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Engineering Change Management (ECM) for Aseptic Processing Facilities (APFs)

Introduction

The International Society for Pharmaceutical Engineering (ISPE) defines change as anytime a system is "modified, altered, added to, removed, or improved in the way that make its functions, physical features, or performance different from what they were before the change." Engineering Change Management (ECM) is a Good Engineering Practice process to effectively manage creating, reviewing, and documenting formal approval for engineering change requests, ensuring such changes do not adversely impact the facility, system, or equipment. This article concentrates on facility infrastructure and utility change, in particular the engineering change management process for NIH Aseptic Processing Facilities (APFs), and is not meant to cover changes to the manufacturing process and product.

Background

All facility infrastructure and utility systems supporting APFs are operated and maintained by the NIH Office of Research Facilities (ORF) Division of Facilities Operations and Maintenance (DFOM). The ORF Division of Technical Resources (DTR) Facilities Compliance and Inspection Section (FCIS) provides quality assurance (QA) oversight to ensure that changes to APF systems and equipment are planned, executed, managed, and approved following a controlled process. The ECM Standard Operating Procedure (SOP) for APFs[1] is applicable to all ORF-owned facility systems, equipment, computer systems, instruments, and utilities (i.e., those which create, maintain, and monitor an APF's environment, excluding the User's scientific and environmental monitoring systems and equipment) supporting operational APFs.

ECM Process

The ECM process is designed to use a risk-based approach and involve Subject Matter Experts (SMEs) and End User QA. Whenever there is a change with potential quality impact, the ECM could provide traceability and documentation to support change control that is processed by the End User. There are five primary steps in the ECM SOP procedure,[2] which are described below. An APF-specific, task-specific change management board (CMB) is established to review and approve or deny each request and to provide guidance to change requesters for the development and implementation of the proposed changes. The CMB is made up of representatives from DTR/FCIS, the Office of Research Support and Compliance (ORSC), DTR/Technical Services Branch (TSB), DFOM, APF End User QA, SMEs and other stakeholders as required.

Step 1 - Change Control Screening Assessment (CCSA): A CMB will determine if the proposed change needs to be managed through the ECM process. The CCSA is developed by the requester to capture the Current Situation, Proposed Change, Justification of Change, Impact to Facility and Documents, and whether the proposed change is related to a System Deviation (SD), Corrective and Preventive Action (CAPA), or audit observation. The FCIS change coordinator performs a completeness review prior to submittal for review by a CMB.[3]

Step 2 - Change Request Form (CRF): This form captures the Current Situation, the Proposed Change, and Justification; identifies any Post Implementation Requirements; identifies all affected change-controlled documents; and enumerates the results of the Risk Assessment (RA) which is performed to identify and assess the impact of the change. The FCIS change coordinator performs a completeness review prior to submittal for review by a CMB.[3]

Step 3 - Pre-Execution Review and Approval of the CRF by the Change Management Board (CMB): During this step, the CMB will review and approve or deny the CRF.

Step 4 - Implementation and Completion of the Change (Execution): The change requester shall follow up to ensure that required changes have been completed and documented in the CRF accordingly.

Step 5 - Post-Approval and Close-out of the Change (Post Execution): The FCIS change coordinator performs a completeness review prior to submitting the documents for CMB review. After verifying all post-implementation testing has been completed, all affected documents have been updated, and all applicable attachments have been completed, the CMB approves and closes the CRF. The approved document is then archived.

CMB Meetings

Each week, CMBs are scheduled to meet separately by APF to review and discuss change request documents. CMB members and the change requester are required to attend this meeting, as well as other individuals and groups as needed, so that all comments and concerns can be effectively discussed and resolved.

Conclusion

The ECM process can be time-consuming and complicated. The DTR SOP is therefore designed to manage change requests for ORF-owned facility systems and equipment supporting operational APFs. The SOP utilizes a risk-based approach and collaboratively engages all stakeholders to ensure both that their concerns are reviewed and mitigated prior to execution and that there is sufficient post-execution assessment and documentation to demonstrate whether the cause(s) of the change request have been satisfied.

References

1. DTR-SOP-10004: Engineering Change Management for Facility Operation and Maintenance of Aseptic Processing Facilities.
2. DTR-SOP-10004, Appendix 1, Engineering Change Management Flow Diagram
3. Currently under development, this step is being updated in DTR-SOP-10004 (rev. 3) and will be automated via FCIS CCSA application (https://dtrdata.orf.od.nih.gov/ccsa).