

Lessons Learned Procedure on Aseptic Processing Facility Projects

Introduction

The Lessons Learned procedure is intended to provide feedback on events that happened during a project which may be beneficial to future projects. At project initiation, the Contracting Officer Representative (COR) is responsible for reviewing and implementing relevant Lessons Learned from previous projects into new projects.

Meetings

There are two types of meetings that can be used during a Lessons Learned process: Interdepartmental Meetings, conducted between two or more departments; and Intradepartmental Meetings, conducted within a department. The intent of these meetings is to collect the Lessons Learned data from previous successes and failures that can be transferred to other Aseptic Processing Facility (APF) projects, facilities, and programs. These meetings can be held in-person or virtually and should be held at the end of at least the Construction and Project Turnover Phases (e.g. a minimum of twice per project). All observations and suggestions need to be fully documented during these meetings.

Roles & Responsibilities

A person or department should be appointed the role of facilitator to lead and coordinate the procedure efforts for a project. The facilitator also supports the department(s) meeting sessions if needed and will develop the Lessons Learned Summary Report for senior management.

The Lessons Learned procedure requires participation from all involved parties within an organization throughout all phases of an APF project lifecycle, including contractors and consultants outside of the organization. These responsible parties conduct Lessons Learned sessions and review and approve the Lessons Learned Summary Report.

Lessons Learned Process

In a standardized process, a Lesson Learned should be identified, documented, analyzed, actioned, monitored, assessed, and stored in a manner and place to facilitate retrieval for the use on future projects.

Identification

A Lesson Learned is characterized by relevant phase of the project: Planning, Design, Construction, Commissioning, Qualification and Validation (CQV), or Turnover Phase. The procedure describes the requirements for conducting a survey to identify the Lessons Learned gained from executing the project; this survey is conducted at the conclusion of each phase, which helps ensure important information is captured accurately and contextually. The survey includes questions to capture information such as, asking parties to identify what went well, what did not go well, early warning signs, and improvement recommendations.

Documentation

All informational data gathered by surveys, tracking worksheets, and meetings should be documented in an organized database that is accessible to all project stakeholders. A summary report should also be generated and shared with project stakeholders and senior management.

Analysis

For Lessons Learned, the lead department will review, organize, and analyze the comments and recommendations gathered, then identify actionable items for improvement.

Action

The lead department will generate specific tasks to implement identified recommendations, including performing the necessary actions, delegating them, or referring them to the appropriate group(s) for development and implementation.

Monitoring

The lead department will monitor and report on the schedule and progress of implementing the Lessons Learned based on reporting from the assigned group(s) responsible for each action item.

Assessment

The lead department will assess the impact of action items to measure whether the changes have effectively mitigated the issue as intended, and whether an action has had any discernable unintended consequences. The lead department will work with the responsible group(s) to adjust mitigations which perform poorly, or which yield negative unintended consequences.

Storage & Retrieval

The Lessons Learned data is stored electronically in a location that is accessible for all project stakeholders, where it can be used for current and future projects. Reports are also stored in this location and may be made available on a recurring basis to senior management via email or other means.

Conclusion

It is important to implement a Lessons Learned procedure from the beginning of an APF project, and the process should be continuous throughout the life of a facility. One key factor to remember is to view Lessons Learned as a constructive procedure and not simply a process to place blame or point fingers. The focus should be on the knowledge obtained from both the successes and failures of the project and the opportunity to use the collected knowledge to create a more efficient process for future projects.

