MALCOM ASSOCIATES
OPTIMIZING DOCUMENTATION AND QUALITY SYSTEMS

Pharmaceutical Manufacturer *Improve Production Data Integrity*

Client Situation

- Site adding new high volume products due to capacity and compliance issues at another facility.
- Need to develop streamlined Batch Records for new products to expedite validation and training of personnel.
- Per lot product run is 5 to 10 days based on lot size.
- Existing product Batch Records are complex, have too many satellite forms contributing to redundancy and extended Product Release times.

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, standardize, and implement consistent documentation rules and industry best practices across product lines to improve overall data integrity.
- Define and incorporate parametric release to reduce cycle time.

Key Issues and Internal Barriers

- Speed to market.
- 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

- Improve production data integrity and cycle times by:
  - Developing Guidance document to define documentation rules, best practices, and eliminate barriers between QA and manufacturing.
  - Redesigning Batch Records that *'fit'* the actual process.
  - Improving work flow and reducing procedural errors.
  - Eliminating redundant and unnecessary data requirements, and forms.
  - Reducing Batch Record review and Product Release cycle times.
  - Reducing deviations and investigations.
  - Improving and reducing time to train new personnel.
  - Developing Batch Records to support implementation of data collection and monitoring system (DCS).

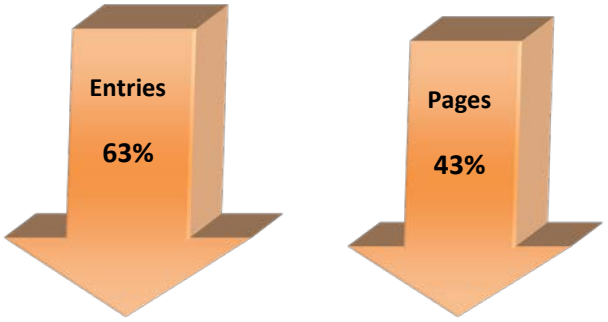
Results and Improvements

- Developed guidance to establish rules, consistent documentation practices, and data collection across operations.
- Reduced number of Batch Record pages by 45% for solid dose products and 72% for transdermal products.
- Reduced 61% of the data entries for solid dose products and 89% for transdermal products.
- Error rates and review cycle times reduced.
- Eliminated redundant information and supplemental forms, and developed Batch Records to support DCS implementation.

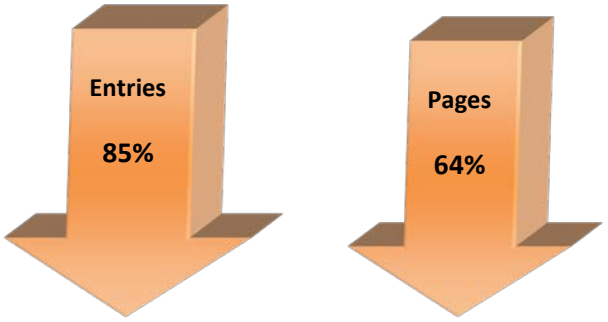
As a result of Malcom's redesign initiative, the client expanded the new redesign and guidelines to the remaining business units and products.

Primary measurable results:

Average Reduction - *Solid Dose* Products



Average Reduction - *Transdermal* Products



Client Quotes

"Great job to the team! Change is not always easy, but a good partner will bring about good change!"

Quality Operations, Batch Record Review

Tel: 859.689.5321 | info@malcom-us.com | www.malcom-us.com