MALCOM ASSOCIATES
OPTIMIZING DOCUMENTATION AND QUALITY SYSTEMS

Cell and Gene Therapy — *Preparing for Increased Demand*

Client Situation

- Regulatory approvals increasing demand for new, unique patient specific product.
- Batch Record and Work Procedure not synchronized resulting in data integrity and production issues.
- New staff being added to provide 24-7 coverage and additional production.
- Corporate initiative to improve data integrity.
- Implementation of MES stalled due to complex workflow and batch documentation.

Client Strategic Objectives

- Reduce Batch Record errors and define data requirements.
- Improve compliance with the corporate mandate for data integrity.
- Simplify the transition from laboratory/start-up documentation to commercial documentation.
- Simplify and optimize the workflow in the Batch Record and Work Procedure.
- Reduce Batch Record review cycle time.

Key Issues and Internal Barriers

- Time critical manufacturing process.
- Change controls to accommodate corrective actions, and US and other regulatory agency requirements.
- A clean-room environment with 2-person teams.
- Shared equipment that cannot be allocated to more than one batch at a time.
- A 150+ page Batch Record and a 200+ page Work Procedure workflow not synchronized.
- A Work Procedure that mixes sequential steps with bulleted lists that can be completed in any order.
- A Work Procedure that is hard to read in clean-room environment and lacks appropriate step references.
- Leveraging SAP or MES (electronic equipment log book) data and signature capture.

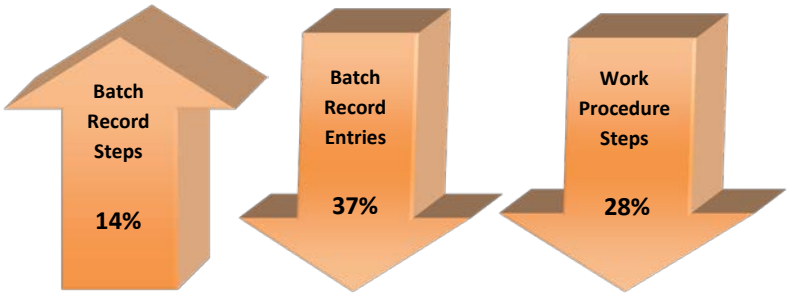
Key Program Components

- Develop a guidance document that defined signature rules to leverage database applications (i.e., SAP and MES equipment logbooks)
- Redesign a Batch Record to improve and meet corporate and regulatory requirements for data integrity.
- Eliminate or simplify satellite forms.
- Test each Batch Record/Work Procedure document to confirm workflow, data accuracy, and instructions.

Results and Improvements

- Added 'Witness' as a 3rd role for batch record sign-offs. This role is primarily used to record fleeting data not otherwise captured, (e.g. times, weights/volumes). No additional staffing was required.
- Added pre-cleaning and post-cleaning batch record steps for shared equipment.
- Synchronized the step numbers between the Work Procedure and Batch Record.
- Replaced bulleted lists in the Work Procedure with alpha-characters to identify sequential steps and to improve references to specific instructions.
- Streamlined links/references in the Work Procedure where logic paths were convoluted and subject to misinterpretation.
- Eliminated the requirement to reconcile in-process WIP and LIMS labels. Added requirements to specifically check the batch number on each label against the batch record at receipt of the labels.
- Prepared Batch Record and workflow for MES deployment.

Primary measurable results:



Client Quotes

"Well Done! Thank you all for all your hard work. This was a very successful project."

Site Quality Head

"After conducting the first test of the batch record we knew it would reduce errors and significantly help with training all the new operators."

Process Improvement Lead

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