REGULATORY COMPLIANCE ASSOCIATES®

A Nelson Labs company

Implementation of the EU MDR (2017/745) Requirements

Founded in 2000

Expertise backed by over 500 SME's

Headquartered in Southeastern Wisconsin

Florida, Colorado and Eastern Europe

ISO 9001:2015

At RCA, we provide worldwide services to the pharmaceutical, medical device, biologics, combination products, and compounding pharmacies industries for resolution of compliance and regulatory challenges.

Our backgrounds include every facet of R&D, operations, regulatory affairs, quality and manufacturing. We are used to working on the front lines and thriving in the scrutiny of FDA and globally regulated companies.

As your partners, we can assist with the following services related to the EU MDR requirements:

- **Review of Product Portfolio**
- **Staff Augmentation**
- **Gap Assessment of QMS**
- **Remediation and Implantation**

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Perform a Comprehensive Review of Client's Entire Product Portfolio

- Confirm whether Products have been affected by the MDR Definitions and/or Reclassification of certain types of products
- Prepare Product Rationalization Strategy Reports
- Check the status of MDD Certificate expiry dates and prepare an EU MDR Certificate Compliance Strategy for each product

Remediation and Implementation of EU MDR Compliance Plan

- Supply Chain Requirements
- Development/Implementation of an EU MDR Compliance Plan for systems and devices
- Remediation of EU MDR Compliance Gaps
- Development/Implementation of EUDAMED Database compliance plan

Staff Augmentation

- Readiness Audits / Pre-Certification Audits and/or Assessments

Perform a Gap Assessment of the current Quality Management System (QMS) and its Current Processes and Procedures Compliance

Technical Documentation Requirements

- Labeling
- FDA Unique Device Identification (UDI) System
- Data entered into the EU MDR EUDAMED Database
- Clinical Data
- Post-Market Surveillance System (PMS)
- Vigilance Activities
- Market Surveillance Activities
- Safety and Performance

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