pharmakon

Navigating Drug–Device Combination Products (CP's)

Cross-functional development and lifecycle management of CPs; assess risks and interfaces

Learn how drug and device come together in development, approval, and lifecycle. Focus on risks, interfaces, and practical challenges across functions (i.e. EDDOs), with clear examples from EU and US regulatory expectations.

Drug–device combination products are products where a medicinal product and a medical device are combined into one system. These products are regulated differently across regions and require alignment across multiple functions.

In this course, you learn how development, regulatory, quality, clinical, and usability aspects interact across the lifecycle. You gain a clear overview of regulatory frameworks in the EU and US and understand how to apply them in practice.

You work with practical examples to understand common pitfalls and cross-functional risks. The course focuses on interfaces between drug and device, including risk management, usability, clinical validation, and submission responsibilities. It also introduces the role of clinically relevant performance considerations, including Essential Drug Delivery Outputs (EDDOs), in connecting device performance to clinical outcomes.

The course uses presentations, examples, and cross-functional discussions to support learning. It follows a high-level approach with focus on practical understanding rather than detailed regulatory depth.

At this course you will meet:
Javad Jabbari, Director, Global Regulatory Affairs, Ascendis Pharma
Casper Folsing, Director, Global Regulatory Affairs, Ascendis Pharma
Anja Skands, Vice President, Drug Product and Device Development, Hemab ApS
Claus Rømer Andersen, CEO & Technical Advisor, Rømer Consulting ApS
Morten Purup Andersen, Senior Human Factors Specialist, MGS Design & Development
Haya N.H. Pedersen, Clinical Development & Clinical Evaluation Expert, MedEvi Consulting
Rie Selchau Kallerup, Senior Manager & QA Commercial Drug Product & Finished Goods, Ascendis Pharma

Course facts

FORMAT
2 days

PRICE THIS YEAR
17.500 DKK excl. VAT, overnight stay included

Sign-up dates

Hillerød
5. okt. – **6. okt.**
2026

Do you have questions about this course?

Kontakt
Kursuskoordinator
Andreas Goldschadt
+45 48 20 62 63
ag@pharmakon.dk

Target group

Professionals working with drug–device combination products across Regulatory Affairs, Quality, R&D, Clinical, and project leadership. The course is for participants with general regulatory knowledge who need cross-functional understanding of combination products.

Your benefits

- You understand drug–device combination products, including definitions, regulatory frameworks, and how development, risk management, usability, clinical validation, and submission responsibilities connect across the lifecycle
- You can distinguish between design validation, clinical validation, and human factors validation, and understand how clinically relevant device performance, including Essential Drug Delivery Outputs (EDDOs), links device design to clinical outcomes
- You can identify cross-functional risks, understand interface challenges between constituent parts, and make informed, risk-based decisions to avoid common pitfalls across development and lifecycle

Your company's benefits

- Stronger organizational understanding of drug–device combination products, including regulatory frameworks and how development, risk management, usability, clinical validation, and submission responsibilities align across the lifecycle
- Improved capability to interpret and apply different validation approaches, including design validation, clinical validation, and human factors validation, and to connect device performance, including Essential Drug Delivery Outputs (EDDOs), to clinical and regulatory expectations
- Reduced risk of cross-functional gaps and interface issues, enabling more consistent, risk-based and regulator-aligned decisions across development, submission, and lifecycle management

Course agenda

The course duration is 2 days. Accommodation is included.

- Definition, Classification, and Types of Combination Products
- Drug Development in the Context of Combination Products
- Medical Device Development and Design Controls
- Combination Product Risk Management
- Regulatory Frameworks: United States vs European Union
- Human Factors and Usability Engineering
- Clinical Development for Combination Products
- Quality Management Systems for Combination Products
- CMO and Supplier Management
- Lifecycle Management and Post-Approval Changes
- Post-Market Surveillance and Vigilance

Sign up online at

www.pharmakon.dk