MedDev Day

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MDR 2017/745 Reality Check – Readiness of the EU System

Date
27 September 2022

Language
English

Location
Barcelona, Spain

SPONSORS

MEDIA PARTNERS

CREATIONKnowledge
HCP insights for leaders in healthcare

ABOUT

The EU MDR 2017/745 was published in May 2017 with a transition period of three years which was extended by one additional year to address COVID 19 restrictions and limitations.
This additional year was taken away from the predefined grace period in Article 120 of the EU MDR 2017/45. During the grace period, which will end in May 2024, manufacturers are still allowed to place devices certified under the Medical Device Directives to the Union Market.

With approximately 2 years to go till the end of the grace period, manufacturers and notified bodies are under growing time pressure to move devices from the old Directives to the EU MDR 2017/745. This move is leading to a lot of issues which are connected to capacity limitations, continuous new interpretations, and administrative burdens.

After more than 4.5 years after publication of the regulation just 50% (n=27) of the notified bodies who applied (n=54) to be designated and notified for the new regulation were successful and are enabled now to perform their task under the new legislative framework.
Nevertheless, just 10% of these notified bodies hold a full scope of designation.

More than 90 guidance documents were published since the publication of the regulation to explain the meaning of the legal text, leading to new interpretation in a continuous manner and impacting already running conformity assessment processes critically. Common specifications which are essential for the system are still under preparation. Voluntary consultation process to address the missing pre-assessment elements and technical meeting services of notified bodies is not available.

During this annual Medical Device conference, keynote speakers from the various sectors will share their views, current experiences, and recommendations towards a smoother implementation of the EU MDR 2017/745.

Enrol in this face-to-face Medical Device conference to take place in Barcelona on 27th September 2022!

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 - *Medical Writing & 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.

PROGRAMME

27 September 2022	
09:00 **09:30**	**Registration**
09:30 **09:40**	**Welcome from the Scientific Board**
09:40 **10:10**	**Impact of the EU Regulations on the daily work of Competent Authorities** **Thomas W. Møller** Former Director for Medical Devices at Danish Medicines Agency and former chair of the CAMD
10:10 **10:40**	**European MDR update – Status of implementation** **Dario Pirovano** Senior Regulatory Adviser at MedTech Europe
10:40 **11:20**	**Capacity of Notified Bodies** **Sabina Hoekstra-van den Bosch** Regulatory Strategy Principal at TÜV SÜD
11:20 **11:50**	**Coffee break**

11:50 **12:30**	**First Experience with EU MDR Certification – are we there yet?** **Elizabeth Gfoeller** Corporate Director, Regulatory Affairs at MED-EL Elektromedizinische Geraete GmbH
12:30 **13:10**	**Lessons Learned with MDR Consultation Requirements** **Bassil Akra** Chief Executive Officer at AKRA TEAM GmbH **Arkan Zwick** Corporate Regulatory Affairs Director at CROMA Pharmaceutical, Austria
13:10 **14:10**	**Networking lunch**
14:10 **14:50**	**Compliance in the Grace Period – Balancing MDD vs. MDR** **Philippe Auclair** Senior Director, Regulatory Strategy and Advocacy at Abbott Quality and Regulatory
14:50 **15:30**	**How to ensure better Readiness of your Application?** **Gert Bos** CSO at Qserve Group
15:30 **16:00**	**Coffee break**
16:00 **16:30**	**Round Table: What? When and How?**
16:30 **16:40**	**Conclusions**
All day long	**Meet-the-Experts one-on-one slots: MDR State of the Art & Medical Writing**

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, Austria

Speaker
Philippe Auclair
Senior Director, Regulatory Strategy and Advocacy at Abbott Quality and Regulatory

Speaker
Gert Bos
CSO at Qserve Group

Speaker
Elizabeth Gfoeller
Corporate Director, Regulatory Affairs at MED-EL Elektromedizinische Geraete GmbH

Speaker
Thomas W. Møller
Former Director for Medical Devices at Danish Medicines Agency and former chair of the CAMD

Speaker
Dario Pirovano
Senior Regulatory Adviser at MedTech Europe

TRAINING

The pre-conference training is SOLD OUT!

