

Medical Device Manufacturer

Prepare for Product Transfer/ 87% Reduction in Error Rates

Client Situation

- Increase in sales with launch of new products.
- Needed better clarity in manufacturing documents for transfer of products to off-shore manufacturing.
- Needed guidelines for creation of Device History Records (DHRs) and writing Work Instructions.
- Needed documentation and work flow to align with Electronic Device History Record (EDHR) initiative.

Client Strategic Objectives

- Clarify work instructions, make DHR user friendly, and reduce documentation and procedural error rates.
- Prepare DHR and Work Instructions for easier transition of off-shore transfer of product manufacturing.
- Reduce timeline for definition, requirements planning, and document migration to EDHR.

Key Issues and Internal Barriers

- Small manufacturer experiencing rapid growth in volume.
- Initial work instructions written by Engineering with little input from the work force.
- Drift between the procedures expressed in the Work Instructions and actual practice.
- Resource, workload, time constraints, and priorities of other initiatives.
- Difficulty training new personnel quickly on a very manual manufacturing process.

Key Program Components

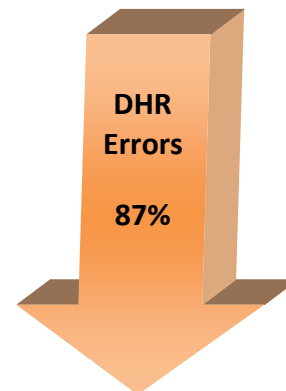
- Develop a Guidance document to define documentation rules and best practices for creation of DHRs.
- Develop a Guidance document to define format and rules for composition of Work Instructions.
- Redesign the DHR to better comply with GMP, and various international regulations.
- Edit Work Instructions to improve illustrations, user understanding, best manufacturing practices, and compliance with engineering requirements.
- Improve DHR review cycle times.

Results and Improvements

- Developed 2 guidance documents, one for DHRs, and one for Work Instructions to facilitate product transfer.
- Redesigned 7 History Records.
- Redesigned 51 Work Instructions into 58 Manufacturing Process Instructions.
- Added over 300 new illustrations to the Manufacturing Process Instructions for clarity, ease of use and off-shore training.
- Eliminated redundant information, included clear, consistent identification of specifications to meet process requirements.
- Client expanded the new redesign and guidelines to the remaining business units and products.

Client monitored DHR error rate metrics for 6 months after implementation. As a result of the Malcom documentation redesign program, there was an 87% average reduction in error rates per DHR executed.

Primary measurable results:



Client Quotes

"Congratulations to our personnel and the Malcom team on great execution of the project. This will be key to our ability to meet our quality and manufacturing goals as we grow in the coming years."

VP Operations