MALCOM ASSOCIATES
OPTIMIZING DOCUMENTATION AND QUALITY SYSTEMS

Diagnostic Test Kit Manufacturer — *Batch Record Redesign & Simplification*

Client Situation

- Demand for test kits increase due to regulatory approvals in foreign markets.
- Batch Record content, sequence, and flow does not fully follow actual process.
- Batch Record requires unnecessary and redundant data entries.
- High percentage of Batch Record errors and missing entries leading to extended Product Release times affecting speed to market.

Client Strategic Objectives

- Reduce Batch Record errors and Batch Record review and Product Release cycle times.
- Develop a Batch Record model with guidelines that can easily be used as a design and template for future products.
- Reduce training time for current and new operators and QA reviewers.
- Focus more time on the process, not the documentation.
- Keep costs in line and prepare organization to meet current demand without hiring additional QA review personnel.

Key Issues and Internal Barriers

- Providing a Batch Record that supports speed to market.
- Resource, workload, time constraints, and lack of redesign expertise.
- 36 Batch Records per lot with different documentation, work instruction, and data requirements.
- Lack of process control specifications stated in Batch Records.
- Difficulty training current and new personnel quickly on documentation changes.

Key Program Components

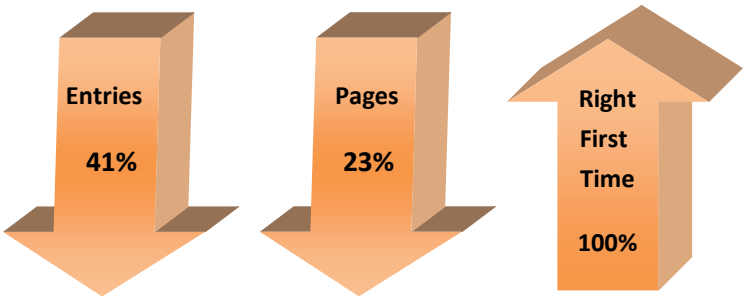
- Develop Guidance document to define documentation rules, best practices, ease of use, and consistency.
- Redesign a Batch Record that *'fits'* the manufacturing process and remove left over R&D elements.
- Eliminate redundant and unnecessary data requirements, and reduce errors.
- Reduce Batch Record review and Product Release cycle times to avoid hiring additional QA review personnel.
- Improve and reduce time to train current and new personnel.

Results and Improvements

- First redesigned Batch Record implemented (36 different Batch Records per lot) reviewed **100% "Right-First-Time" - no errors**. First time in client's history.
- Reduced number of Batch Record pages by 23%, entries by 41%, and eliminated 40% of the redundant supplemental forms.
- Error rates, review cycle times, and training time reduced.
- Developed guidance and facilitated QA and manufacturing agreement to establish rules and consistent documentation practices across all operations.
- Developed guidance document to establish rules and consistent documentation practices across operations.
- Utilized guidance document to standardize documentation rules with European affiliate.

Since implementing the redesigned Batch Record, the client has had a number of FDA audits with no observations as a result of the redesign initiative.

Primary measurable results:



Client Quotes

"On our last FDA audit, the investigator reviewed over 60 Batch Records and no errors were found. The investigator complimented us on the clarity of the records and ease of reviewing the completed documents. The audit only took 2 days versus the 5 days scheduled. I attribute this mostly due to the redesigned Batch Records that showed we took steps to improve our work flow and processes. The investment to do the redesign paid for itself and was absolutely worth it."

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