**New EU Medical Device Regulation | Updated Regulation 2018**

**Course "The New EU Medical Device regulation" has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.**

**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. 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

**Agenda:**

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**

**Speaker**

#### 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 and is a Chartered manager.

Location: **Zurich, Switzerland** Date**: May 17th & 18th, 2018 and** Time: **9:00 AM to 6:00 PM**

**Venue**:  **Hilton Zurich Airport Hohenbuhlstrasse 10, 8152 Opfikon-Glattbrugg, Switzerland**

**Price:**

Price: $1,695.00 (Seminar Fee for One Delegate)

Register for 5 attendees Price: $5,085.00 $8,475.00 You Save: $3,390.00 (40%)\*

Register for 10 attendees Price: $9,322.00 $16,950.00 You Save: $7,628.00 (45%)\*

Register now and save $200. (Early Bird)

Until April 10, Early Bird Price: $1,695.00 From April 11 to May 17, Regular Price: $1,895.00

**Sponsorship Program benefits for “New EU Medical Device Regulation | Updated Regulation 2018” seminar**

**For More Information**- <https://www.globalcompliancepanel.com/control/sponsorship>

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