REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

EU MDR Compliance and Regulatory Submission

Client

Global medical device organization based in USA.

Industry

Medical Device

Business Challenge

EU MDR Preparation and Submission

Project Timeline

Regulatory Documentation - 4 Weeks

Clinical Evaluation Report - 6 Weeks

EU MDR Submission - 4 Months

Client Challenge

A global medical device firm needed to meet the May 26, 2021 regulatory EU MDR compliance deadline. Collecting the reference documentation from suppliers was a challenge based on localities. Based on the new CE mark regulatory articles, the client moved from a self-submission regulatory status to a Class 1 device and the new regulatory information needed.

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RCA Approach

Preparation and consulting time was spent with the client's leadership team to create a cohesive strategy based on the new EU MDR regulatory environment. Training meetings were conducted between RCA and the client to explain the new changes from MDD and MDR, and what path to regulatory compliance was needed. The current state assessment involved Design History File and current state of QMS.

A Project Plan was developed that outlined the development or revision of 12 Standard Operating Procedures, and development of complete design history files for 3 current/legacy product families. Clinical Evaluation Reports were conducted for three product families to help the client better determine their new MDR classification.

The client's QMS was investigated to confirm alignment between the quality manual and existing standard operating procedures. Documentation had been located in many places and lacked the efficiency of a culture of quality.

RCA increased the efficiency of the client's documentation process so a single hub of information was available for future assessments or audits. Change control processes were implemented to improve how revisions of SOP's and quality records followed the updated MDR regulations.

Results

The client's EU MDR submission for the three product families was successfully delivered on time. The client was able to continue their business as normal operating conditions in each global market.

Packaging validation was also optimized based on improved procedures that met the new MDR regulatory guidelines. Supply chain partners and suppliers were educated on the client's new requirements for optimized validation protocols. Finally, RCA helped the client identify additional opportunities to optimize their QMS and portfolio decision analysis based on the new regulatory environment. This led to a portfolio analysis of where expansion opportunities may exist based on the current certification approval.

Client Takeaways

- Technical file for EU MDR submission was optimized including generation or updates for every element of the file.
- Client is now moving toward ISO certification
- One of the client's suppliers was impressed with RCA in working with our team. This led to additional assessment projects with vendors in the client's model.
- The client enjoyed working with the entire RCA team and vendors who were apart of the process have now engaged RCA to help their organization.