Med Dev day

LIFE SCIENCE ACADEMY

MedDev Day

Attractiveness of the EU market with the MDR
Where the Regulation stands - what is next?

Date
26 September 2023

Language
English

Location
Vienna, Austria

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ABOUT

The MDR has been applicable since May 2021.
Over the last years, industry and regulators have made significant efforts to adapt to the Regulation. Recent improvements are, among others, the number of notified bodies designated under MDR, the preparation and voluntary use of EUDAMED modules, the significant increase of MDCG Guidance documents and the activities and opinions of expert panels for certain high-risk devices.
This is in line with the overall goal of the Regulation to increase the attractiveness of the EU market as well as the quality, safety and performance of devices for patients and consumers.

Despite positive developments, the overall capacity of the regulatory system still needs to be improved.
While manufacturers have concerns about meeting the requirements of the MDR by the end of the transition, the system's capacity needs to be increased to process the number of certificates that need to move from MDD/AIMDD to MDR.

In early 2023, a legislative proposal by the European Commission was published that aims to extend the transition period and validity of certificates under certain conditions to 2027 for high-risk and to 2028 for medium and low-risk devices. This legal proposal is accompanied by supporting non-legislative measures that aim to support notified body capacities, back the industry and ensure the uninterrupted availability of medical devices.

In this dynamic context, the 5th edition of MedDev Day will give you a chance to rest and understand where the regulation stands. The conference will give insight into recent developments impacting MedTech industry and bring representatives from competent authorities, notified bodies and industry to share strategies, best practice solutions and recommendations.

A **pre-conference workshop** will precede the MedDev Day on *Writing the Summary of Safety and Clinical Performance (SSCP): from good to excellent!*

The conference will highlight the regulators' perspective on the MDR state of play, non-legislative support measures, and conditions to be met by manufacturers to benefit from transition provisions and extended certificates. Also, practical insights on how to apply for temporary bridging measures under Article 97 will be conferred.

The MedDev Day will further reveal developments in clinical evaluation consultation opinions and state of play for the voluntary advice to manufacturers on clinical development strategy and clinical investigations. Participants will finally have the opportunity to understand the next steps and an outlook on the future of the regulatory system beyond 2024.

The Scientific Committee:

Scientific Board
Bassil Akra - *Chief Executive Officer* at AKRA TEAM GmbH
Sabina Hoekstra-van den Bosch - *Regulatory Strategy Principal* at TÜV SÜD
Arkan Zwick - *Corporate Regulatory Affairs Director* at CROMA Pharmaceutical

MedDev Day Scientific Coordinator
Laura C Collada Ali - *Senior Medical Writer & Scientific Manager* at LS Academy

Who should attend?
The conference is designed for professionals in the field of Medical Devices, devoted to departments such as:

- Clinical Operations
- Product Managers
- Regulatory Affairs
- Quality Assurance/Control
- Risk Management
- Medical Device Engineering
- Device Vigilance
- R&D
- Medical Affairs
- Medical Writing

from Pharmaceutical, Biotechnology and Medical Device companies, CROs, Universities/Hospitals, Academic Research, Patient Associations and Healthcare Organizations., competent authorities, EU Commission and Surveillance authorities.

PROGRAMME

26 September 2023	
09:00 **09:30**	**Registration**
09:30 **09:40**	**Welcome from the Scientific Board**

09:40 **10:25**	**OPENING PANEL DISCUSSION | Expert Panel: First experience Voluntary and Enforced Consultation** **Rob Nelissen** Professor and Chairman department Orthopaedics, Rehabilitation, Physiotherapy at Leiden University Medical Center (LUMC) **Nataliya Deych** Vice President Regulatory Affairs EMEA, Latam, Canada at Edwards Lifesciences **Arkan Zwick** Corporate Regulatory Affairs Director at CROMA Pharmaceutical
10:25 **11:05**	**Outlook on the Future of the Regulatory System - an Industry wish list** **Christina Ziegenberg** Deputy Managing Director, Head of Regulatory Affairs at BVMed, Berlin
11:05 **11:35**	**Coffee Break**
11:35 **12:15**	**Navigating the 2nd MDR Amendment** **João Martins** Associate Director Regulatory Strategy at Abbott
12:15 **12:55**	**Experience from Industry with MDR Transition Extension** **Bassil Akra** Chief Executive Officer at AKRA TEAM GmbH
12:55 **13:55**	**Networking Lunch**
13:55 **14:35**	**Is an EU MDR Article 59 and Article 97 Derogation a Way to Continue to Market?** **Nataliya Deych** Vice President Regulatory Affairs EMEA, Latam, Canada at Edwards Lifesciences
14:35 **15:15**	**Key Considerations for Device Drug Combination and Impacts of MDCG 2020-12– A NB Perspective** **Theresa Jeary** Principal Technical Specialist, Medicinal & Biologics Team at BSI Group, The Netherlands B.V.
15:15 **15:45**	**Coffee Break**

15:45 **16:25**	**Company Experiences with Device-Drug Combination** **Arkan Zwick** Corporate Regulatory Affairs Director at CROMA Pharmaceutical
16:25 **16:40**	**Q&A Session**
16:40 **16:45**	**Conclusion**

SPEAKERS

Scientific Board
Bassil Akra
Chief Executive Officer at AKRA TEAM GmbH

Scientific Board
Sabina Hoekstra-van den Bosch
Regulatory Strategy Principal at TÜV SÜD

Scientific Board
Arkan Zwick
Corporate Regulatory Affairs Director at CROMA Pharmaceutical

Speaker
Nataliya Deych
Vice President Regulatory Affairs EMEA, Latam, Canada at Edwards Lifesciences

Speaker
Theresa Jeary
Principal Technical Specialist, Medicinal & Biologics Team at BSI Group, The Netherlands B.V.