We're planning a new edition. Contact us for more info ilaria.butta@lsacademy.com

26 September 2022

PRE-CONFERENCE TRAINING

From 14:00 to 18:00 | H10 Marina Barcelona, Barcelona

Periodic Safety Update Report (PSUR)
Are you ready to satisfy the regulator's expectations?

Introduction

The Periodic Safety Update Report (PSUR) is an entirely new type of report that has been introduced in Article 86 of the Medical Device Regulation (MDR). It requires manufacturer of class IIa, class IIb and class III devices to prepare a Periodic Safety Update Report (PSUR) for each device and where relevant for each category or group of devices summarizing the results and conclusions of the analyses of the PMS data gathered.

The regulatory requirement is set, yet the PSUR is a new document and manufacturers often do not have a clear view of what it entails:

- What do MDCG guidelines say?
- What are the expected data sources that need to be analysed and presented?
- Which type of preventive and corrective actions need to be listed in the PSUR?
- What are the main findings that should come out of the PSUR?
- Where does it fit within the PMS context and other post-market documents such as the PMCF Evaluation Report, the CER and the SSCP?

This workshop will provide relevant information to draft a PSUR, including what data should be presented and how it should be reported. It will offer the experience of an industry-expert for all representatives involved in working with medical devices under the MDR umbrella.

Programme

- The regulation, the guidelines and their context
- Submission obligations and timelines
- Data to be presented and how it should be presented
- Reportable data and main findings
- Challenges and lessons learned from first experiences

Who should attend?
The course is addressed to:

• Clinical Affairs
• Post-Market Surveillance
• Regulatory Affairs
• Medical Writers
• Product Managers
• CROs

Teaching methods
Interactive training

Lecturer
Markus Pöttker – *PMS EU MDR Workstream Lead* at Smith&Nephew

Markus is a member of the EU MDR Project team at Smith&Nephew leading the Post Market Surveillance work stream. In this role, he is responsible that the requirements of the EU MDR are correctly interpreted and implemented across the company. Prior to this, he spent seven years in Quality & Regulatory roles, at last he was the Director of Complaint Management and Head of Regulatory Compliance with global responsibility for Complaint Handling, Medical Device Reporting and interaction with Regulatory Agencies. Markus is co-chair of MedTech Europe's PMS & Vigilance Working Group and a member of the MDCG Task Forces for Vigilance, PSUR and PMS. Markus holds a master's degree in law from WWU Münster, Germany.

Markus is a bridge builder between the regulatory requirements for medical devices and practical

implementation in companies. In addition to complex regulatory issues, he is passionate about digitalisation and lean process optimization – but also about human communication. He believes that technical innovation will continue to transform the medical technology industry.

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

- Understand the regulatory requirements for PSUR
- Identify the relevant input documents for your PSUR
- Prepare PSURs for different device classifications
- Understand challenges and lessons learned from first experiences of PSUR preparations

REGISTRATION FEE

Pre-Conference Training + Conference:

€ 1.045,00* SUPER Early Bird fee until 01 July 2022
€ 1.105,00* Early Bird fee until 09 September 2022
€ 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 Training – SOLD OUT
€ 560,00* Early Bird fee until 09 September 2022
€ 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 2022
€ 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:

H10 Marina Barcelona
Av. Bogatell, 64-68 – E08005 – Barcelona

H10 Marina Barcelona is 10 minutes walk from the beach and 5 minutes away you have the Olympic Village. Closer to the Metro stop, Bogatell: it is just 2 minutes behind the hotel and can take you into the city centre in 15 minutes, or you could even walk in about 30-40 minutes.

100 m from Bogatell metro station (Line 4)
300 m from Marina metro station (Line 1)
15 km from Barcelona-El Prat airport

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

H10 Marina Barcelona
Av. Bogatell, 64-68
E-08005 – Barcelona