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

Date : Feb 21, 2018 - 09:00 AM

Event URL : http://www.BostonEventsList.com/events/2-days-workshop-preparing-for-the-new-eu-medical-device-regulations-mdr-feb-2018

Organizer : wcsseminars

Venue : Burlingame

Location : WCS Consulting Inc.3190 Stirling Rd, Unit K4, Hollywood, FL 33021, Hollywood, Florida, United States, ZIP: 33021

Ticket Price: Seminar One Registration - $1,395.00 Special Group Discount Register for Four attendees - $ 3885

Description

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.

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

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

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 :