



Presented by
Management Forum

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

6 June 2024
+ 10 October 2024

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.



Format:
Live online



CPD:
6 hours for your records



Certificate of
completion

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

Attendees will gain:

- **A deep understanding** of the intention of the regulatory requirements for PMS
- **A knowledge** of the available sources of guidance on the subject of PMS
- **A chance to practice** the setting of objectives and criteria for collection of PMS data
- **An insight** into some possible PMS methodologies for a range of example products covering Medical Devices and IVDS including software
- **A full understanding** of 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:

- 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 dates

6 June 2024

Live online

09:30-16:30 **UK (London)** (UTC+01)

Course code 14327

GBP **649**

EUR **929**

USD **1,049**

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:

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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.

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

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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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