

Client Situation

- Equipment cleaning SOPs are extremely complex and hard to follow, work flow jumps around and repeats identical information the same way or only slightly different.
- SOPs do not always follow work flow of the actual equipment cleaning steps/tasks.
- Work instructions too detailed or sometimes irrelevant.
- No defined philosophical approach to writing procedures.
- FDA observations regarding inability of operating staff to follow cleaning procedures as written.

Client Strategic Objectives

- Provide a structure and philosophical approach to writing procedures.
- Address remediation plan to redesign and simplify SOPs that are user friendly, follow process, and readied for FDA follow-up visit.
- Develop a consistent SOP authoring process to be expanded across functional areas.
- Train selected senior operating and packaging staff to write procedures.

Key Issues and Internal Barriers

- Numerous past efforts to write understandable and usable procedures with limited results.
- No guidelines for authoring SOPs.
- Excessive, irrelevant document cross references.
- Slow progress with remediation efforts and results.
- EDMS does not always fully render content when it generates PDF versions.

Key Program Components

- Develop '*Guidance for Writing SOPs*' to establish authoring consistency.
- Use a structured program to understand, revise, and finalize cleaning SOPs by:
 - Developing value stream work flows by observing the tasks and steps during the cleaning process.
 - Reviewing flows with Subject-Matter-Experts. (SMEs)
 - Revise cleaning SOPs utilizing the '*Guidance for Writing SOPs*' and process work flows.
 - Developing cleaning checklists used as a reference tool by SMEs.
- Finalize value stream work flows, '*Guidance for Writing SOPs*', and cleaning SOPs with cross-functional management team.
- Train users through hands-on application of the process with coaching.

Results:

- The 'cleaning' sections for a number of major equipment SOPs were revised and submitted to Document Services for review and approval.
- Added value stream work flows, photographs, and checklist to the cleaning sections of the revised SOPs to elevate process understanding and enhance compliance.
- Trained and coached selected manufacturing and packaging SMEs on SOP authoring process to implement for remaining cleaning SOPs.
- Conducted workshop to review the principles and justifications for using '*Guidance for Writing SOPs*' with remaining authors and reviewers in manufacturing and packaging.
- The cleaning checklist(s) designed for future migration to electronic logbooks.
- Client expanding effort to jumpstart other departments to improve SOPs.
- Client to continue utilizing Malcom to develop the initial departmental SOPs, coach, and train SMEs on the program approach and use of the '*Guidance for Writing SOPs*'.