IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Post-Market Surveillance - Practical Application for Medical Devices and IVDs

10 October 2024

In this practical, one-day course, learn the regulatory requirements needed for successful post-market surveillance of medical devices and IVDs.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

Understanding the regulatory requirements for successful post-market surveillance of medical devices and IVDs is increasingly important and practical application of the regulations is key to a successful PMS system.

This course will provide a clear understanding of the intention of the requirements, and discuss the responsibilities of the manufacturer, notified bodies and competent authorities. It will also provide advice on where to find useful guidance and will include an insight into some possible PMS methodologies for a range of example medical devices and IVD products, including software.

A review of the reporting and documentation obligations will be included, to enable participants to fully understand and comply with the documentation requirements.

The regulations for PMS under the MDR and IVDR are complex and this course provides an excellent opportunity to gain essential knowledge, practical application and interpretation of the requirements.

Benefits of attending

- **Understand** the intention of the regulatory requirements for PMS
- **Gain** knowledge of the available sources of guidance on the subject of PMS
- **Practice** the setting of objectives and criteria for collection of PMS data
- **Explore** some possible PMS methodologies for a range of example products covering Medical Devices and IVDs including software
- **Learn** the reporting and documentation obligations

Who should attend?

This course will be valuable to those with an existing knowledge of the regulations who are tasked with PMS, but not sure where to start or who have encountered difficulties obtaining PMS data. Personnel in the following roles and departments will benefit:

- Quality managers within manufacturers
- Quality associates within manufacturers
- Regulatory affairs specialists within manufacturers
- QA/RA responsible people in authorised representatives
- Person responsible for regulatory compliance (PRRC) within manufacturers & authorised representatives (per Article 15 of MDR/IVDR)

Programme

Welcome and objective of the day

Background of regulatory requirements for PMS

- EU requirements – MDR 2017/745 and IVDR 2017/746 – Articles 83-100
- UK Medical Device Regulations 2002 No. 618 as amended
- Responsibilities of the manufacturer/notified bodies/competent authorities with respect to PMS

Overview of guidance sources available on PMS

Practical application of PMS

- Objectives of PMS
- Relationship of risk management to PMS
- Commercial benefits of good PMS

Possible methodologies

- Discussion of potential sources of PMS and methods available depending on device type
- Trend reporting/signal management

Case studies - Interactive session and workshop

- Walk through of case studies representing different risk classifications of medical devices, including software and in-vitro diagnostics

PMS system documentation

- PMS Plan/Report
- Periodic Safety Update Report (PSUR)

Q&A discussion

Presenters

Karen Pearson

Karen Pearson has over 30 years' experience of market research in the healthcare and business-to-business sectors.

Karen started her market research career with IMS, providing market data to the European pharmaceutical sector, before moving on to 3M Health Care, BASF and The Royal Society For The Prevention of Accidents (RoSPA). She started Active Research in 1998 offering a full market research service to pharmaceutical, medical product and business-to-business organisations as well as the public sector.

Active Research focuses on finding practical research solutions that will deliver actionable results for clients, whether that be through, qualitative, quantitative or desk research.

Active Research's clients include 3M Health Care, Napp Pharmaceuticals, the Cell & Gene Therapy Catapult, Takeda, Kyowa Kirin, Aristo Pharmaceuticals, Lockdown Medical and other leading names in their fields.

Qualifications/Accreditations:

BA (Hons) Modern Languages

DipCIM

MMRS (Full membership of the Market Research Society)

Anne Jury

Anne Jury is a regulatory affairs consultant with over 25 years experience in the medical and diagnostic healthcare products industries. With a degree in Microbiology, she went to work as company microbiologist for Smith & Nephew Textiles on sterile wound dressing products. Later she went on to work for Notified Bodies, BSI and then TÜV Product Service as a lead auditor covering over 200 medical companies in Europe and USA.
Anne is a member of TOPRA, (The Organisation for Professionals in Regulatory Affairs) and RAPS, (Regulatory Affairs Professionals Society) and a regular speaker at conferences world-wide. Through close association with like minded organizations such as Medilinks, the DTI and NHS Innovations Hubs as well as biotechnology incubators around the UK, she is active in the promotion of integrated management and regulatory systems to assist the successful introduction of new products to market.
Since March 2020, she is also Vice President of Team-PRRC.
Specialties: Technical guidance on regulatory strategies and quality management systems for new medical device product commercialization, including CE marking requirements, implementation of management systems to ISO 13485:2016 and training / coaching in these areas.

Gap analysis compliance audits for manufacturers and subcontract third party auditor for Notified Bodies.

Past visiting lecturer at Cranfield University (through TOPRA) on MScs in Medical Technology Regulatory Affairs.

Vice-President of Team-PRRC, a non-profit association in EU to support those taking on the PRRC role under MDR and IVDR.

Course date

10 October 2024

Live online
09:30-16:30 **UK (London)** (UTC+01)
Course code 14328

GBP **549** ~~649~~
EUR **789** ~~929~~
USD **893** ~~1,049~~
Until 05 Sep

How to book

Online:
ipi.academy/2717

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

Reviews

★★★★★

Overall, I found the webinar to be highly informative and well-organized. The content was comprehensive and relevant, covering key aspects of post-market surveillance for medical devices and IVDs in a clear and understandable manner. The presentation was engaging and well-structured, making complex topics accessible even for beginners like myself. The speakers were knowledgeable and articulate, effectively conveying their expertise and experience. Their willingness to engage with participants and answer questions added significant value to the session. Overall, it was a valuable learning experience that exceeded my expectations.

Ajla Music
Pharmacovigilance Officer
Billev farmacija vzhod d.o.o.
Jun 6 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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