IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Post-Market Surveillance and Vigilance of Software as a Medical Device (SaMD) and Medical Device Software (MDSW)

15-16 March 27
+ 4-5 October 27

Learn the essential regulatory requirements for post-market surveillance (PMS), post-market clinical follow-up (PMCF), and vigilance of digital health technologies, ensuring product safety, compliance, and continued value creation throughout the product lifecycle

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

This intensive course provides a comprehensive overview of regulatory obligations, risk management, incident reporting, and corrective actions, together with practical tips to ensure that such products remain compliant and safe throughout their lifecycle.

Post-market surveillance (PMS), post-market clinical follow-up (PMCF), complaints, and vigilance handling are vital to ensure compliance of digital health technologies with or without the use of artificial intelligence. In this practical one-day course, you will learn the regulatory requirements needed for successful PMS, PMCF and vigilance of digital health technologies (DHTs). The intensive course will exemplify how proactive and reactive sources of information are essential in PMS procedures of such devices. Also, the course will highlight why developing a PMS plan and PMCF early in software development, will ensure that different sources of information can be targeted to enable a cost-effective product launch. Identifying the right post-market information will assure continued compliance and will trigger consumer shifting needs, enabling a total product life cycle development, and continous value creation in the post-market chain.

The program will be highly interactive, using real-life examples and state-of-the-art practices across different global jurisdictions. Practical insights will be provide, hands-on exercises, and case studies to guide you through the intricate decisions needed that affect your market access processes.

The course will cover:

- Overview of PMS requirements for SaMD and MDSW in different global regulatory frameworks (e.g., EU MDR, USA FDA).
- Understand Risk Management and PMS Planning: a PMS plan tailored for software products.
- Monitoring and Data Collection: insights on the use of real-world data and user feedback to improve product safety and performance.
- Incidence reporting and vigilance:
  - Identifying reportable events, incidents, and serious adverse events.
  - Regulatory requirements for vigilance reporting and timelines.
- Corrective and Preventive Actions (CAPA)
- Ensuring continuous product improvement through PMCF: changes to the benefit-risk profile and intended-use.

Benefits of attending

- **Confirm** the regulatory requirements for PMS for SaMD & MDSW, and how these are interpreted in ISO 13485, ISO 14971 and various guidance documents.
- **Create** a Post-market Surveillance procedure that is both proactive and reactive.
- **Implement** cost-effective and targeted PMCF using various techniques.
- **Recognize** when a complaint needs to be reported as an adverse event or incident for marked devices.

Who should attend?

This training is suitable for all professionals involved in the post-market surveillance and vigilance of software as a medical device and medical device software, including:

- Regulatory Professionals
- Quality Managers
- Clinical Affairs Specialists
- Complaint Handling Specialists
- Design and Development Professionals
- EU Authorised Representatives

Programme

Day 1

Overview of requirements

- PMS requirements for SaMD and MDSW in different global regulatory frameworks (e.g., EU MDR, USA FDA).

Understand risk management and PMS planning

- A PMS plan tailored for software products.

Monitoring and data collection

- Insights on the use of real-world data and user feedback to improve product safety and performance

Day 2

Incidence reporting and vigilance

- Identifying reportable events, incidents, and serious adverse events
- Regulatory requirements for vigilance reporting and timelines

Corrective and Preventive Actions (CAPA)

Ensuring continuous product improvement through PMCF

- Changes to the benefit-risk profile and intended-use

Presenter



Catarina Carrao

Catarina Carrão is the founder of BioSciPons, a life sciences research organisation specialising in health technologies clinical development, evaluation and assessment, with expertise in AI/ML-enabled technologies. She co-ordinates expert teams to bridge the gap between innovation and regulatory compliance, helping developers navigate complex requirements while meeting the expectations of Notified Bodies and the FDA.

Catarina's academic background includes a Marie-Curie Fellowship at Charité Berlin, and Postdoctoral Fellowship at Yale's University Cardiovascular Research Center. She is a Fellow of the American Heart Association (FAHA) since 2013, Delegate of the European Society of Cardiology (ESC), and Professional member of the Health Technology Assessment International (HTAi) organization. She is an expert for the European Commission HaDEA on clinical investigations and Digital Health Technologies, and for the European Innovation and Technology (EIT) Council Health Cluster.

She has presented at RAPS Euroconvergence, the ESC Digital & AI Summit, and DIA Europe on AI/ML medical device regulation, post-market monitoring, and reimbursement pathways. Her recent publications include book chapters and articles on machine learning best practices, AI trustworthiness, and EU MDR/IVDR clinical evaluation.

Course dates

15-16 March 27	**Live online** 09:00-12:30 **UK (London)** (UTC+00) *Course code 17775*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 18 Jan**
4-5 October 27	**Live online** 09:00-12:30 **UK (London)** (UTC+01) *Course code 17776*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 09 Aug**

How to book

Online:
ipi.academy/3117

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

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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