WEBCAST SERIES

FORUM

MedTech FORUM International 2026

Stay Informed with Regulatory Updates!

THE UPCOMING WEBCASTS AT A GLANCE

- Global Regulatory Strategy in MedTech
- EUDAMED 2026 Readiness
- EU Manufacturers: Post-Market Obligations in Selected non-EU countries
- AI in Regulatory Affairs: From Global Intelligence to Workflow Integration
- UDI 2026: Digitalisation, Data Integrity & Global Alignment
- Classification, Registration & Lifecycle Management of Combination Products and Substance-based Devices - EU vs. US

YOUR BENEFITS

- Bi-monthly lunchtime updates with leading MedTech experts
- Concise, practice-oriented updates for your daily work
- Interactive sessions with live Q&A and downloadable slides

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MedTech FORUM International

Concept

Stay up to date on MedTech regulatory affairs. Every two months, our experts share key developments and trends in compact **1.5–2-hour live sessions,** held conveniently during lunchtime from **11:00 AM to 1:00 PM (CET).** The presentations are streamed live and accompanied by downloadable slides for your reference. Your questions will be coordinated by a chairperson and addressed directly to the speakers during the session, creating an engaging and interactive learning experience.

Additional benefits

Missed a session? Watch the recorded webcast on demand at any time.
Optional multiple-choice tests allow you to earn your personal certificate of participation.

Programme: MedTech FORUM International 2026

Your experts

Dr iur. Arkan Zwick
CROMA PHARMA GmbH,
Leobendorf, AUSTRIA
Regulatory Affairs Director

Przemysław Kowalski
p36 GmbH, Bad Hersfeld,
GERMANY
UDI Subject Matter Expert

Date, time and programme

23 January 2026, 11am CET
Global Regulatory Strategy in MedTech

- Prioritising target markets based on regulatory effort and commercial opportunity
- Comparing regulatory pathways - CE marking, FDA, NMPA, ANVISA, PMDA
- Choosing submission strategies
- Coordinating global approvals - timelines, local partners, and project milestones

17 March 2026, 11am CET
EUDAMED 2026 Readiness

- How can you prepare most effectively? What should be prepared and when?
- Current steps and practical implementation of Actor registration, SRN and UDI data
- What to consider for certificates, clinical investigations and vigilance
- Cross-functional coordination & data quality

Christoph Kiesselbach

Schrack & Partner
Reutlingen, GERMANY
Consultant and Partner

20 May 2026, 11am CET

EU Manufacturers: Post-Market Obligations in Selected non-EU countries

- Post-market surveillance in an international context
- Monitoring and vigilance requirements
- Integration of distributors, market authorisation holders and other stakeholders
- Integrating international requirements in the QMS
- Use of international post-market data for the MDR PMS requirements

Samuel Kilchenmann

ISS AG, Integrated Scientific Services,
Bern, SWITZERLAND
Senior Expert Consultant Digital Health & AI

2 July 2026, 11am CET

AI in Regulatory Affairs: From Global Intelligence to Workflow Integration

- Leveraging AI-powered platforms to automatically capture global regulatory updates
- Applying Natural Language Processing (NLP) to analyse complex legislation and guidance documents
- Integrating regulatory intelligence tools into market access and marketing authorisation workflows

Jürgen Mehring

Mehring Consulting,
Ahlen, GERMANY
Senior Consultant RA/QA

8 September 2026, 11am CET

UDI 2026: Digitalisation, Data Integrity & Global Alignment

Dr Francisco Rodríguez Gómez

ASPHALION S.L.,
Barcelona, SPAIN
Scientific and Regulatory Affairs I Medical Technology I In vitro Diagnostic Medical Devices I Combination Products

10 November 2026, 11am CET

Classification, Registration & Lifecycle Management of Combination Products and Substance-based Devices - EU vs. US

- Definitions and Classifications: combination products and substance-based devices – types, key features, borderline cases
- EU certification process: conformity assessment, consultation procedures and relevant stakeholders
- Overview of regulatory requirements for demonstrating safety and performance, TD
- Post-approval activities: Vigilance, change control, lifecycle updates
- Comparison with US regulatory jurisdiction

MedTech FORUM International

HOW TO REGISTER

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REGISTRATION

Yes, I want to join the

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☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

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Street address

Postal Code/City/Country

Tel. No.

Date, Signature

Fee:
Membership of the MedTech FORUM International is valid for one year. The annual membership fee of €1,100 (plus German VAT) is payable upon registration. Membership is automatically extended by a further year unless written notice is submitted no later than six weeks before the end of the membership. Membership for 12 months may begin at any time.

We also offer group accounts: For €1,990 (plus German VAT) you can watch with your colleagues in the conference room via a single account (without the possibility to receive certificates), for €2,500 (plus German VAT) you receive up to five individual accounts including the possibility of a certificate for each participant; and for €3,750 (plus German VAT) you receive up to ten individual accounts including the possibility of a certificate for each participant.

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CANCELLATION POLICY

Our general terms and conditions (as of 01 June 2024) apply and are available upon request. We can send them to you at any time. Alternatively, you can access them online at www.forum-institut.com/t&c

YOUR CONTACT

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