NEW

REGSTALK

Program Breakdown

Regulatory Saturdays EU-MDR Simplified!

MODULE 01

EU-MDR Essentials: Structure, key players & Core concepts

Overview of EU-MDR Structure- Background - Key Bodies - Key Definitions & Core Concepts - General obligations of EOs Manufacturers, Importers, Distributors, AR - PRRC

MODULE 02

Classification & Conformity Assessment Foundation

8 Steps for EU-MDR Compliance- MDR Annex VIII Device Classification- Introduction to Key MDR Annexes Relevant to Conformity Assessment- EU Declaration of Conformity (Annex IV) - CE Marking (Annex V) - Notified Bodies

MODULE 03

Selecting the Conformity Assessment Route

In-depth Review of GSPR (Annex I), Technical Documentation Requirements (Annex II and Annex III)- Detailed Overview of Annex IX, X, XI- Selecting the Conformity Assessment Route- Consultation Procedures - Common Pitfalls and Best Practices

MODULE 04

Clinical Evaluation & EU Registration systems

Clinical Evaluation Basics - Clinical Evaluation Documentation (CEP/CER)- High-level template walkthrough, SSCP (Article 32), Basics of UDI - Introduction to EUDAMED - Actor and UDI Registration Requirements.

MODULE 05

Clinical Investigations

Clinical Investigations (Annex XV) - Informed Consent Process - Conducting Clinical Investigations- Required Documentation (High-Level Overview)- Roles & Responsibilities in a Clinical Investigation - Coordinated Assessment Procedure - Timelines

MODULE 06

Post-Market Surveillance

PMS Planning- PMS Reports - PSUR - Trend Reporting - PMCF - Vigilance Reporting - Timelines- Market Surveillance