IPI Academy

MANAGEMENT forum

Presented by
Management Forum

An Introduction to Human Factors for Pharmaceutical and Medical Device Professionals

23 October 2024

This course will cover the key regulations used globally in human factors and usability engineering, the specific standards and guidances that detail processes, methods, and the tools commonly used in medical device development that focus on the user, as well as the interaction with risk management and future business success.

Format:
Live online

Certificate of completion

Overview

This intensive one-day course will introduce those who are new to medical device design and development to the critical elements of the human factors and usability engineering process. The programme shall cover the key regulations used globally in human factors and usability engineering, the specific standards and guidances that detail processes, methods and the tools commonly used in medical device development that focus on the user, as well as the interaction with risk management and future business success.

The key regulations of the Medical Device Regulation and In-vitro Diagnostic Regulation, the Code of Federal Regulations from the USA (CFR 820.30 and Titles 50 and 56) and the UK MHRA Guidance for Human Factors and Usability Engineering shall be described, along with the specific processes and tools used in IEC 62366-1 and other ISO standards specific to special medical devices. A focus on ethics, consent and user safety shall be described, along with how ISO 14971:2019 is used alongside any human factors process.

The key areas of user research and design inputs shall be described along with verification and validation activities – formative and summative human factors studies and tests so that their purpose, methodology, process and outcomes are understood. Post-market surveillance human factors shall also be detailed since this area is becoming increasingly important to include. Finally, a basic understanding of ergonomics, anthropometry, user experience and biomechanics shall be detailed before an end of the day discussion on the wider use of human factors and usability engineering shall be discussed.

Attending this event will provide delegates with a comprehensive appraisal of key aspects of human factors in medical device design and an opportunity to discuss the complexities involved with an experienced industry expert.

Benefits of Attending

- **Gain** a comprehensive overview of the human factors engineering process
- **Comply** with global regulatory requirements and standards in human factors
- **Learn** about design controls and their interaction with human factors
- **Review** tools that are commonly used to determine human factors data
- **Access** key information on documentation management and systems
- **Understand** how risk should be managed from the perspective of the user
- **Determine** the benefits of human factors and usability studies

Who Should Attend

This course will be beneficial for all those new to the area of human factors, or those who require an update or refresher working in the following departments/roles:

- Human Factors and Usability Engineering
- Project Management
- Device Development
- Technical Authors and Medical Writers
- Regulatory Affairs
- Quality Engineers and Managers
- Production Engineers and Managers

Programme

Part 1: Introduction to Human Factors and Usability Engineering

- Defining human factors and usability
- Understanding what they cover
- Use errors, difficulties, close calls, frustrations
- Root causes

Part 2: The Common Porcesses in Human Factors Engineering

- Design controls and development methods
- IEC 62366-1
- MHRA Human Factors Guidance
- FDA Guidance for medical devices
- FDA Guidances for pharmaceutical products
- FDA Guidances for related aspects
- Related ISO standards for specific medical devices
- Post Market Surveillance and Clinical Feedback

Programme

Part 3: Risk Management

- ISO 14971 Risk Management for users
- Hazard-related Use Scenarios and Task Analysis
- Human Factors Risk Assessment
- Use-related Risk Assessment
- Formative Usability Studies
- Summative Human Factors Tests

Part 4: Biomechanics, Ergonomics, Anthropometry and User Experience

- What are biomechanics?
- What is ergonomics?
- What is anthropometry and why it is important?
- User Experience for medical devices
- Discussion on human factors engineering and its value.

Presenter

Greg Thay

Greg Thay is owner and founder of THAY Medical, a Human Factors and Usability Engineering consultancy based in the UK and in Europe. He has worked in Human Factors since 2008 and has practised this specialism on many medical devices of all types. He has interviewed and evaluated thousands of people of all healthcare disciplines all over the world and completed many medical device developments from the human factors perspective.

Prior to human factors, Greg gained experience in orthopaedic device development, infusion therapy device development, wound care and superconductivity product development for large and small manufacturers. Since branching out into consultancy in 2010, he has grown his knowledge of design controls and human factors to ensure that he can train his staff to be competent in this field of human factors and usability engineering.

Course date

23 October 2024	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 14251*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 18 Sep**

How to book

Online:
ipi.academy/2702

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

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% 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

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:

ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipi.academy