IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Human Factors and Usability Engineering in the Development of Drug Delivery Products

16-17 September 2025
+ 11-12 February 2026, 15-16 September 2026

This two-day workshop has been designed specifically for product developers who want to incorporate human factors testing into their product development, or need to provide the regulators with specific usability data for their device.

Format:
Live online, Classroom

CPD:
12 hours for your records

Certificate of completion

Course overview

This two-day workshop has been designed specifically for product developers who want to incorporate human factors testing into their product development, or need to provide the regulators with specific usability data for their device to comply with the MDR. The format for the day will be interactive with the presenter sharing his experiences as a specialist with extensive knowledge and understanding of the requirements of the MDR, IEC 62366 and FDA human factors Guidance. There will be questions posed for discussion and delegates will work through some of the key aspects of performing a successful human factors study.

Benefits of attending

- **Understand** the requirements of IEC 62366 and FDA human factors Guidance
- **Know** how to provide the regulators with specific usability data for your device
- **Understand** human factors and the design process
- **Learn** how to validate combination products
- **Consider** human factors and risk
- **Discuss** generic combination products – ANDAs and HF
- **Find out** what HF data FDA require for biosimilars

Who should attend?

This event will be beneficial to those working in the following areas:

- Engineering and device development
- Packaging
- Regulatory affairs
- Quality systems
- Quality assurance
- Risk management
- Marketing
- Usability and human factors engineering

Programme

Day 1

Background to human factors

- Human factors, usability and ergonomics defined
- Trends in drug delivery device technology
- Use errors – scale, scope and implications
- Defining the user interface
- Usability research, clinical research and market research compared

Legal and regulatory requirements

- US law and design control – implications for HF
- MDR and usability requirements
- Article 117 and implications for combination products
- UK medical device regulations

IEC62366, FDA guidance and expectations

- IEC62366 usability engineering process
- FDA human factors guidance
- ISO14971 applied to combination products
- EMA guidance on combination products
- Chinese human factors guidance 2022

Human factors methods and best practices

- Human factors engineering
- Perception, cognition and action model
- Heuristic analysis

Design control, design and development

- Design and development planning
- Role of human factors in design control
- UE methods and outputs
- UE integration with combination product development

User needs & user interface specifications

- Regulatory requirements for user needs
- Defining formal user needs
- User requirements and the design trace matrix
- Building a user interface specification

Formative and validation testing methods

- Formative testing methods
- Human factors validation methods

Day 2

Use-related risk

- Regulatory requirements for use-related risk
- ISO14971 applied to combination products
- Risk analysis methods
- Risk control
- Residual risk analysis

HF and clinical trials

- How HF and clinical trials differ
- How to gather HF data during clinical trials
- Changing the user interface during the trial program
- HF requirements for INDs and IDEs

Technical data requirements

- HF contents of a design history file
- HF contents of a EU technical file

Predicate devices, platform devices and post-market surveillance

- Platform devices – how to incorporate HF
- Platform device due diligence
- Post-market HF requirements – US and EU

Generic devices, biosimilars and ANDAs

- How to do a database and literature search for known use problems
- ANDA submissions and HF
- ANDA versus 505(b)(2) HF requirements
- FDA HF requirements for biosimilars

Practicalities – how to stay legal

- GDPR, IRB, HIPAA and the Sunshine Act
- When to apply for ethics/IRB approval
- Common GDPR problems during HF testing

Wrap-up

- Common pitfalls and top tips
- Top tips

Presenter

Richard Featherstone

Richard Featherstone was one of the early pioneers of applying human factors research methods to combination products, having set up Medical Device Usability in 2008. Richard has been designing and conducting human factors studies for over 15 years, and his experience includes a wide range of drug delivery technologies including inhalers, auto-injectors, nasal sprays and associated devices such as tele-health systems. Following his most recent role as Research Director in Human Factors for Emergo by UL, Richard is now providing freelance consultancy and training services. Richard has advised some of the world's largest pharmaceutical and medical device companies as well as small start-ups. Over 15 years of human factors work has meant that Richard has built a considerable body of knowledge of the regulatory requirements for usability testing, in particular in a European context.

Course dates

16-17 September 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 14723*	GBP **1,499** EUR **2,099** USD **2,399**
11-12 February 2026	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 15753*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 07 Jan**
15-16 September 2026	**Classroom** London *Course code 15727*	GBP **1,499** ~~1,699~~ EUR **2,099** ~~2,379~~ USD **2,407** ~~2,719~~ **Until 11 Aug**

How to book

Online:
ipi.academy/2117

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

★★★★★

As a newcomer to this field, I had hoped for a thorough introduction to Usability Testing. I am pleased to say that my expectations were met. Additionally, I had looked forward to networking, and I found ample opportunity to do so.

Bettina Meervaldt Larsen
Global Trial Manager
Novo Nordisk
Jun 5 2024

★★★★☆

The speaker has remarkable experience that he tried to share with us, which was really appreciable. He had also the ability to adjust the agenda to cover our points of interest. He tried to mix between theory and real-life examples. Discussing with him was really informative.

Haymen Girgis
Associate Director Medical Affairs
Becton Dickinson
Jun 5 2024

★★★★☆

I was hopping to understand the meaning of Human Factor and Usability in the Generic context and I obtained this knowledge.

Iñigo Gamboa
Medical Advisor
Cinfa S.A.
Jun 5 2024

★★★★★

Richard is very knowledgeable in the topic and was able to answer all questions by providing both regulatory references and examples which made understanding requirements easier.

Geno Govender
Senior Manager - Quality Devices
Vectura Limited
Nov 27 2023

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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