Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

The New EU Medical Device regulation

Chicago, IL

June 27th & 28th, 2018

9:00 AM to 6:00 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$4,485.00** You Save: $2,990.0 (40%)*

~~$7,475.00~~

Register for 10 attendees

Price: **$8,222.00** You Save: $6,728.0 (45%)*

~~$14,950.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

Salma Michor

PhD, MSc, MBA, CMgr, RAC

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

Overview :

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.

Agenda:

Day One

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

Areas Covered in the Session:

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

Day Two

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 (90 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

Who will benefit:

- Clinical Trial Managers
- Regulatory Affairs
- Medical Officers

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.

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
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Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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