2 Day Workshop: Preparing For The New EU Medical Device Regulations (MDR)

Date : Feb 21, 2018 - 09:00 AM

Event URL : http://www.BostonEventsList.com/events/-worldcomplianceseminars-com-seminardetails-31

Organizer : conference Manager

Venue :

Location : WCS Consulting Inc.3190 Stirling Rd, Unit K4, Hollywood, FL 33021,
Hollywood, Florida, United States, ZIP: 33021
Phone: 347 282-5400

Ticket Price: Seminar One Registration - $1,295.00 Special Group Discount Register for Four attendees - $ 3885
Course has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.

The new Medical Device Regulations (MDR) were published in the Official Journal of the European Union on May 5, 2017. From that date, manufacturers, suppliers, Notified Bodies, and national competent authorities have a transition period of three years to comply with the new set of rules. Given the large scale of changes, there is great pressure on all actors to analyze the MDR, conduct impact assessments, and implement compliant processes. After May 2020, non-compliance threatens CE-mark certification, access to the European market, or, in the case of Notified Bodies, re-designation.
The European Union released the Medical Devices Regulation (MDR 2017/745/EU) to eventually replace the Medical Devices Directive and Active Implantable Medical Devices Directive. The MDR introduces numerous changes, including a shift from the pre-approval stage to more of a life-cycle approach. It also incorporates a variety of European guidance documents (MEDDEVs) into the regulation and emphasizes the importance of Post-Market Surveillance (PMS), clinical data, clinical evaluations, and Post-Market Clinical Follow-up (PMCF). MDR compliance presents many new challenges to medical device manufacturers. Our in-depth MDR training is designed to help you and your team prepare for these challenges and transition

smoothly to the MDR.
This seminar provides a solid understanding of medical device regulation in the EU. It covers the history of medical device regulation in Europe and follows the regulatory requirements throughout the product lifecycle. You will gain a strong foundation of the key elements of the EU directives governing medical devices. These include: Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC, Medical Devices Directive (MDD) 93/42/EEC and In Vitro Diagnostic Devices Directive (IVDD) 98/79/EC in their latest revision, including the 2007/47/EC amendments to AIMDD and MDD. This course examines how devices are classified, and the effect classification has on labeling, registration, marketing and postmarketing requirements. Learn about the new requirements in the Medical Device Regulation (MDR), including those related to quality systems, product classification rules, technical documentation, clinical evaluations, Unique Device Identification (UDI), and postmarket surveillance; and more importantly learn how to plan an efficient transition.

Areas Covered

- Understand the Medical Device Regulations approach in Europe
- Understand the structure and purpose of the Medical Device Directives
- Explain the use of Essential requirements, including the use of (harmonized) Standards
- Understand the key changes upcoming in the new EU MDR
- Understand the essence of early start in the transition
- Understand how to prepare a transition plan
- Apply the Classification Criteria and Implementation rules
- Identify the conformity assessment routes
- Identify Technical Documentation requirements
- Importance and Role of Clinical Data
- Identify the importance and contents of Post Market Surveillance
- Explain and differentiate between the scope of the three EU device directives
- Outline how medical devices are classified using the European regulatory framework
- Identify the important contents of each EU directive
- Discuss the general requirements of preclinical and clinical testing in Europe
- Describe the conformity assessment pathways for obtaining CE marking
- Cite the key requirements for postmarketing surveillance
- Explain the overall regulatory requirements for medical devices in the EU
- Comply with the implementation details and requirements of the EU MDR & IVDR
- Develop a “systems approach” for data usability/management
- Label and mark your products
- Internalize the core data elements
- Distinguish the similarities and differences
- Seminar attendees are encouraged to bring examples of their work from the functional area on the various topics as applicable for group discussion
- Review and discuss pain points, challenges and solutions
- Current and future trends

Who will Benefit

This seminar is designed for new regulatory professionals and others in related departments interested in understanding the basics of EU regulation of medical devices and the impact on medical device companies. Participants and attendees will be provided with a stimulating and practical working environment.

- Senior Management
- Regulatory Affairs Managers and Quality Managers
- Design, Development, Manufacturing and Marketing Managers
- Auditors
- Compliance/Regulatory affairs professionals
- QA/QC professionals
- Manufacturing managers, supervisors
- Project Managers
- Compliance Officer
- Compliance Specialist
- Clinical Affairs
- Marketing & Sales Management
- Distributors/Authorized Representatives
- Legal Counsel
- Consultants

Learning Objectives

- Class I, II and III/In Vitro Diagnostic medical device manufacturers
- Contract medical device manufacturers
- Contract sterilizers
- Repackagers, relabelers, specification developers, reprocessors of single-use devices
- Manufacturers of accessories and components sold directly to the end user
- U.S. manufacturers of "export only" devices
- Distributors
- Importers
- User Facilities (e.g., hospitals, nursing homes)

Event Categories :