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

6-8 October 2026 | 13:00-17:30 CEST

Overview

Post-Market Surveillance (PMS) activities, including generation of clinical evidence, are essential activities conducted throughout the lifecycle of medical devices and drug-device combination (DDC) products. These activities require collecting and analyzing data from multiple sources to evaluate device safety and performance in real-world conditions.

This virtual workshop specifically addresses devices used with drugs or biologics and that serve to support or deliver these medicinal products effectively. For such devices, maintaining robust PMS is also important to demonstrate the ongoing safety and performance, confirm that the benefit-risk remains acceptable based on current available knowledge, meet regulatory requirements under the EU MDR and other frameworks, and protect patient safety while ensuring product performance.

Over three days, this virtual workshop will equip you with practical knowledge to establish and maintain an effective PMS system for medical devices and DDC products. Through presentations from Notified Body and Industry experts, real world case studies, and interactive discussions, you will learn how to navigate the interdependencies between PMS, clinical evidence and risk management processes with particular focus on DDC products.

Learning Objectives

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

- Apply PMS requirements for medical devices and device constituents of DDC products in accordance with EU MDR and relevant regulatory frameworks
- Recognize the interdependencies and outputs loops within a PMS, clinical evidence, and risk management process
- Implement effective safety reporting systems for device constituents while understanding the interface between device vigilance and pharmacovigilance
- Address challenges associated with connected DDC products in PMS activities

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
- Quality Assurance

Workshop Director

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

Workshop Speakers

Speaker invited
Head Medical Device Vigilance
Novartis, Spain

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

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

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

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

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

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Schedule-At-A-Glance

DAY 1

13:00 WELCOME

13:05 SESSION 1

INTRODUCTION, GENERAL OVERVIEW AND OBJECTIVES

Anna Amich, AstraZeneca

BLOCK 1: REGULATORY FOUNDATION AND PMS BASICS

13:35 SESSION 2

PMS OVERVIEW FOR MEDICAL DEVICES AND DRUG-DEVICE COMBINATION PRODUCTS AND INTERFACES

Anna Amich, AstraZeneca

- Defining PMS, its objectives and its role in ensuring device safety and performance
- Types of DDC and PMS implications
- Components of PMS for devices and combination products
- Linkage to risk management and clinical evaluation

14:15 BREAK

14:30 SESSION 3

INTRODUCTION TO RISK MANAGEMENT: INTERFACES WITH PMS AND PMCF

Speaker invited

- Risk Management - ISO14971
- Production and post-production activities
- Interaction of safety relevant information and the risk management process
- Standardisation of the interface between the risk management and PMS

15:10 SESSION 4

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

15:50 BREAK

16:05 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

BLOCK 1 CONTINUED: REGULATORY FOUNDATION AND PMS BASICS

13:05 SESSION 6

INTRODUCTION TO 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

PMS, POST-MARKET CLINICAL FOLLOW-UP (PMCF) AND EVIDENCE OVERTIME - 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 BREAK

BLOCK 2: PUTTING PMS, RISK MANAGEMENT AND CLINICAL EVIDENCE TOGETHER

14:40 SESSION 8

PMS FOR A SPECIFIC DEVICE

Milos Stojkovic, F.Hoffmann-La Roche

- What is a PMS plan a PMS report?
- Real-world example of a simplified PMS plan structure and PMS report

15:20 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

16:00 BREAK

16:15 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

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DAY 3

13:00 WELCOME

BLOCK 3: COMPLAINTS, SAFETY SURVEILLANCE AND SIGNALING

13:05 SESSION 11

COMPLAINT HANDLING FOR COMBINATION PRODUCTS IN A PHARMA INDUSTRY

Anna Amich or Harminder Mudhar, AstraZeneca

- AEs and complaints – medical device language vs pharma definitions
- Relevant information needed for a complaint
- How complaint data ties to vigilance to drug PV in DDCs

13:45 SESSION 12

ADVERSE EVENTS IN DIGITAL AGE

Speaker invited, 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

14:40 SESSION 13

POST-MARKET DEVICE SAFETY REPORTING FOR DDC PRODUCTS

Josep Pane, UCB

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

15:20 SESSION 14

DEVICE POST MARKET SURVEILLANCE FOR COMBINATION PRODUCTS: PRACTICAL STRATEGIES FOR SUCCESSFUL IMPLEMENTATION

Josep Pane, UCB

- Building an integrated PMS system for device constituents of combination products
- Practical Implementation Strategies

16:00 BREAK

16:15 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

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REGISTRATION FORM

Medical Devices and Combination Products Workshop # 26535
6-8 October 2026 | 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 8 Sep 2026	MEMBER valid from 9 Sep 2026	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'080.00 ❑	€ 1'200.00 ❑	€ 1'460.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 600.00 ❑	€ 860.00 ❑
A special discount is available for organisations which are listed in the EMA SME register. Number of discounted seats is limited.			

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