Package Features

The Audit Process Package combines the QUMAS ProcessCompliance application, together with pre-defined configuration to manage Audits 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 Audit 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 online 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

## Audit Overview

Two processes have been defined to support Auditing:

1. 'Audited' is to manage the investigation and resolution of issues arising from 'being audited'.
2. 'Auditing' is for recording any findings, developing a report and reconciling the responses when performing an audit on somebody else.

Either process can be used for both internal and external use. Both processes allow the people carrying out the activity to capture data and then run a report to be sent to the other party (saving a copy in the process instance).

An Audited process instance is run following receipt of an Audit report. It allows the various findings of the report to be allocated for investigation, checked and for those investigations to take place. A report can be generated to document the response from the investigations – this report can then be sent to the Auditors for comment.

The Audited Instance can be closed down following reconciliation of the comments from the Auditors and the activation of any CAPA or other actions that result from this.

*See Figure 1. as an example of an Audited Process*

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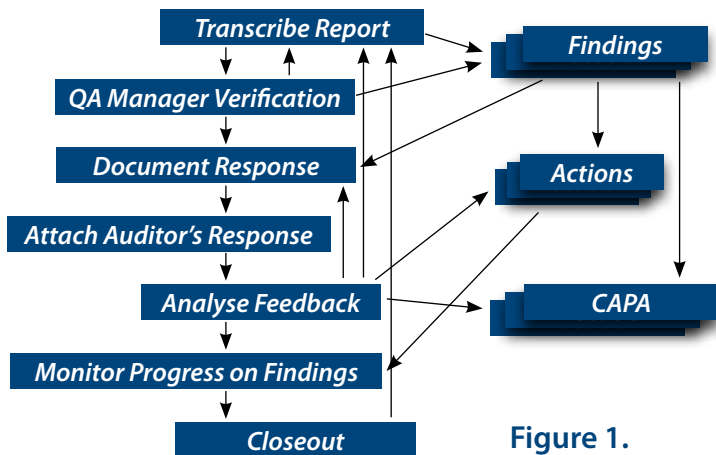


Figure 1.

An Auditing process instance is run when you are planning to audit somebody else (either internal or external). It requires details about the organization and people being audited and that audit meetings are scheduled. It supports the capture of information gathered at Audit meetings and the documentation of any findings that come from them. A report is generated to collate all the findings into a single document – this is recorded in the system and is sent on to the Auditees. The Auditees response is loaded on return and the various responses to each finding can be assessed before either sending a new report or closing the finding and the audit actions.

See Figure 2. as an example of an auditing process

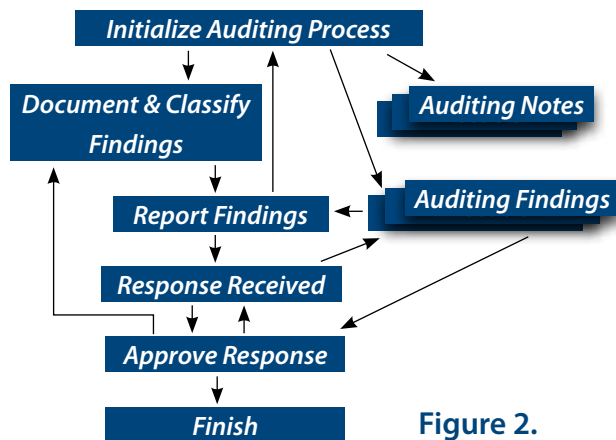


Figure 2.

## Package Benefits

The Audit Process Package design enables authorized users to create and contribute to electronic Audit forms to document the investigation, report and propose resolution actions and manage the 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. Benefits also include:

- Availability - Central common repository for all instances
- Security - Forms don't get 'lost in the mail'
- Legibility - Electronic rather than hand written forms
- Accessibility - Ability to search for trends, previous occurrences, etc
- Consistency - Single repeatable process, generation of consistent output
- Accountability - 21 CFR part 11 compliant signatures and audit trail, reports and analysis possible

## This Package provides

- Industry standard design mapped to common Audit 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
- Pre-defined reports that generate an Audit report or a 'Response to an Audit' report

## 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