

Med Dev_{day}



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MedDev Day

Shifting Mindsets: The Future of Global Medical
Device Regulation - How Regulatory Changes Are
Reshaping Global Business Strategies

Date

13 and 14 October 2025

Language



English

Location

Budapest

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MedDev Day 2025 - Shifting Mindsets: The Future of Global Medical Device Regulation

How Regulatory Changes Are Reshaping Global Business Strategies

Regulatory approaches across the EU, the USA, and many other regions worldwide are evolving, requiring companies relying on these markets to adapt to increasingly stringent requirements.

Join **MedDev Day 2025** to discover the latest regulatory updates, with a focus on the EU, USA, Asia, and MEA. Learn how to maintain a competitive edge, ensure compliance, and foster innovation in the medical device sector.

What to expect at MedDev Day 2025:

- In-depth analysis of new regulatory frameworks and specific pathways (e.g., orphan devices and Scientific Advice procedures).
- A focus on the value of real-world evidence (RWE) in pre- and post-market strategies, covering data quality and relevance.
- A workshop session on Artificial Intelligence and Machine Learning to explore benefits and challenges in quality, regulatory, and clinical environments.
- An overview of the appeal of various regulatory contexts, with particular attention to technological and sustainable solutions.
- Opportunities to network with industry professionals (manufacturers, notified bodies, competent authorities) and develop practical strategies to boost operational efficiency.



This seventh edition, **held over one and a half days**, will highlight how cost and technology factors drive the evolution of the regulatory landscape, offering methodologies and best practices to guide your business decisions. Dedicated sessions on real-world case studies will demonstrate how to manage documentation effectively and promote evidence-based decision-making.

Scientific board

Bassil Akra, *Chief Executive Officer at AKRA TEAM*

Arkan Zwick, *Corporate Director Regulatory Affairs at CROMA Pharma*

WHO SHOULD ATTEND?

MedDev Day 2025 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.

Join us in Budapest on **13 -14 October 2025** to stay up to date with regulatory changes, forge valuable connections, and develop winning strategies in the medical device world.

Register now and help shape the future of regulation.

PROGRAMME

13 October 2025	
13:00 13:30	Registration and Light Lunch
13:30 13:40	Welcome by the Scientific Board
	SESSION REGULATORY UPDATES FROM DIFFERENT REGIONS
13:40 14:20	Insights into Medical Device Registration in Japan and in China Irene Lu Vice President at Qualtech Consulting Co.
14:20 15:00	Impact of the EU MDR on the Regulatory Landscape in the MEA Region Rana Chalhoub Regulatory Affairs Director at MECOMED - the MEA MedTech Association



15:00 15:40	One Union to Rule Them All: Medical Device Registration in the EAEU (Eurasian Economic Union) Lyudmila Dashdamirov Regulatory Affairs Director EMEA at HOYA Surgical Optics
15:40 16:10	Coffee break
16:10 17:25	WORKSHOP: AI in Regulatory Affairs - Buzzword or Game-Changer? Steven Reichen Founding Member at FLINN - AI Solutions for Regulatory Affairs Tibor Zechmeister Head of Quality and Regulatory at FLINN - AI Solutions for Regulatory Affairs
17:25 17:30	Wrap-up Day 1
14 October 2025	
9:00 9:15	Start Day 2
	SESSION EU REGULATORY UPDATES
9:15 9:30	Living in Transition - Challenges and Opportunities Ágnes Horváth Clinical Lead at CE Certiso Kft.
9:30 9:45	MDR State of Play - Manufacturers' Perspective Jana Russo Regulatory Affairs (IVDR & MDR), Manager Medical Devices at MedTech Europe
9:45 10:00	Breakthrough Innovation in the field of High-risk Implants: Balancing Risks and Benefits Nataliya Deych Vice President Regulatory Affairs EMEA, Latam, Canada at Edwards Lifesciences
10:00 10:20	Q&A Session
	SESSION CLINICAL DATA EXPECTATIONS, PRE- AND POST-MARKET, RWE
10:20 10:35	Managing the Pre- and Post-Market Expectations Bassil Akra Chief Executive Officer at AKRA TEAM GmbH



10:35 10:50	Legacy, NPD, and unmet Medical Need - How much is enough? Richard Holborow Global Head of Clinical Compliance for BSI Notified Body (NL) & BSI Approved Body (UK)
10:50 11:20	Coffee break
11:20 11:35	Benefits and Limitations of Surveys Marcus Torr Head of Post Market Surveys at Purdie Pascoe
11:35 11:50	RWE: How can this source of data be useful in Regulatory and R&D? Amelia Hufford Senior Vice-President, Clinical and Regulatory Science Operations at 3Aware
11:50 12:10	Q&A Session
12:10 13:10	Networking Lunch
	SESSION REGULATORY STRATEGY
13:10 13:40	Introduction into Regulatory Strategy Arkan Zwick Corporate Regulatory Affairs Director at CROMA Pharmaceutical, Austria
13:40 14:10	How to Use Clinical Data Derived Outside the EU for EU MDR Submissions Andrew Gibson Senior Managing Consultant at AKRA TEAM
14:10 14:40	Coffee break
14:40 15:40	WORKSHOP: Regulatory Strategy in Practice
15:40 15:50	Conclusions by the Scientific Board

SPEAKERS



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Scientific Board

Bassil Akra

Chief Executive Officer at AKRA TEAM GmbH



Scientific Board

Arkan Zwick

Corporate Regulatory Affairs Director at CROMA Pharmaceutical, Austria



Speaker

Rana Chalhoub

Regulatory Affairs Director at MECOMED - the MEA MedTech Association



Speaker

Lyudmila Dashdamirov

Regulatory Affairs Director EMEA at HOYA Surgical Optics



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Vice President Regulatory Affairs EMEA, Latam, Canada at Edwards Lifesciences



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Speaker

Amelia Hufford

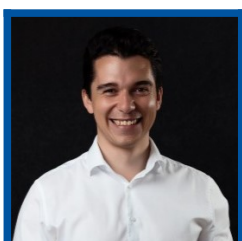
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Head of Post Market Surveys at
Purdie Pascoe



Speaker
Tibor Zechmeister
Head of Quality and Regulatory at
FLINN – AI Solutions for
Regulatory Affairs

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REGISTRATION FEE

€ 670,00 Early Bird fee **extended until 30 September 2025**

€ 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:

NH Budapest City

Vígszínház u.3 – 1137 Budapest

The NH Budapest City hotel is in the Újlipótváros business district on the Pest side of the river. Some of Budapest's star attractions are right on the doorstep, and the nearby metro station whisks you to more tourist hotspots.

From the airport

Taxi: it's a 40 minutes trip.

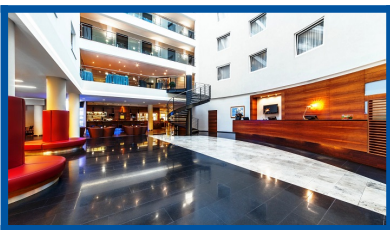
Bus: you can take the bus line 200 from the Airport Budapest, station "Repülőtér, P+R" to get to the station "Kobanya-Kispest". From there take the metro line M3 (blue line) for the station "Nyugati Pályaudvar". You can reach the hotel in a walking distance from about 5 minutes.

From the train station

From Nyugati Station: exit the station and turn right for the street "Szent István Krt". From there please turn right again for the street "Hegedüs Gyula". Afterwards please turn left for the street "Vígsház". The hotel is located on the right.

Closest metro station: Nyugati Pályaudvar (M3-blue line).

CONFERENCE VENUE



NH Budapest City

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