MALCOM ASSOCIATES
OPTIMIZING DOCUMENTATION AND QUALITY SYSTEMS

Vaccine Manufacturer — *Batch Record Redesign & Simplification*

Client Situation

- High percentage of Batch Record errors and missing entries contributing to extended Product Release times.
- Extended manufacturing and product release cycle times negatively impacting supply chain and profitability.
- Client attempted internal effort for over 9 months with limited success, needed direction and guidance.
- Needed a redesigned Batch Record to prepare for migration to Electronic Batch Record.

Client Strategic Objectives

- Improve content, clarify work instructions, reduce Batch Record errors, make the documents user friendly, increase *'right first time'* quality, and reduce Batch Record review and Product Release cycle times.
- Develop and implement consistent documentation rules and industry best practices.

Key Issues and Internal Barriers

- Past efforts to streamline and simplify Batch Records have not produced the expected and necessary results.
- Resource, workload, time constraints, and priorities of other initiatives.
- Lack of methodology and inability to get agreement between QA and manufacturing on what constituted *'good documentation practices'.*
- Difficulty training new personnel quickly on documentation.

Key Program Components

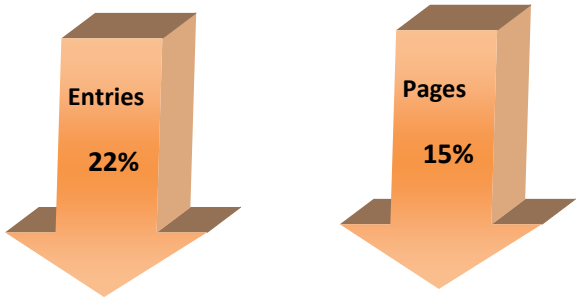
- Develop Guidance document to define documentation rules, best practices, and eliminate barriers between QA and manufacturing.
- Redesign a Batch Record that *'fits'* the actual process.
- Reduce procedural errors and potential for errors.
- Eliminate redundant and unnecessary data requirements, and forms.
- Reduce Batch Record review and Product Release cycle times.
- Reduce deviations and investigations.
- Improve and reduce time to train new personnel.

Results and Improvements

- Developed guidance and facilitated QA and manufacturing agreement to establish rules and consistent documentation practices across operations.
- Reduced number of Batch Record pages by 15% and eliminated 40% of the redundant supplemental forms.
- Reduced 22% of the data entries even after adding 10% additional data entries to address compliance issues.
- Error rates and review cycle times reduced.
- Eliminated redundant information, included clear, consistent identification of specifications to meet process requirements.

As a result of Malcom's redesign initiative, the client expanded the new redesign and guidelines to the remaining business units and products.

Primary measurable results:



Client Quotes

"I feel that the redesigned BPR (batch production record) overall, is a great improvement to our current BPR. It allows us (as Managers) to spend less time on reviewing records and more time on other important tasks."

Operations Manager

"I like the new format, it makes it easier for both the users and myself (as a reviewer), to notice where entries are required and where entries are missing, as well as easier to notice whether or not the result recorded is in compliance with the specification."

Quality Operations, Batch Record Review

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