PEC PHARMA EDUCATION CENTER

## HIGHLIGHTED COURSE

# Combination Products in EU and US

April, 7 - 8 | 2022
ONLINE

# Learning objectives

After the completion of the course, participants should be able to:

- Understand how combination products are defined and classified in EU and US
- Learn how borderline products are classified in EU and US
- Understand the regulatory pathways and how to successfully navigate between drugs, devices and combination products in each jurisdiction
- Learn about the EU Medical Device Regulation impact on Combination Products
- Gain a deeper understanding of the roles of EU Competent Authorities and Notified Bodies

# Speaker

## Tina Amini

Dr. Tina Amini is the director of medical device division at NDA Group where she has been supporting MedTech and Pharma companies with their combination products, medical devices, and in vitro diagnostic devices (IVD) including companion diagnostics for both EU and US markets. Tina formerly held the positions of Head of Notified Body and Pharmaceutical & Medical Device Expert at EU Notified Bodies, where she was responsible for combination products, conformity assessment of a wide range of medical devices and onsite assessments of Quality Management Systems (QMS) as the lead auditor. Tina was also involved in the classification of borderline products, EU pre-submission scientific advice procedures for medical devices, the consultation process with several EU competent authorities and EMA for device/drug combination products. She was a member of Team-NB Working Group: Borderline issues and new technologies, Classification and borderline; Post Market and Clinical. Prior to joining Notified Bodies, Tina worked in the pharmaceutical industry on the development of medicinal products and combination products in several therapeutic areas for both US and EU markets.

# Purpose

Enhancing capabilities to develop and launch successful combination products will remain a top priority; with product usability, integrating digital platforms and general management across the total product life cycle becoming critical. However, with a regulatory landscape that is inconsistent between EU and US, remaining compliant, maintaining quality and ensuring safety requires clear, concise and consistent guidance on regulations.
This course will explore the EU and US regulatory landscape defining the key differences, similarities and provide an overview of the regulatory pathways and how to successfully navigate between drugs, devices and combination products in each jurisdiction. The course will also provide a detailed overview of impact of the EU medical device regulation on combination products and the life cycle management of combination products.

# Who should attend?

TThis Training Course is of particular interest to professionals working in:

- Quality Assurance
- Quality Control
- Regulatory Affairs
- Design and development of Combination Products
- Suppling medical devices to the pharma/biotech industry

# Program

## Day 1

9:30 **Introduction & speed networking**
9:40 **Combination Products in EU**
**• Definitions in EU**
- Combination Product
- Medicinal Product
- Medical Device
**• Legal framework**
- Medicinal product and medical device legislations
- Revision to EU Medical Device Regulation (MDR)
- Regulatory similarities and differences
**• Borderline classification in EU: Medical Device or Medicinal product?**
**• The importance of classification & its implication**
**• Decision Making on the Borderline**

**Q&A time**

10:20 **EU Market access for Drug Device Combination Products (DDCs)**
• Single integral non-reusable DDCs
• Non-integral Combination Products (kit)
• Data requirements
• Labelling requirements
• Guidance documents

**Q&A time**

11:25 Break

11:45 **Combination Products in US**
• Combination Product Definition
• History and Legal Framework
• Borderline Products
• Types of Combination Product (Definitions)
• Primary Mode of Action and FDA's Assignment Algorithm
• Jurisdiction and Designation Process for Combination Products

**Q&A time**

13:00 **Closure of day one**

## Day 2

9:30 **EU market access for Device Drug Combination Products**
• EU MDR Classification and applicable rule(s)
• Notified Body's role and obligations
• What is CE Marking?
• CE certification process at a glance
• Documentation requirements at top level

**Q&A time**

10:15 **EU MDR key changes and its Impact on Drug Device Combination Products**
• Impact on combination products regulated as medicinal product
• Article 117 and Notified Body Opinion report (NBOp)
• Notified Body selection and Interaction
• Documentation requirements
• Life Cycle management: New or updated NBOp?
- Team-NB position
- Industry perspective

**Q&A time**

11:00 **Break**

11:20 **US market access for Combination Products**
• FDA's approach to Combination Products
• Submissions and Regulatory Pathways
• Current Good Manufacturing Practice (cGMP) Requirements
• Strategies for Development of Combination Products

**Q&A time**

12:30 **Conclusion**

12:40 **Final Questions session**

13:00 **Closure of the course**

**TERMS OF PAYMENT**

Advance payment is required with respect to the event date by bank transfer to BANCO BPM Spa – Firenze, IBAN IT81P0503402801000000007431, Bic/SWIFT BAPPIT21N25 made payable to Pharma Education Center S.r.l., Via dei Pratoni 16, 50018 Scandicci (FI), VAT number 02173670486, specifying event title along with name and surname of the participant enrolling. Attendance to the event will be allowed upon payment received. Invoice of payment will be issued after the second half of the month after the course.

**For further information and/or further assistance please contact (+39) 0550465181 or email: amministrazione@pharmaeducationcenter.it**

**COURSE/EVENT CANCELLATION**

If the minimum number of participants is not reached, Pharma Education Center reserves the right to cancel or schedule the event for another date. Formal communication will be given within 5 days before the event date. In this case Pharma Education Center will refound the registration fee in full and without additional charges. Alternatively, the participant can request a spendable coupon for participating in another PEC event scheduled in the current year.

**CANCELLATION TERMS**

In order to cancel enrolment to a event, please email info@pharmaeducationcenter.it within 2 weeks before the starting date of the event. Once this term will be expired, the entire fee will be charged.

**PARTICIPANT REPLACEMENT**

It is possible to replace a participant attendance without additional cost, simply by contacting info@pharmaeducationcenter.it. It is asked to notify the participant replacement request within 5 days before the starting date of the course/event, specifying the full name and surname of the enrolled participant as well as the full name and surname of the substitute.

**HOW TO REGISTER**

Please, fill the form on the web site https://www.pharmaeducationcenter.it/

**ENTRY FEE**
850 €

750 € until March 7, 2022

Discounts are not cumulative

VAT not included

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