Medical Devices and Drug-Device Combination Products Workshop: Post-Market Surveillance and Clinical Evidence

21-23 October 2025, 13:00-17:30 CEST

Overview

Post-Market Surveillance (PMS) activities including Post-Market Clinical Follow-up (PMCF) are conducted throughout the lifecycle of a medical device. These require compiling data from multiple sources, including sufficient clinical evidence to conduct a proper determination of the benefit-risk profile and to demonstrate acceptability of that profile based on current knowledge/state-of-the-art in the medical device field concerned.

This virtual workshop specifically addresses devices used with drugs or biologics and that serve to support or deliver these medicinal products effectively.

You will learn how to set up a PMS system, understand it's challenges and opportunities, and see the interdependencies between PMS, clinical evidence, and risk management. This workshop will help you to know how to continuously evaluate the safety and performance of a medical device and confirm the acceptability of the benefit- risk profile when used as a stand-alone device or as a constituent part of a drug-device combination (DDC) product.

It will offer experience from notified body and industry experts.

Learning Objectives

At the conclusion of this workshop, participants will be able to:

- Follow the requirements of PMS for medical devices and device constituents of DDC products
- Identify the relevant clinical data needed to confirm the acceptability of the benefit-risk profile of your medical device
- Recognize the interdependencies and outputs loops within a PMS, clinical evidence, and risk management process

Who Will Attend

This course is intended for professionals working within the pharmaceutical industry in:

- Post-Market Surveillance
- Pharmacovigilance
  - Vigilance/Device Safety
- Regulatory Affairs
- Clinical Affairs
- Digital Health

Workshop Director

Anna Amich
Director, Patient Safety Device & Digital
AstraZeneca, Spain

Speakers

Taylor Dieringer
Quality Engineer - Risk Management
iRhythm Technologies, United States

Laura Gamez Santin
Head Medical Device Vigilance
Novartis, Spain

Glory Msacky
Senior Clinical Affairs and PMS specialist
Phillips-Medisize, Denmark

Harminder Mudhar
Director, Device & Digital Safety
AstraZeneca, United Kingdom

Josep Pane
Head of Device, Digital Vigilance and Safety
UCB, Spain

Ana Simoes
Clinical Reviewer - ENT, Global Operations, Clinical Center of Excellence
TÜV SÜD Medical and Health Service, Portugal

Amie Smirthwaite
Founder
Salvae Medical, United Kingdom

Milos Stojkovic
Safety Process Director
F. Hoffmann-La Roche, Switzerland

Surash Surash
Clinical Reviewer, Centre for Clinical Excellence
TÜV-SÜD, United Kingdom

DIA

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

Schedule-At-A-Glance

DAY 1

13:00 WELCOME

13:05 SESSION 1

INTRODUCTION, GENERAL OVERVIEW AND OBJECTIVES

Anna Amich, AstraZeneca

13:50 SESSION 2

FUNDAMENTALS OF POST-MARKET SURVEILLANCE FOR MEDICAL DEVICES AND DRUG-DEVICE COMBINATION PRODUCTS

Anna Amich, AstraZeneca

- Defining PMS, its objectives and its role in ensuring device safety and performance
- Types of DDC and PMS implications
- Connecting to Risk Management and Clinical Evaluation

14:30 SESSION 3

RISK MANAGEMENT: INTERFACES WITH PMS AND PMCF

Taylor Dieringer, iRythm Technologies

- Risk Management - ISO14971
- Production and Post-production activities
- Interaction of safety reelvant information and the risk management process
- Standardisation of the interface betwen the risk management and PMS

15:10 BREAK

15:30 SESSION 4

BENEFIT-RISK ASSESSMENT FOR MEDICAL DEVICES

Amie Smirthwaite, Salvae Medical

- Key principles of BR assessments for medical devices, focus also on DDC
- Qualitative and Quantitative methods for assessing benefits and risks
- Regulatory expectations for benefit-risk assessment

