REGULATORY SATURDAYS

NEW BATCH

EU-MDR SIMPLIFIED!

Master the EU-MDR Essentials in 6 weeks!

6 SESSIONS - EVERY SATURDAYS
9:30 AM TO 11:30 AM EDT
MAY 10, 2025 - JUNE 14-2025

1 MASTERY SESSION - JUNE 15, 2025

JOIN FROM ANYWHERE IN THE WORLD!
Check your timezone in the Website

JOIN US TODAY

Master the EU-MDR step by step in bite-sized modules during your weekends.

Commit just 2 hours every Saturday to meet your learning goals, then enjoy the rest of your weekend with no regrets.

Wondering how your 2 hours will fly by?

Segment 1: Topic Presentations

Clear, structured insights into key EU-MDR concepts.

See Breakdown in Appendix 1.

Segment 2: MDR in Action

Engaging real-time examples, scenarios, demos, and hands-on activities

Segment 3: Quiz Time

Test your knowledge and track your progress with interactive quizzes.

Bonus: After Hours Q&A

An extra 20 minutes after each class for live questions and deeper discussion

REGSTALK

WHY CHOOSE US?

- High Quality Lectures
- 16 hours live Training
- 6 Quizzes - 20 questions each
- 2 Practice Tests - 120 questions each
- Access to training materials
- Live demos & real-world MDR scenarios
- Hands-on EU-MDR Assignments
- Forum For Collaboration & Networking
- Certificate of Learning
- Customized Support & Feedback
- Missed a class? Recordings provided
- Structured to support exam prep for regulatory credentials like RCC-MDR *

PROGRAM BREAKDOWN

Appendix 1

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Module 1 - Foundations of EU-MDR

Overview of EU-MDR Structure - Background - Key Bodies - Key Definitions - Placing on the market - Putting into service - Harmonized Standards - Common Specifications - General obligations of Manufacturers - Distributors - Importers - AR- PRRC

Module 2 - Step-by Step EU-MDR Implementation

Steps for EU-MDR compliance - Classification Intro- Selecting conformity assessment routes Intro - QMS - GSPR (Annex I) - Tech Doc Intro (Annex II & III) - EU- DOC (Annex IV) - CE Marking (Annex V) - Notified bodies

Module 3 - Classification, Tech Doc, Conformity assessment

Classification rules with examples, Tech Doc requirements (Annex II & III) - Conformity assessment routes - Annex IX, X, XI with practical cases - Conformity certificates - Consultation procedures

Module 4 - Registration & Clinical Evaluation

Device registrations - Economic operators - Introduction to UDI - SSCP (Article 32)- Custom made devices - Basics of Clinical Evaluation (Annex XIV)- Clinical Investigations

Module 5 - Clinical Investigations

Clinical investigations (Annex XV) - Informed Consent Process -Conducting clinical investigations - Coordinated Assessment Procedure - Timelines - Overview of Post-market Surveillance

Module 6 - Post Market Surveillance & EU Systems

PMS Planning - PMS Reports - PSUR - Trend reporting - Market Surveillance - Vigilance reporting - Timelines - EUDAMED - MDCG - Competent Authorities - Commission - Expert panels

All inclusive Price

~~99 CAD~~ 25% OFF✅

75 CAD$

Sign up Today

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