EU MEDICAL DEVICE REGULATION (EU MDR) COURSES

EU MEDICAL DEVICE REGULATION (EU MDR) – A COMPREHENSIVE OVERVIEW
2 hours | Online / Virtual

This online computer-based learning course provides comprehensive instruction on the European Union Medical Device Regulation (EU MDR) 2017/745. It walks students through every aspect of the regulation and identifies key topics and changes, including the new roles associated with EU MDR, standard requirements that must be met by all manufacturers regardless of class and the requirements for conformity assessments. The module also provides premarket and postmarket requirements of conformity assessment. By the end of this course, you will be able to: (1) recognize the regulatory background in Europe, (2) identify the roles associated with the EU MDR, (3) discuss the Manufacturing Requirements of the EU MDR and (4) explain how to comply with premarket and postmarket requirements for conformity assessments.

This class is helpful for all medical device professionals, management and executive personnel looking to expand their knowledge of the EU MDR.

INTERNAL AUDITOR TRAINING, BASED ON EU MDR AND MDSAP
3 days | Instructor-led / On-site

This course is a highly interactive, practical workshop that will prepare internal auditors for the EU MDR and MDSAP requirements. Students will gain valuable knowledge on how to prepare for the upcoming changes from the MDD to the MDR. The course provides practical instruction on how to plan and conduct internal and supplier audits against the EU MDR, ISO 13485:2016 and MDSAP, as well as how to address gaps during the audit. Instruction includes how to select appropriate samples of audit evidence, and how to identify nonconformities and prepare an audit report against specific articles of the EU MDR and in accordance with MDSAP.

This class is intended for experienced internal and lead auditors seeking to expand their auditing knowledge of the EU MDR and MDSAP.

EU MDR – STRATEGIC PLANNING FOR THE COMING CHANGES
2 days | Instructor-led / On-site

Students will learn the detailed structure of the regulation via a step-by-step guide of the regulation’s chapters and annexes. Students will discuss the regulation in the context of planning their gap analysis approach, including getting tips for getting started, timelines and more, while also gaining knowledge into the impacts of Brexit.

This class is helpful for all management and executive personnel with responsibility for medical device regulatory lifecycles, involvement with the design and implementation of quality management systems or involvement with product design and development.
EU MDR – TECHNICAL FILE ACADEMY
4 days  |  Instructor-led / On-site

Students will learn the technical documentation requirements, including pre-clinical review specifics, safety and performance, risk management, use of harmonized standards, auditing and other requirements associated with the EU MDR and the notified body review requirements. Additionally, students will gain knowledge on how to (1) conduct a technical review, (2) develop a postmarket surveillance plan and (3) report nonconformities.

This class is helpful for all management and executive personnel with responsibility for medical device regulatory lifecycles, involvement with the design and implementation of quality management systems or involvement with product design and development.

DEVELOPING AN EFFECTIVE STRATEGY FOR REGULATORY COMPLIANCE – PRACTICAL WORKSHOP
1 day  |  Instructor-led / On-site (with post-workshop expert review of the strategy)

This workshop will provide detailed hands-on practical instruction on the requirements and steps to develop an effective strategy for regulatory compliance for implementing EU MDR. Students will be guided through components of a regulatory compliance strategy template and will work through developing a strategy specific to their organization.

This class is helpful for all management and staff involved in developing the strategy for regulatory compliance. Best if attended by team members from regulatory, quality, design/engineering and clinical departments.