Course Title: EU Medical Device Regulation (MDR) 2017/745 Fundamentals Training Course

Course Duration: 2 Days (9.30 am - 4.30 pm)

Pricing: € 785.00 per person

Format: Live - virtual.

Queries: info@thelearningreservoir.com

Course Details	
Course Description	This practical and interactive 2-day course focuses on what is required to bring a Medical Device to market under Medical Device Regulation (EU) 2017/745 (MDR). On April 5, 2017, the Medical Device Regulation (EU) 2017/745 replaced the two existing directives, the Medical Devices Directive (MDD) and the Active Implantable Medical Devices Directive (AIMDD). The Medical Device Regulation entered into force on May 25, 2021, after a four-year transition period. EU MDR compliance is accomplished by demonstrating conformity with all relevant aspects of the Medical Device Regulation (EU) 2017/745. Manufacturers will need to demonstrate compliance to gain regulatory approval of their medical devices.
Delivery Method	Taught live by an expert tutor via Zoom. You can interact with other delegates and ask questions, just as you would in a traditional classroom.
Instructor	Dr. Fiona Masterson With over 25 years' experience in quality management, operations management, and higher education, Fiona combines technical expertise with highly engaging training. She has worked in fast-paced manufacturing environments and lectures part-time in universities. She has Bachelor and Master of Science degrees, and a Doctorate in Mechanical Engineering. Her PhD focused on the regulatory pathways of bring drug/device combination products to the market in the EU and US. Fiona has published in peer reviewed Regulatory Science journals on topics such as combination product, medical device and pharmaceutical regulatory affairs.

Learning Objectives	On completion of this training, participants will be able to: • Understand the history, purpose and structure of the MDR • Understand the transition period to the new MDR • Be able to identify the types of devices covered by the MDR and the rules for classifying these devices. • Be able to identify the key steps in conformity assessment and the role of Notified Bodies • Describe the roles and responsibilities of the manufacturer, Economic Operators and the Personnel Responsible for Regulatory Compliance (PRRC) • Understand requirements for post-market surveillance, post-market clinical follow-up and vigilance. • Explain the quality management system requirements in the MDR • Understand the Unique Device Identification (UDI) requirements and the purpose of EUDAMED database
Who should take this course	This course is for medical device organizations who need a foundation in the EU MDR, specifically: • Personnel working in the medical device industry • Anyone new to the medical device industry • Personnel in quality management • Research and design engineers • Manufacturing engineers • Regulatory professionals
Course Certificate	A certificate of completion will be issued on successful course completion.
Materials	Each participant will receive course materials in the days prior to the course beginning. Please ensure you have access to these on the day.

Course Content Breakdown	
Day 1	Introduction to the MDR • History of EU medical device legislation and the EU MDR • Transition period to the EU MDR • Scope, purpose, and structure of the MDR • Key terminology and definitions • Economic Operators (Manufacturer, Authorized Representative, Importer and Distributors) • The Person Responsible for Regulatory Compliance (PRRC) role and responsibility Classification and Conformity Assessment • Classification of products • Conformity assessment procedures and the role of Notified bodies notified bodies. Exercises: Exercises will be conducted throughout the day so participants can apply what they have learned.
Day 2	Safety and Performance • Safety and performance requirements • Risk management • Design & manufacture requirements • Device information • The use of (harmonized) standards • Quality management systems under MDR Clinical data, technical documentation, and labelling • Clinical evaluation • Unique Device Identification requirements Post-Market surveillance (PMS) and Vigilance • Post market surveillance • Post-market Clinical Follow-up (PMCF) • Vigilance • Periodic Safety Update Report (PSUR) • EUDAMED Exercises: Exercises will be conducted throughout the day so participants can apply what they have learned.