Razalution

YOUR ULTIMATE BUSINESS ORACLE

COURSE DESIGN DOCUMENT & AGENDA

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EU MDR Transition Training (Europe's Medical Device Regulation 2017/745)

3 DAYS

Purpose

The new European Union Medical Device Regulation (EU MDR) and In Vitro Diagnostic Device Regulation (IVDR) present the first major changes to the EU medical device regulatory environment in more than 20 years.

The two regulations replace the three existing Medical Device Directives. Learn about the significant new requirements found in the EU MDR, their impact on manufacturers, and how to plan a transition to comply with these requirements.

Target Audience

Intended for medical device professionals working for manufacturers, distributors, importers, and other related parties that market (or plan to market) devices in Europe. Designed for professionals in quality and regulatory affairs, as well as personnel involved in design, risk management, postmarket activities, R&D, and manufacturing. The new regulation expands the organization's quality management system into new functions impacted by the regulatory requirements, such as production and postmarket activities.

Major Topics Covered

The objectives of the EU MDR, including the significance of replacing directives with a regulation.

- Quality management system requirements in the EU MDR
- Device classification and conformity assessment route changes in the EU MDR
- Technical documentation requirements in the EU MDR
- Clinical evaluation process requirements in the EU MDR
- UDI and traceability requirements in the EU MDR
- Postmarket surveillance and reporting requirements in the EU MDR
- Life-cycle review of products linked to risk management and clinical evidence
- Auditing impact of the EU MDR

Learning Objectives

At the end of this workshop, participants will be able to:

1. Describe the objectives and structure of the EU MDR.
2. Identify the key differences between the requirements found in the existing directives and the EU MDR.
3. Explain the impact of the new EU MDR requirements on economic operators, including manufacturers.
4. Describe the different regulatory requirements through the life cycle of a device (e.g., premarket, design and development, product realization, and postmarket).
5. Identify the necessary steps to prepare an organization to transition to the EU MDR.
6. Plan a gap assessment to transition an organization to compliance.

Highlighted Handouts

- Matrix of Annex I Requirements (MDD Essential Requirements Compared to EU MDR General Safety and Performance Requirements)
- EU MDR Transition Quality Plan Tool
- Spiral-bound copy of the regulation, its annexes, and a glossary of EU terms written in plain language

Daily Agenda

Class will begin at 8:00 a.m. every day.

Morning and afternoon breaks will be given at appropriate times.

Day 1			
Module	Topics	Methods	Time
Section 1: Welcome and Course Overview	• Introductions • Overview of course and objectives	Presentation, discussion	8:00-8:30 a.m.
Section 2: Introduction to Reasons driving the European Union Medical Device Regulation (EU MDR) the Medical Device Regulation (MDR)	• Reasons driving the European Union Medical Device Regulation (EU MDR) • the Medical Device Regulation (MDR) • The transition timeline • Compare the MDD and EU MDR structures • Major entities and roles in the EU MDR • An overview of major changes in the EU MDR and quality management system linkages • EU MDR Implementing Acts and other updates	Presentation, discussion	8:30-10:15 a.m.
EXERCISE	• Check Your Understanding	Exercise	10:15-10:45 a.m.
Section 3: Quality Management System Requirements	• Impact of the EU MDR and ISO 13485:2016 on the quality management system (QMS) • Relationship between ISO 13485 and EN ISO 13485 • QMS requirements in the EU MDR • Roles and responsibilities for QMS implementation and requirements • Describe a roadmap for EU MDR compliance and ISO 13485:2016 conformance	Presentation, discussion	10:45 a.m.- 12:00 p.m.
LUNCH			
WORKSHOP	• Assessment of EU MDR QMS Requirements	Exercise	1:00-1:45 p.m.
Section 4: Premarket Activities	• The risk-based approach to classification for medical devices in the EU MDR • Changes related to device classification and new classification rules • Changes related to conformity assessment routes • Additional requirements for high-risk devices	Presentation, discussion	1:45-3:45 p.m.
WORKSHOP	• Assess Impact of Premarket Requirements	Exercise	3:45-4:45 p.m.
Daily Wrap-Up •	• Questions and answers • Daily evaluations	Discussion	4:45-5:00 p.m.

