



RCA Case Study

Quality Systems

Technical File
Remediation

Background

A Notified Body warned a large medical device company that their ISO certification would be withdrawn unless serious inadequacies in the Technical Files supporting their products were addressed in a timely manner. ISO certification withdrawal would mean that the CE-Mark could no longer be applied to product labeling, and the products could no longer be sold in countries where the CE-Mark is required.

Challenge

Regulatory Compliance Associates, Inc. (RCA) was contracted to provide program oversight as well as teams of resources, spread across several design centers and manufacturing sites, to coordinate the required remediation activities.

Due to the extent of remediation needed, a phased risk-based implementation strategy was used to ensure efficient progress in accordance with budget limitations.

Approach

RCA led and resourced remediation teams in the following areas:

- Customer Requirements
- Risk Management – Use, Design & Process
- Sterilization Validation
- Design Validation Testing
- Essential Requirements Checklist
- Product Specifications
- Design Verification Testing
- Shelf Life Testing – Product & Package
- Process Validation

Remediation included gap analyses, development and execution of test protocols, risk analyses and updating of documentation as required to support the Technical Files for each Product Family.

Result

Technical Files for each product family were updated as comprehensive testing and documentation was completed. The Notified Body was satisfied with the program progress and the quality of remediation accomplished, and withdrawal of ISO certification was avoided.

References

1. ISO 13485 (2003) Medical devices – Quality management systems – Requirements for regulatory purposes
2. ISO 11137 (2006) Various Parts – Sterilization
3. ISO 14971 (2007) Application of Risk Management to Medical Devices
4. ISO 11607-2 (2006) Packaging for Terminally Sterilized Medical Devices Part 2 – Validation Requirements for Forming, Sealing and Assembly Processes