



TRAINING

Combination products

Duration: **4 hours** | 1 – 5:00 PM CET

Date: **March 7th 2023, Online**

Speaker: **Dr Rima Padovani**

Training objectives:

Combination Products combine two or more regulated components (i.e. drug, device, biologic), each of which, when considered individually, would be governed by different regulations. As a result, the regulatory framework of Combination Products is complex, as it often requires the involvement of different Regulatory Authorities (in the EU, Competent Authorities and/or Notified Bodies; in the US, different FDA centers), and, in some cases, may result in the so-called “borderline cases”. This training is intended to provide a thorough understanding of the regulatory framework of Combination Products in the EU and in the US, by looking at how these products are classified, how they are regulated, and who are the Regulatory Authorities implicated in the approval of clinical investigations and marketing authorizations.

Training content:

- Types of Combination Products within the US regulatory framework (single entity, co-packaged, and cross-labeled Combination Products);
- Definition of Primary Mode of Action, and how this defines the assignment to FDA lead-center, and the related type of marketing authorization;
- Corresponding definitions within the EU regulatory framework (integral products and “non-integral” products, which include devices incorporating a medicinal product and devices intended to administer a medicinal product);
- Changes introduced by the Medical Device Regulation (EU 2017/745), with a particular focus on Article 117, the assessment of the conformity of the device part, and the involvement of the Notified Body (the so-called “Notified Body Opinion”);
- Borderline cases and interaction programs with Regulatory Authorities (such as the “Request for Designation” with the FDA);
- QMS and GMP requirements (21 CFR Part 4) for Combination Products.

Training format:

- Presentations with interactive discussions
- End of training assessment

Price:



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- EUR 415 incl. course material and certificate

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