IPI Academy

MANAGEMENT forum



Presented by
Management Forum

An Introduction to the Design and Development of Medical Devices and Device-Drug Combination (DDC) Products

28-29 June 27
+ 8-9 December 27

A comprehensive introduction to the design and development of medical devices, including device constituent parts of combination products

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Step into the world of medical device and DDC innovation with this intensive two-day course designed specifically for those new to the field of medical device design and development. Whether you're transitioning into MedTech or starting your journey in the industry, this course offers a comprehensive introduction to the essential elements of the development process.

Over two focused days, you'll gain valuable insight into the tools and techniques required to bring a medical device from concept to reality. The course also provides a clear and up-to-date overview of the current regulatory landscape, helping you understand how compliance and standards impact each stage of development.

Key topics include the importance of ensuring safety and efficacy through design controls, effective risk management strategies, and the critical documentation needed throughout the lifecycle of a device. With combination products representing a significant and growing segment of the market, the programme also explores the device constituent parts of these innovative therapies.

By attending, you'll walk away with a solid understanding of the core aspects of medical device development and have the opportunity to engage directly with an experienced industry expert to discuss the challenges and complexities involved.

Benefits of attending

- **Gain** a comprehensive overview of the design and development process, equipping you with the knowledge to confidently approach each stage
- **Comply** with the international regulatory requirements and standards by understanding the current expectations and how to meet them effectively
- **Learn** about design controls and their essential role in ensuring quality and consistency throughout product development
- **Review** materials and biocompatibility to ensure safety, performance, and compliance in real-world applications
- **Access** key information on documentation management and systems to support efficient, audit-ready development processes
- **Understand** how risk should be managed throughout the product lifecycle to enhance safety and reduce potential issues
- **Consider** human factors and usability studies to design user-friendly, effective devices that meet both clinical and patient needs

Who should attend

- Design and development personnel
- Development engineers
- Quality personnel
- Regulatory personnel
- Design control professionals
- Documentation managers
- Programme managers
- Anyone who needs an overview of the medical device design and development process

Programme

Day 1

Overview of the regulations and market routes

- Do I have a medical device or a DDC?
- Regulatory pathways
- Roles and responsibilities
- Medical Device Directive (MDD) vs Medical Device Regulation (MDR) - key differences
- EU vs US (FDA) - and other markets to consider
- Medical device vs combination product (drug/device and device/drug) - which regulation applies?
- Device classification and the implications for your product
- Resources and sources

The design and development process

- The stages of design and development
- Key considerations
- Terminology
- Intended use
- Project complexity
- Mandatory requirements
- Design and development tools
- Inspiration, innovation and determination
- Materials and biocompatibility
- DFx, Design for……?
- Manufacturing - key considerations

Day 2

Design control

- Appropriate design and development planning
- Translation of marketing requirements
- SMART design inputs
- Is a trace matrix appropriate?
- Meaningful design outputs
- Verification and validation
- Design reviews
- Design transfer
- Design history file vs technical file
- Change control

Risk management - what is required?

- What is risk management and when should it be applied?
- What does the guidance say?
- Accountability Vs Responsibility
- What is reasonably forseeable
- Help or hindrance?
- How to implement a practical risk management plan
- Tools and techniques to help you succeed
- Reporting and post-market surveillance

Clinical evaluation, human factors and usability - how to comply

- Planning your clinical evaluation
- How to incorporate human factors and usability studies into your design and development process - MDR and FDA requirements
- User instructions
- Approaches to Task Analysis
- Training considerations - when and who do you need to train?
- Leveraging literature reviews
- Formative studies
- Validation/summative studies - are they always necessary

Presenter



David Howlett

In 2003 David established PharmaDelivery Solutions Ltd as a specialised consultancy service in the field of drug delivery combination products (especially respiratory) device technology. This has led to involvement in projects with focus in pulmonary, nasal and other delivery routes, with an international client base. Much of the activity of PharmaDelivery Solutions Ltd is focused in the area of development programme support, regulatory GAP analysis and generation of documentation supporting development and test programmes, together with data review and contingency evaluation.

David has over 35 years experience in the development, industrialization and approval of inhalation drug delivery systems, combination products and medical devices.

PharmaDelivery Solutions Ltd has provided input ranging from GAP analysis and comment to complete remedial implementation in areas including

- Design Control
- Risk Management
- Materials strategies
- Regulatory documentation
- Technical reviews and opinion

In addition to activities supporting commercial organizations, David has been involved in the following roles;

Honorary Teaching Fellow in the School of Pharmacy and Pharmaceutical Sciences at the University of Manchester and is author/ tutor for the Pharmaceutical Industry Advanced Training (PIAT) MSc module on Inhalation dosage forms.

A UK national expert representing the British Standards Institute on ISO TC84 developing new international standards for pulmonary and nasal delivery devices syringes and catheters.

David has also worked with the United Nations and various national governments to develop and establish transition strategies from the use of CFC in Metered Dose Inhalers and to secure appropriate budgets from the Multi-lateral fun for the implementation of the Montreal Protocol in emerging markets around the world.

Course dates

28-29 June 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17265*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 03 May**
8-9 December 27	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 17572*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 13 Oct**

How to book

Online:
ipi.academy/2047

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

I think the course was extremely informative. The connection between real-world examples to the texts was helpful.

Joshua Parker
NPI Engineer
PolarSeal
Dec 3 2025

★★★★★

Good speaker, clearly very knowledgeable in the area. He was happy to have conversations about any specific scenarios/examples/questions we had. Very friendly and i applaud his speaking almost continuously on this topic for two days

Michaela Hume
Engineer
42 Technology
Jul 24 2024

★★★★☆

Very good, lots of relevant material and clearly outlined.

Kurt Blinston
R&D Manager
Medtrade Products Ltd
Jul 24 2024

★★★★☆

Good content, covered all aspects that I required.

Anna Short
Design Manager
DM Orthotics
Jul 24 2024

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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