MALCOM ASSOCIATES
OPTIMIZING DOCUMENTATION AND QUALITY SYSTEMS

Pharmaceutical Manufacturer — *Remediation - Regulatory Closure*

Client Situation

- Compliance expertise needed to address remediation commitments.
- Customer complaints and product field recalls.
- Equipment set-up procedures and Batch Records not sufficiently robust.
- Lack of equipment set-up instructions, critical parameters, and tolerances.
- Need to enhance equipment accept/reject challenges.
- Need to develop yield specifications for all Batch Records.

Client Strategic Objectives

- Redesign the equipment set-up SOPs and Work Instructions and enhance inspection criteria and increase the frequency of more robust checks.
- Improve the overall work flow in Batch Records and SOPs, define and clarify operator responsibilities and inspection requirements.
- Research and summarize yield data and include in all Batch Records the appropriate yield specifications for each product/presentation produced.
- Meet remediation commitments ahead of scheduled timeline.

Key Issues and Internal Barriers

- Additional efforts to validate the equipment and associated product specifications extending overall remediation timeline.
- Lack of methodology, resources, time constraints, and priorities of other initiatives.
- Inability of Production and QA to agree on what constitutes effective procedures and documentation for line clearance and line release for filling/packaging.

Key Program Components

- Work with mechanics to modify and enhance the equipment set-up activities, sequence of activities, critical parameters, change parts requirements, and components used.
- Organize and simplify the SOP with "*step-by-step*" instructions to improve the set-up process, lists applicable set-up points, specifications, tolerances, ranges, challenges and verification.
- Perform Line Trials to confirm the set-up process and finalize the SOPs for change control.
- Add the necessary set-up information and critical parameters to the applicable Batch Records.
- Data mining to develop accurate yield specifications.

Results and Improvements

- **Project completed on time and FDA letter of closure for commitments achieved ahead of schedule**.
- Developed 45 equipment set-up SOPs and associated Work Instructions for set-up, change parts requirements (cleaning and use), components used, parameters, specifications, tolerances, ranges, challenges and verification checks.
- Added relevant equipment setup information and critical parameters to applicable Packaging Batch to ensure the equipment and line setup conforms to the specifications.
- Modified over 280 Packaging Batch Records that;
  - Enhanced inspection criteria and frequency covering fill weight control, container sealing, and lot number and expiration date legibility.
  - Added additional challenges to comply with §211.68 to confirm that the automated equipment properly performs the specified operation.
  - Defined and enhanced inspection Pass/Fail criteria and action to take if a criterion is not met.
  - Improved line release and line clearance procedures and provided training to line leads and QA personnel on how to effectively perform line clearances.

As a result of Malcom's remediation program, the client now has the necessary equipment setup instructions and Batch Records to ensure that the equipment setup and the packaging line operation will produce a quality product that meets specifications and customer expectations.

Client Quotes

"I didn't think we would be able to meet the schedule on the Batch Records that had been committed to, but we did it, a number of them have been approved and are in use and the response from the operators and QA has been very positive."

Operations Director

"I like the fact that everything is now in the setup SOP. Previously, the specifics covering equipment setup was not available, so there was a lot of trial and error and time spent trying to get the lines ready to run."

Senior Setup Mechanic

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