Day 2

Module	Topics	Methods	Time
Daily Check-In	• Review of previous topics for understanding • Additional discussion on significant topics	Presentation, discussion	8:00-8:15 a.m.
Section 5: Technical Documentation	• EU MDR changes from the existing technical file requirements • Technical documentation structure/contents • New requirements found in the general safety and performance requirements (GSPR) (Annex I) • Technical documentation and postmarket surveillance • Role of common specifications (CS) and harmonized standards • Use of life-cycle management strategies to maintain device compliance to the EU MDR	Presentation, discussion	8:15-10:00 a.m.
WORKSHOP	Examine and Apply Selected GSPR Requirements	Exercise	10:00-11:00 a.m.
WORKSHOP	Assess Technical Documentation Requirements	Exercise	11:00 a.m.- 12:00 p.m.
LUNCH			
Section 6: Clinical Evaluation	• Role of MEDDEV 2.7/1 rev. 4 in EU MDR compliance • EU MDR and: – Clinical evaluation – Device equivalence – Clinical evidence – Clinical literature searches – Clinical investigations – Clinical investigation data system – Reporting clinical investigation adverse events – Clinical evaluation report (CER) – Postmarket clinical follow-up (PMCF)	Presentation, discussion	1:00-3:45 p.m.
WORKSHOP	• Clinical Evaluation Requirements	Exercise	3:45-4:45 p.m.
Daily Wrap-Up	• Questions and answers • Daily evaluations	Discussion	4:45-5:00 p.m.

Day 3			
Daily Check-In	• Review of previous topics for understanding • Additional discussion on significant topics		8:00-8:15 a.m.
Section 7: Unique Device Identification (UDI)	• UDI traceability requirements in the EU MDR • UDI responsibilities and impacts on economic operators • UDI electronic system and Eudamed • Global impacts of UDI systems	Presentation, discussion	8:15-9:15 a.m.
EXERCISE	• UDI Assignment and Placement	Exercise	9:15-9:45 a.m.
Section 8: Postmarket Activities	• EU MDR postmarket surveillance system and reporting requirements, including: – Vigilance reporting – Trend reporting – Serious incidents and field safety action • EU MDR postmarket requirements in Annex III Part B (technical documentation) • Role of the Eudamed database in postmarket surveillance	Presentation, discussion	9:45-11:15 a.m.
WORKSHOP	• Postmarket Surveillance Requirements	Exercise	11:15 a.m.-12:00 p.m.
LUNCH			
Section 9: Impact on Auditing	• EU MDR requirements for Notified Bodies and their impact on manufacturers • Describe how Notified Bodies will audit under the EU MDR, including assessing the QMS, technical documentation, clinical evaluation, and performing product verification • Certification under the EU MDR, including: – Surveillance assessments – Unannounced audits • Impact of Notified Body requirements on internal audits	Presentation, discussion	1:00-2:00 p.m.
WORKSHOP	• Develop a Strategy for Notified Body Audits of Selected Activities	Exercise	2:00-2:45 p.m.
Section 10: Making the Transition	• Steps to prepare for a transition to the EU MDR • Link internal audit function to EU MDR transition planning • Best practices for EU MDR transition planning and implementation • Group Activity: Identify responsibilities for planning the EU MDR transition	Presentation, discussion	2:45-4:00 p.m.
Wrap-Up	• Open discussion • Q&A • Course evaluations	Discussion	4:00-5:00 p.m.

Razalution Bureau Profile

Razalution Bureau is a brainchild of Salman Raza, a visionary and reformist at heart who has a passion for assisting companies and developing win-win partnerships. Through professional development and academics (MEng, MBA, MS) over the last two decade he has conquered medical device regulations, management systems, strategy and organizational culture awareness. As the founder and Principal Consultant of Razalution Bureau, Salman is assisting start-ups and helping mid-market growth firms realize their potential, by providing 360 degrees in services i.e. from vision, strategy, management system development, and regulatory strategy to effective team development through harmonized & productive work culture.

Razalution facilitate our clients to:

- Understand /fine tune their vision, and identify their 'value proposition'
- Formulate their short- and long-term competitive strategy
- Develop their management system
- Formulate (medical devices) regulatory compliance strategy
- Conduct 3rd Party regulatory and quality management system audits in accordance with ISO 13485;2016, MDSAP:2017 and MDD 93/42/EEC & MDR 2017/745 etc.
- Technical Documentation Preparation for CE Mark assessment (medical devices).
- Soft-skills development through personality and cultural awareness.
- International and Organization Culture Awareness through Hofstede Cultural Dimensions.

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MANAGEMENT SYSTEMS*

- General Consultancy
- System Development
- Process Improvement / Problem Solving
- System / Process Audits [2nd / 3rd Party Audits]
- Customized Training

STRATEGY FORMULATION

- Innovation Strategy
- Value Proposition Identification
- Competitive Strategy
- Strategy Formulation Process
- Customized Training

ORGANIZATION CULTURE

- Leadership Development
- Induction Management
- 'Life's Non-Conformities' Awareness
- Intercultural Dimensions [Hofstede Model]
- Customized Training

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For further information about Razalution Bureau , please visit www.razalution.com or call +1 832 704 8169.

