IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Medical Device Studies: Regulatory Requirements and Adverse Event Reporting

16-17 March 27
+ 16-17 September 27

An essential overview of medical device clinical evaluations, clinical investigations, post-market clinical follow-up requirements and adverse event and vigilance reporting.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

This course provides an essential overview of medical device clinical evaluations, clinical investigations and PMCF studies with particular emphasis on the adverse event reporting requirements during these studies.

Concentrating mostly on the new Medical Device Regulations (MDR) with some references to the existing Medical Device Directives, there will also be a review of the post Brexit implications for device management in the EU & UK.

Benefits of attending

- **Gain** an insight into medical device clinical studies
- **Stay** updated of the regulatory changes
- **Learn** the methods of handling adverse events during the study period
- **Discuss** the new requirements regarding periodic safety update reports (PSURs) and the summary of safety and clinical performance

Who should attend?

- Regulatory affairs specialists
- Quality assurance specialists
- Clinical research associates
- Junior clinical research associates
- Professionals involved in reporting adverse events during pre- and post-market clinical studies

Programme

Day 1

Clinical evaluation – an overview

- What is a clinical evaluation?
- How do you conduct a clinical evaluation?
- The regulatory requirements pertaining to clinical evaluation

Clinical investigations – an overview

- What is a clinical investigation?
- When are clinical investigations needed?
- The regulatory requirements

PMS and PMCF

- What is PMS?
- What is PMCF?
- When are PMCF studies necessary?

Quiz on clinical evaluation, clinical investigation and PMCF

New requirements of the MDR

- Summary of safety and clinical performance
- Periodic safety update report (PSUR)

The competent authority and the Notified Body

- What is their role in the above processes?
- What are the responsibilities of the manufacturer?
- What to communicate and when

Workshop on the new requirements of the MDR

Day 2

Vigilance reporting

- What is vigilance?
- The requirements for vigilance reporting during medical device studies
- The EU and UK on Medical Device Reporting post Brexit

How to define and classify adverse events

- Definitions
- Types of events
- Determining categories

Vigilance workshop

The regulatory requirements for monitoring and reporting adverse events during regulatory and PMCF studies

- MEDDEV guidance document
- ISO 14155 harmonised standard
- Responsibilities
- Templates

The MDR – clinical elements

- Focus on changes in the clinical arena
- Chapter 6: clinical evaluation and investigation
- Annex 14: clinical evaluation and post-market clinical follow-up

Presenter



Graeme Ladds

Graeme Ladds, Director of PharSafer, has over 30 years' experience in the pharmaceutical industry. He began his career in 1989 at Ashbourne Pharmaceuticals as Head of Drug Safety & Medical Information, before going on to become Head of Global Pharmacovigilance at Shire Pharmaceuticals.

He later founded his consultancy and specialist CRO, PharSafer Associates Ltd, where he has supported companies in establishing pharmacovigilance systems, conducting audits across Europe and the USA, developing SOPs, acting as a QP, and supporting regulatory inspections.

Since 1994, Graeme has also been involved in the monitoring of medical devices, including drug–device combinations, structural devices and electrical medical devices. His experience spans clinical trials and global device vigilance, alongside pharmacovigilance activities across both clinical development and post-marketing phases.

Course dates

16-17 March 27	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 16960*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 19 Jan**
16-17 September 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17328*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 22 Jul**

How to book

Online:
ipi.academy/2269

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 the person responsible of safety assessment and reporting in my department (clinical), I was hoping to strengthen my knowledge in this area. Especially when it comes to event assessment and classification. This course helped me achieve that goal. [Speaker] is very knowledgeable on several topics.

Stéphanie Trznadel
Clinical Trial Coordinator
SPINEART
Sep 16 2024

★★★★★

Understanding what requirements for RA through the cases of Medical Devices studies is very important for me to deal with Korean Medical devices. So this course make me more knowlegable about Europe's MD handling and also distinguish how to adapt on some agenda between Korean and Europe Medical Devices.

Heejun Hong
Student
Dongguk University, Republic of Korea
Oct 3 2022

★★★★★

Fantastic speaker. I truly enjoyed listening to Janette, her ability to relate real life examples helped make sense of the topics.

Melissa Patterson
Associate Manager, Corporate Clinical Compliance
Edwards Lifesciences
Mar 9 2022

★★★★★

Excellent course, excellent trainer. Found it very valuable and will be taking away knowledge gained to further improve processes and understanding within my department.

Sarah Collins
Pharmacovigilance Manager
PharSafer
Mar 9 2022

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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