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EVENTS LIST

The New EU Medical Device regulation

Date : May 17, 2018 - 09:00 AM - May 18, 06:00 PM

Event URL : http://www.sfbayeventslist.com/events/the-new-eu-medical-device-regulation-may-2018

Organizer : GlobalCompliancePanel

Venue : Hilton Zurich Airport

Location : 1 Main St,
Los Angeles, CA, US, ZIP: 00000

Regulation proposals of the European Commission Background

In 2012, the Commission adopted a package of measures on innovation in health. The package consisted of a Communication and two regulation proposals to revise existing legislation on general medical devices and in vitro diagnostic medical devices. In particular, the Directives on active implantable medical devices (90/385/EEC) and on medical devices (93/42/EEC) are intended to be replaced by a Regulation on medical devices, while the Directive on in-vitro diagnostic medical devices (98/79/EC) is intended to be replaced by a Regulation on the same subject.The revisions therefore affected all kinds of medical devices including in vitro diagnostic medical devices, from home-use items like sticking plasters, pregnancy tests and contact lenses, to X-ray machines, pacemakers, breast implants, hip replacements and HIV blood tests.

This Seminar will look at what to expect when the new regulation is implemented. Including: the transition period, Effect on Notified Bodies, Impact of the MDR on Quality Management Systems (QMS), technical documentation, clinical trial requirements, UDI and combination products.

Why you should attend:

Because the current Directive will be significantly altered and replaced by a Regulation which is legally binding on all Member States.

Areas Covered in the Session:

- The updated Regulation
- Implementation dates and transition
- Main changes and products affected
- Effect on medical device manufacturers

Who will benefit:

- Clinical Trial Managers
- Regulatory Affairs
- Medical Officers

Day 1 Schedule

Lecture 1 (90 Mins):

The new MDR main changes

- Main updates
- Transition periods
- Effect on medical device manufacturers
- Regulatory landscape

Lecture 2 (90 Mins):

Notified Bodies under the New MDR

- Effect on NBs
- When will NBs begin conformity assessment against the new Regulation?
- Main effect on medical device manufacturers

Lecture 3 (90 Mins):

Impact of the MDR on Quality Management Systems (QMS)

- When do I need to update my QMS?
- What main points need to be considered?
- Effect on medical device manufacturers

Lecture 4 (90 Mins):

Technical Documentation

- Class I and IIa devices
- Effect on class IIb devices

- Class III devices

CASE STUDY 1 - Including a walkthrough of expected outcomes for all case study exercises

Wrap up of day 1 & Q&A's

Day 2 Schedule

Lecture 1 (90 Mins):

Clinical aspects and testing

- Class I and IIa devices
- Effect on class IIb devices
- Class III devices

Lecture 2 (90 Mins):

Periodic Safety Update reports

- Content of PSUR
- Frequency

Lecture 3 (30 Mins):

Common Specification (CS)

Common Tech Specifications

Lecture 4 (90 Mins):

Combination Products

- Definitions
- Requirements
- Technical documentation

CASE STUDY 2 - Including a walkthrough of expected outcomes for all case study exercises

Wrap up of day 2 & Q&A's

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Salma Michor is founder and CEO of Michor Consulting Schweiz GmbH, serving such clients as Johnson & Johnson, Novartis, Shire, Pfizer and Colgate Palmolive. Previously, Michor worked for Chiesi-Torrex, Wyeth Whitehall Export Croma Pharma GmbH. She teaches regulatory affairs and clinical strategies at the University of Krems, Austria, and is an independent expert to the European Commission. She holds a PhD in thermal process engineering and an MSc in food and biotechnology from the University of Applied Life Sciences in Vienna, Austria; an MSc from King's College, University of London in food technology; and an MBA from Open University, and has earned the RAC (EU), CQA and is a Chartered manager.

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