

## Tissue Manufacturer

## Documentation 'Road Map' for EBR

### Client Situation

- High incidence of Batch Record/SOP related deviations.
- Poorly designed Batch Records and SOPs do not follow actual work flow.
- Cumbersome, redundant data entries in Batch Records and Forms.
- Change Control process burdened by excessive document revisions.
- Difficult to follow, complete and review Batch Records.
- Instructions in SOPs are incorrect, out of sequence, and/or poorly written, and difficult to follow.
- Difficulty migrating existing documentation and work flow to selected EBR application.

### Client Strategic Objectives

- Redesign and simplify Batch Records and SOPs to be clear, definitive, consistent, and easily understood.
- Simplify instructions, reduce data entries, number of documentation related errors, and deviations.
- Correctly define instructions and requirements for accurate execution of process steps in Batch Records for seamless migration to EBR.
- Redesign SOPs to improve instructions and align with process flow.

### Key Issues and Internal Barriers

- Past efforts to redesign and streamline documentation have not produced the expected and necessary results.
- Lack of methodology, understanding of documentation 'best practices' and immediacy of redesigning documentation to meet EBR implementation schedule.
- Ensure redesigned Batch Records comply with both 21CFR 820 and 21 CFR 1271 regulatory requirements.

### Key Program Components

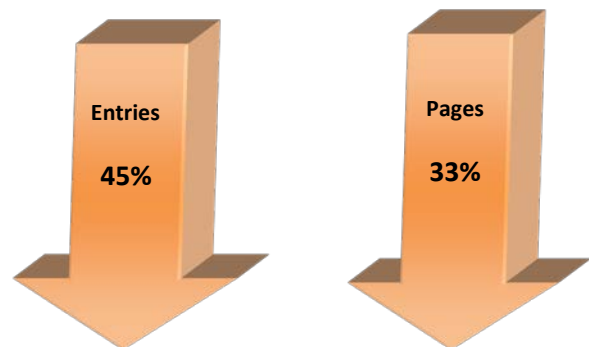
- Develop a *Guidance Document* to establish ground rules and 'best practices' for Batch Record redesign and execution.
- Design Batch Records that eliminate redundant data entries and errors, and clear step-by-step work instructions.
- Redesign SOPs that are streamlined, with clear instructions, and follow actual work flow.
- Design documentation and work flow that provides 'Road Map' for EBR definition and implementation.

### Results and Improvements

- Improved Batch Records that define process requirements/specifications and are aligned with the work flows, providing a clear 'Road Map' for EBR implementation.
- Improved and streamlined design of SOPs eliminating redundancy and with clear, active voice instructions, and simplified numbering scheme.
- 45% reduction in data entries.
- 33% page reduction for Batch Records.

As a result of Malcom's redesign program, the client's EBR implementation is on schedule.

#### Primary measurable results:



### Client Quotes

*"The improved format of the Batch Records has not only reduced the amount of entry points, reducing the possibilities of errors, but has also provided the Operator with a document that is easier to follow."*

**Production Trainer II**

*"I like that the redesigned documents are simpler to use because redundant entries and instructions were removed. I also like that the documents are easier to follow and are aligned with the actual process flow."*

**Production Supervisor**

*"Malcom Associates took proprietary interest from day one. Their experience, depth of knowledge, and determination to get it right has resulted in documentation that is compliant, easy to understand, and most importantly, approved by our sharpest critics....the people closest to the process! Job well done."*

**Manager Manufacturing Documentation & Training**