Med Dev day

LIFE SCIENCE ACADEMY

MedDev Day

Medical Devices Regulation Update: Exploring the Thriving Regulatory Landscape

Date
07 and 08 October 2024

Language
Inglese

Location
Copenhagen

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ABOUT

As the European medical devices regulations (MDR) enters its third year of application, the industry is striving to comply with MDR compliance in a challenging economic and regulatory environment.

As first movers approach their recertification dates, other companies are achieving their initial product and quality system certifications, while some industry players are still in the application phase to meet the transitional requirements.

At the same time, the regulatory system is scrutinised to see how it delivers on its promises of better regulation, less burdensome requirements, and competitiveness and attractiveness in a global perspective.

This year's MedDev Day will focus on the attractiveness of the European regulatory landscape for medical devices, improvements made and future developments.

Delegates will get practical insights on:

- how to meet MDR requirements and cost of compliance,
- the comparison of the European system to other regulatory regimes and global regulatory and clinical strategy
- how to streamline and cost effectively meet post market obligations
- how to achieve recertifications in a least burdensome approach
- how to minimize efforts for phasing out MDD/AIMDD and how to successfully shift to MDR as for transition delegates
- latest developments on the regulation, EUDAMED and clinical standards

The one-and-a-half-day program features Industry and competent authority talks followed by interactive workshops to allow elaborate solutions for post market programs and clinical strategy.

Scientific Board:

Bassil Akra, *Chief Executive Officer at AKRA TEAM*
Arkan Zwick, *Corporate Director Regulatory Affairs at CROMA Pharma*

Who should attend?

The conference is aimed at medical device professionals from Regulatory Affairs, Quality, Clinical Operations, Medical Affairs, Post Marketing Surveillance departments working in Pharmaceutical, Biotechnology and Medical Device companies, CROs, Universities/Hospitals, Academic Research, Patient Associations and Healthcare Organisations, Competent Authorities, EU Commission and Regulatory Authorities.

PROGRAMME

07 October 2024	
13:00 **13:30**	**Registration**
13:30 **13:40**	**Welcome by the Scientific Board**
13:40 **15:15**	**OPENING PANEL DISCUSSION | Legislation from Different Perspectives: Regional Update** **Daniel Delfosse** Vice Director and Head of Regulation & Innovation at Swiss Medtech **Martin Penver** Team Leader for product assessment at TÜV SÜD Denmark **Monisha Phillips** Head of Certification Body (MHS UK) at TÜV SÜD **Amra Racic** Sr. Director Global Government Strategy MedTech at Veeva Systems **Nebojsa Serafimovic** Assessor for Clinical Investigations with Medical Devices at AGES/BASG
15:15 **15:45**	**Coffee break**
15:45 **17:00**	**WORKSHOP SESSION | European Challenges and Opportunities**
17:00 **17:15**	**Wrap-up Day 1**
08 October 2024	
08:45 **09:00**	**Start Day 2**
09:00 **09:40**	**Manufacturer´ Experience with EU MDR Implementation** **Glenda Marsh** Head of EU Regulatory Affairs at Johnson & Johnson

09:40 **10:20**	**Switzerland and UK: New Requirements and Challenges from an Authorised Representative/Manufacturer's Perspective** **Larissa Piñon Ferreira** Regulatory Affairs Manager at Becton Dickinson
10:20 **10:50**	**Coffee break**
10:50 **11:30**	**Medical Device Software: US vs EU Paths to Market** **Elizabeth Gfoeller** Corporate Director, Regulatory Affairs at MED-EL
11:30 **12:10**	**Navigating the MDR Maze: Pragmatic Post-Market Surveillance** **Markus Pöttker** Director, Global Post-Market Surveillance at Smith&Nephew
12:10 **12:20**	**Q&A Session**
12:20 **13:20**	**Networking Lunch**
13:20 **14:20**	**INTERACTIVE SESSION | New, newer, newest - Recommendations of and Musings about Future Evolutions or Improvements of the Regulatory System** **Erik Vollebregt** Partner at Axon Lawyers
14:20 **14:50**	**Coffee break**
14:50 **15:30**	**US 510(k) versus EU MDR Submission** **William Lory** Regulatory Affairs Manager EMEA at Sirtex Medical
15:30 **16:10**	**Is the European Device Regulatory System Still Attractive and Competitive?** **Arkan Zwick** Corporate Regulatory Affairs Director at CROMA Pharmaceutical, Austria
16:10 **16:20**	**Closing Remarks by the Scientific Board**

SPEAKERS

Scientific Board
Bassil Akra
Chief Executive Officer at AKRA TEAM GmbH

Scientific Board
Arkan Zwick
Corporate Regulatory Affairs Director at CROMA Pharmaceutical, Austria

Speaker
Daniel Delfosse
Vice Director and Head of Regulation & Innovation at Swiss Medtech

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Corporate Director, Regulatory Affairs at MED-EL

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NORDIC LIFE SCIENCE

In collaboration with Nordic Life Science, all the participants will receive a digital copy of their latest

issue free of charge at the end of the conference.

REGISTRATION FEE

€ 670,00 Early Bird fee **extended until 16 September 2024**
€ 790,00 Ordinary fee
€ 480,00 Freelance, Individual, Academy, Public Administration

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

USEFUL INFORMATION

The conference will take place at:

Hotel Scandic Copenhagen
Vester Søgade 6, Copenhagen – Denmark

Centrally located, 500 metres from Copenhagen Central Station, this contemporary hotel offers stunning views of the lakes and the Copenhagen skyline. From Copenhagen Airport: only 12 km by car. By public transport (via metro or bus), journey time around 25-minutes.

CONFERENCE VENUE

Hotel Scandic Copenhagen
Vester Søgade 6
Copenhagen – Denmark