16:10 SESSION 5

CASE STUDY 1: RISK MANAGEMENT AND PMS IN ACTION

17:20 RECAP AND Q&A

17:30 END OF DAY 1

DAY 2

13:00 WELCOME

13:05 SESSION 6

CLINICAL DATA AND SUFFICIENT CLINICAL EVIDENCE - NOTIFIED BODY (NB) PERSPECTIVE

Surash Surash, TÜV SÜD

- The necessity for clinical data under the MDR
- Understanding when a clinical investigation is required
- Exploring the types of clinical data sources
- Considerations of the interpretation of NBs of the word “sufficient”

13:45 SESSION 7

DEEP DIVE INTO THE EU MDR PMS AND PMCF - NB PERSPECTIVE

Surash Surash, TÜV SÜD

- Expectations of PMS under the MDR
- Expectations of PMCF under the MDR
- Types of general/specific PMCF activities based on the question that needs answering

14:25 SESSION 8

PMS FOR A SPECIFIC DEVICE

Milos Stojkovic, F.Hoffmann-La Roche

15:05 BREAK

15:25 SESSION 9

PMS FOR CONNECTED DRUG-DEVICE COMBINATION PRODUCT

Glory Msacky, Philips-Medisize

- Challenges associated to connected DDC
- Regulatory considerations for connected DDC
- Strategies for collecting, analysing, and managing data from connected DDC

16:05 SESSION 10

CASE STUDY 2: DEVELOPING A EU MDR PMS PLAN FOR A DRUG DEVICE COMBINATION PRODUCT

17:20 RECAP AND Q&A

17:30 END OF DAY 2

DAY 3

13:00 WELCOME

13:05 SESSION 11

POST-MARKET DEVICE SAFETY REPORTING FOR DDC PRODUCTS

Josep Pane, UCB

- Safety Reporting requirements for device constituents of combination products
- Implementation opportunities

13:45 SESSION 12

ADVERSE EVENTS IN DIGITAL AGE

Laura Gamez, Novartis

- The current regulatory landscape, or lack thereof
- Building a company position on the use of digital data for vigilance purposes: experience and lessons learnt

14:25 SESSION 13

DEMONSTRATING ANNEX I REQUIREMENTS FOR SINGLE INTEGRAL DDC THROUGH PMS AND CLINICAL EVIDENCE (NB PERSPECTIVE)

Ana Simoes, TÜV SÜD

- Specific requirements of Annex I relevant to PMS and clinical evidence
- PMS to demonstrate compliance with Annex I
- Role of clinical evidence (both pre- and post-market) in supporting Annex I compliance

15:05 BREAK

15:25 SESSION 14

PMS FOR DRUG-LED SINGLE INTEGRAL COMBINATION PRODUCT - INDUSTRY PERSPECTIVE

Harminder Mudhar, AstraZeneca

- Practical example of how manufacturers have successfully used PMS and clinical evidence to meet Annex I requirements

16:05 SESSION 15

CASE STUDY 3: US FDA PMSR AND EU MDR PMS FOR A DRUG-LED CONNECTED DDC

17:20 RECAP, Q&A AND CLOSING REMARKS

17:30 END OF THE WORKSHOP

Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!*

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together via email to basel@diaglobal.org.

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To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

For further information on system requirements, please visit the website:
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Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 9 credits.

REGISTRATION FORM

Medical Devices and Combination Products Workshop # 25535
21-23 October 2025, 13:00-17:30 CEST, Virtual Event

REGISTRATION FEES

Registration fee includes full admission to virtual course, electronic access to training course materials. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

FEES	MEMBER EARLY-BIRD valid until 26 Aug 2025	MEMBER valid from 27 Aug 2025	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'215.00 ❑	€ 1'350.00 ❑	€ 1'610.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 675.00 ❑	€ 935.00 ❑
A special discount is available for organisations which are listed in the EMA SME register. Number of discounted seats is limited.			

All registration fees are subject to VAT if applicable.

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- Industry (Member/Non-member) € 200.00
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