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CHALLENGES IN DRUG/DEVICE COMBINATION PRODUCTS

LIVE Online Academy

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Learn the key factors of successful drug/device combination products to ensure a more efficient approval process

COURSE OVERVIEW

Drug/device combination products present unique challenges. Under EU law, combination products must be registered as either pharmaceutical products or medical devices. For drug/device combinations, significant problems can arise in understanding an unfamiliar regulatory environment, product design, corporate collaborations and much else. This essential course provides useful insights into requirements for devices to improve your understanding of additional aspects to be incorporated into your dossier.

You will work with our experienced trainer to understand the medical device world as it applies to your drug/device combination, including risk management, clinical considerations and design control. The course will also feature a session on collaborating with partners in the device world to improve outcomes for your products. There will also be additional time for delegates to discuss the implications of Brexit on this subject matter.

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MEET THE TRAINER

Dr. Tina Amini

Dr. Tina Amini, a pharmacist with PhD in Pharmaceutics, is Director of Medical Device Division at NDA Group. She has over 30 years experience in Pharmaceutical and Medical Devices. She previously held the positions of Head of Notified Body and Senior Technical Specialist at LRQA Notified Body and Pharmaceutical & Medical Device Expert at bsi Notified Body, where she was responsible for Device Drug combination products, Conformity Assessment of a wide range of medical devices and onsite assessments of Quality Management System (QMS) as the lead auditor.

Tina has extensive experience of regulatory expertise for CE marking of medical devices, and has been involved in the classification of borderline products and consultation process with several EU competent authorities
and EMA for device/drug products.

Prior to joining Notified Bodies, Tina worked in the Pharmaceutical Industry in a variety of disciplines where she took products through from discovery to commercialisation.

MODULE ONE

The regulatory environment for combination products

- Medicine-Device Borderline and Classification
- Medicine and Device Regulatory Differences
- Definition of a Combination Product
- Regulatory pathway for combination products in the EU and US

Device regulations and requirements

- Overview of the current regulatory framework for medical devices in the EU
- Roles of Competent Authorities and Notified Bodies
- Impact of the MDR on Combination products

MODULE TWO

Risk management

- What is risk management
- Overview of Standard ISO 14971
- Risk management for a combination product

Labelling

- A brief overview of labelling requirements under MDR
- Labelling for combination products

MODULE THREE

Design & Development

- Expectations when designing and developing a medical device
- Development consideration for a combination product
- Perspectives by constituent part
- Human Factors

MODULE FOUR

Clinical

- Clinical evaluation per MDR requirement
- Clinical requirements for medicinal products

Post marketing Surveillance & vigilance

- PMS requirements for medical devices
- PMS requirements for medicinal products

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WHO IS THIS COURSE FOR?

This course is designed for professionals from the pharmaceutical industry who wish to gain a greater understanding of drug/device combination products, including:

- Regulatory Affairs
- Quality Assurance
- CMC
- R&D
- Project managers
- Consultants

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For information contact our training consultants

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