MALCOM ASSOCIATES
OPTIMIZING DOCUMENTATION AND QUALITY SYSTEMS

Pharmaceutical Manufacturer — *Remediation and Data Integrity*

Client Situation

- FDA observations over a number of years not fully corrected. Warning Letter issued. Compliance expertise needed to address Batch Record remediation response.
- Batch Record(s) cGMP gaps, incorrect workflow, data integrity issues, inconsistent document and step references.
- Yield ranges for major process steps not established across all product lines.
- Batch Records, SOPs, SPECs, and validation not aligned.
- Corporate and site Good Documentation Practice (GDP) SOPs not aligned.

Client Strategic Objectives

- Redesign, simplify, and address compliance gaps in the Batch Records.
- Improve the overall work flow in Batch Records and SOPs, define, add, clarify, and/or remove operator tasks.
- Standardize documentation and data requirements where applicable across all business units.
- Develop classifications and metrics for *"right-first-time"* and GDPs.
- Eliminate all data integrity issues and gaps identified.

Key Issues and Internal Barriers

- Culture of accountability and elimination of mentality *"this is always how we have done it for years"*.
- Lack of methodology, resources, and knowledge base to address Batch Record and procedural compliance gaps.
- Information (data, documentation, employee *"tribal knowledge"*) to justify current requirements difficult to ascertain with current systems.
- Backlog of deviations delaying product release.

Key Program Components

- Work with corporate to revise definitions and eliminate unnecessary GDPs not required by cGMPs.
- Organize and simplify the SOPs with "*step-by-step*" instructions to improve line clearance, set-up and in-process checks, challenges, and verifications.
- Design Batch Records to follow the actual process, comply with cGMPs and remediation commitments.
- Data mining to develop accurate yield specification ranges.
- Train site personnel on enhanced documentation and procedural requirements.

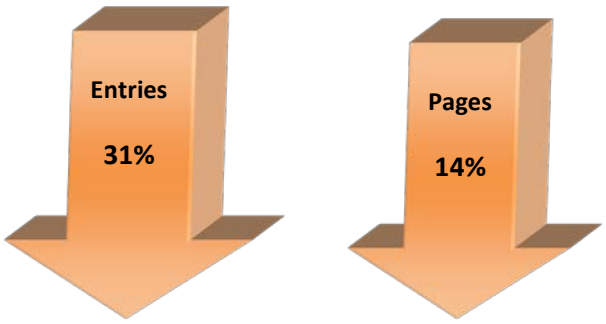
Results and Improvements

- Added information and data capture to the Batch Record that complies with cGMPs, data integrity, and process requirements.
- Addressed systemic and potential validation issues, reject classifications and trending, and elimination of non-value-added steps.
- Steps eliminated based on previous assessments and redundancies.
- Added equipment set-up and first piece inspections to ensure product conforms to the specifications before proceeding with production.
- Removed obsolete and revised incorrect document references in the Batch Records and SOPs.
- Developed a standard format and documentation requirements for Batch Records.
- Partnered with Regulatory Affairs to justify removal and adjustments to steps and current reported data collection.
- **Even with added steps and data points, reductions were achieved.**

As a result of Malcom's Batch Record Redesign remediation program to date, the client is continuing to utilize Malcom's services to redesign and simplify the remaining product batch record and SOP documentation.

Primary measurable results to date:

Total Average Reduction - Products Redesigned



Client Quotes

"I was surprised we were able to get our regulatory group to agree with some of the recommended changes and justifications proposed to the Batch Records. A credit to Malcom Associates and the redesign team.

Associate Director of Operations

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