

Auditing a Change Management System

Title: Auditing a Change Management System					
Auditor Manual: 06					
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Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

Audit Training Manual: 06

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- Ø How will it be tested or validated once the change has been made?
- Ø What is the rationale for the change?
- Ø What is the timing of the change?
- Ø What is the impact to quality once the change is implemented?

A change management request should be issued and circulated to designated parties to review and approve the change.

Each site should have a formal and documented change management system, which evaluates the effectiveness of each change proposed, defines clear roles and responsibilities and assesses the impact of change on the validation/stability and/or registration status of the change.

Audit Strategy

To determine the effectiveness of the change management program, one strategy is to identify a completed change that has taken place at the site and follow it through the change management process. Depending on the actual change, several GMP systems may be impacted.

The site's change management program should be established as part of the Quality system. Under the Quality system, the site's requirements for change control should be described.

Any change made as part of the change management program should be:

- Ø Documented
- Ø Evaluated
- Ø Approved
- Ø Tracked to completion
- Ø Assessed for impact
- Ø Closed

If the change is a production change, within the production GMP system, it should be part of the change management system and assessed to determine if it requires validation, a stability study, communicated to or approved by the regulatory authorities. For each site or contractor, it is important to determine if the proposed change requires global approval.

Change Request

To initiate any type of change a change request must be generated. Minimum information that should be included is the following:

- Ø A description of the proposed change including scope
- Ø Where the change will take place
- Ø The anticipated plan to include schedule for task completion and proposed date(s) of implementation
- Ø Affected documents: specifications, methods, standard operating procedures
- Ø Estimate of resources needed to bring about the change
- Ø Justification/reason for the change
- Ø Supplemental documents supporting the change

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As an approver, they have three responsibilities. The **first** is that they accept the concepts, requirements and responsibilities within the change as they apply to their area. The **second** is that they verify the accuracy of all functions directly affecting their area of responsibility. The **last** responsibility is to provide the required resources to facilitate implementation of the change, whether specific or implied.

If changes to the proposal document are needed prior to approval, the Change Coordinators, Initiators and Approvers should work together to facilitate. If during the review process a change is determined as not needed or additional changes or modifications to the proposal are warranted, the process may have to be reinitiated or require the generation of additional change requests.

Only after documented approval is attained can implementation of any change commence.

Change Implementation

The change as described in the approved request can proceed to implementation according to the plan. If needs for additional changes are encountered during the implementation process, that were not approved as part of the original proposal, then additional change request approvals may be necessary.

Assessment of the Change as Implemented

Procedures should be in place to evaluate and assess implemented changes. The intention is to provide confirmation the original change had the intended effect based on the original justification. For a minor or evident change the assessment can be performed as part of the implementation process. However, for changes that are wider in scope and impact, the assessment could be done initially and/or after appropriate data points are available (based on data generation).

Change Closure

The change request is closed when the change has been implemented, documentation updated, outstanding actions completed, follow-up assessments performed and concluded as effective, and regulatory commitments have been communicated.

Summary

Any change that affects a GMP system or the regulatory compliance of a product or process is to be controlled through a formal approved change control system/process. The change control system should include information from the submission, through to the implementation and effectiveness assessment of the change.

A representative of the Quality unit must approve proposed changes that have the potential to have an impact on the quality, purity, identity, and safety of a drug product. All changes that have regulatory impact must be reviewed and assessed with respect to the product submission by Regulatory personnel.