Speaker
João Martins
Associate Director Regulatory Strategy at Abbott

Speaker
Rob Nelissen
Professor and Chairman department Orthopaedics, Rehabilitation, Physiotherapy at Leiden University Medical Center (LUMC)

Speaker
Christina Ziegenberg
Deputy Managing Director, Head of Regulatory Affairs at BVMed, Berlin

WORKSHOP

25 September 2023

PRE-CONFERENCE WORKSHOP

From 13:30 to 17:30 | NH Vienna Airport, Vienna

From Good to Excellent: The Summary of Safety and Clinical Performance (SSCP)
An advanced training to improve your SSCP and write it in the most efficient way

Introduction

The Summary of Safety and Clinical Performance (SSCP) is a document that is with a unique structure and format: it is intended to include detailed information on a medical device for both healthcare providers and patients and will be available for the public. Many manufacturers already know how to write an SSCP.

We also have read MDCG 2019-9, but how can we go from good to excellence? And how can we improve a document which will be public soon?
To be able to work on your SSCP you need strong technical skills. You also have to be able to translate the technical documentation into lay language: Are we complying with a regulatory requirement or are we really communicating with the public?
Consistency with the Technical Documentation, different expectations from the manufacturer and the Notified Body and strict timelines are additional hurdles.

This workshop will navigate you through the needed skills to achieve excellence and positively impact the final document.

Programme

- Introduction to Article 32 of EU MDR 2017/745 (Summary of Safety and Clinical Performance)
- Structure and Content: The MDCG (Medical Devices Coordination Group) Guidance 2019/9
- How to optimize input documents for more efficient SSCP writing
- Best practice tips to summarize safety and performance data
- How to improve the patients' section of the SSCP

Who should attend?

The workshop is addressed to Clinical Affairs, Quality Assurance, Product Managers and Medical Writers.

Participant experience

This workshop is intended for personnel with little experience in regulatory writing, including the Summary of Safety and Clinical Performance, under the Medical Devices Regulation 2017/745 (EU MDR) and with little experience in the preparation of lay summaries.

Teaching methods

The workshop will be a mixture of presentations, team discussion, brainstorming and practical examples.

Lecturer

Dr. Katharina Friedrich, *MD – Freelance Medical Writing Consultant*
Katharina Friedrich is a medical writer with 5 years of experience in MDR regulatory writing. She is based in Heidelberg, Germany and works as a Freelance Medical Writing Consultant for various medical device companies, including startups and global players. She prepares Clinical Evaluation Plans and Reports, PMCF Plans and Reports and SSCPs in compliance with MDR 2017/745 for class I to class III devices. She also supports development projects and the conduction of PMCF activities. As medical doctor she has experience in the field of orthopedic, spine and trauma surgery and intensive care medicine.

At the end of the training, you will be able to:

- Understand the regulatory requirements for the SSCP
- Optimize the relevant input documents for the SSCP and learn how to extract the most relevant information
- Prepare lay summaries, including product description and summary of study results
- Prepare a summary of safety and performance information for healthcare professionals
- Understand common pitfalls with the preparation of the SSCP and know how to avoid them

REGISTRATION FEE

Pre-Conference Workshop + Conference:

€ 1.045,00* SUPER Early Bird fee until 01 July 2023
€ 1.105,00* Early Bird fee until 09 September 2023
€ 1.310,00* Ordinary fee
€ 660,00* Freelance, Academy, Public Administration

Fee includes: seat at the training. seat at the conference, training material, copy of presentations of Speakers who allow the distribution, coffee breaks, networking lunch, organisational office assistance, certificate of attendance.

Pre-Conference Workshop:

€ 560,00* Early Bird fee until 09 September 2023
€ 670,00* Ordinary fee
€ 310,00* Freelance, Academy, Public Administration

Fee includes: seat at the training, training material, coffee break, organisational office assistance, certificate of attendance.

Conference:

€ 670,00* Early Bird fee until 09 September 2023
€ 790,00* Ordinary fee
€ 430,00* Freelance, Academy, Public Administration

Fee includes: seat at the conference, copy of presentations of Speakers who allow the distribution,

networking lunch, coffee breaks, organisational office assistance, certificate of attendance.

* *for Italian companies: +22% VAT*

USEFUL INFORMATION

The conference will take place at:

NH Vienna Airport
Einfahrtsstrasse 1- 3, 1300 Vienna

The NH Vienna Airport Conference Center hotel enjoys a convenient location just across from the arrivals hall at Vienna Airport. That means we have unbeatable transport links – if you want to head into the city, it's just a 16-minute train ride to central Vienna.

- From Vienna International Airport (VIE): it is a 6 min walk to get to the hotel
- Closest metro station: Flughafen Wien (City Airport Train)
- To get to the city center of Vienna, you can use the City Airport Train, which departs every 30 minutes. The trip will take 16 minutes. Click here for the timetable.

COVID-19
LS Academy is aware of the evolving impact of COVID-19 and is committed to offering safe and secure face-to-face courses and conferences. From physical distancing, protect, detect, cleaning and hygiene. LS Academy ensures that all our events are conducted in accordance with official government guidelines and regulations, understanding that these measures may vary and change as the situation evolves.

CONFERENCE VENUE

NH Vienna Airport
Einfahrtsstrasse 1- 3
1300 Vienna – Austria