MALCOM ASSOCIATES
OPTIMIZING DOCUMENTATION AND QUALITY SYSTEMS

Contract Testing Laboratory — *GMP Enhancement Initiative*

Client Situation

- GMP Enhancement initiative to meet customer requirements.
- High percentage of documentation errors and missing entries contributing to extended testing cycle times.
- Extended testing cycle times negatively impacting customer satisfaction and profitability.
- Repeatedly attempted internal effort with limited success, needed direction and guidance.
- Needed a redesigned Batch Record to prepare for migration to Electronic Batch Record.

Client Strategic Objectives

- Redesign documentation to comply with GMP requirements to meet customer expectations and increase revenue stream by acquiring new customers.
- 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 testing cycle times.
- Develop and implement consistent documentation rules and best practices.

Key Issues and Internal Barriers

- Inability of QA and Operations to agree on minimum GMP regulatory requirements for documentation and what constituted *'best practices'.*
- Design of batch records does not facilitate training of new personnel.
- 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.

Key Program Components

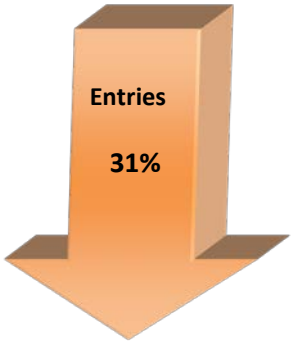
- Develop Guidance document to define documentation rules, best practices, and eliminate barriers between QA and Operations.
- Redesign a Batch Record that *'fits'* the actual testing methodology and complies with GMP requirements.
- Reduce procedural errors, deviations, and number of investigations.
- Eliminate redundant and unnecessary data requirements.
- Reduce Batch Record Review and Test Results Release cycle times.
- Enhance document flow and design to reduce training time of new personnel.

Results and Improvements

- Developed *'best practices'* guidance and facilitated QA and Operations agreement to establish rules for consistent good documentation practices.
- 31% of the data entries reduced even after adding additional data entries to address compliance issues.
- Eliminated redundant information, included clear and consistent instructions and clearly identified specifications for release of test results.
- Clarified GMP regulatory requirements for documentation and identified compliance gaps.

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

Primary measurable results:



Client Quotes

"The presentation of the redesigned records helped to provide a better organization of the information captured. In bringing consistency to how we record data we have reduced the amount of manual entries which will lessen the time spent on record reviews. On behalf of the Molecular Biology department we would like to say, Thank you."

Laboratory Supervisor

"I liked the approach and methodology, involving the SMEs from the Operations, QA and Report Writers areas working together to improve our Laboratory Records and redesign of the information flow. The redesigned Laboratory Records will support our GMP enhancement initiative, increase our lab capacity and improve right first time for us. Thank you for all your hard work and commitment."

Operations Director

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