Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Combination Products

Washington, DC

October 18th & 19th, 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 and is a Chartered manager.

Overview :

This seminar provides Professionals working in this area with

- A thorough understanding of the complexities involved
- Covers all the relevant regulations and guidelines
- Gives real life examples of how to register and maintain various types of combination products
- Interfaces: Change Management and LCM
- Compliant safety reporting for combination products
- Documentation requirements and interfacing

Agenda:

Day One

Lecture 1: A high level overview to Combination Products

Including an interactive group session reviewing individual expectations

Lecture 2: Introduction to Drug/Device Regulations

During this introductory session, delegates will gain a complete guide to the status and impact of the latest guidelines for combination products. Examples (company specific) of combination products will also be discussed to gain insights into their variety and complexities. Regulatory Requirements for: US and EU

Lecture 3: CE Marking, 510 K and PMAs general Overview

- US and EU

Life Cycle Management

- Interfaces: Change Management
- CTA applications
- Annual reporting

Lecture 4: CASE STUDY 1 - Including a walkthrough of expected outcomes for all case study exercises

Wrap up of day 1 & Q&A's

Day Two

Lecture 1: Overview Combination product Regulation and CTD dossier requirements: EU and US (A comparative review)

Lecture 2: Clarifying the regulatory requirements of combination products and addressing life-cycle management

- Examining the regulatory requirements for drug device combinations in the case of a drug and a device and for integral products
- Annual reports
- Case studies

Lecture 3: CASE STUDY 2

Lecture 4: Compliant safety reporting for combination products

- Taking into account your product's combined components when addressing adverse event reporting

Documentation requirements and interfacing

- Documentation requirements for combination products EU
- Documentation requirements for combination products US
- Interfacing, development, quality, regulatory
- Managing third parties and document control.

CASE STUDY 3

Wrap up of day 2

Final Q&A & Summary of 'working smart' with Combination Products

Why you should attend :

Combination products are especially challenging to register and maintain since they consist of two or more regulated components covered by different and usually independent sets of regulations in both the EU and US and various other regions.

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
2. Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
3. PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
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What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
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5. Special price on future purchase of web based trainings.
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8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry's top notch professionals

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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