ONLINE CONFERENCE

ExpertFORUM Global Regulatory Affairs

Trends and Strategies

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Dr. Isabelle Stöckert
Independent Regulatory Science Expert

Mark A. Gray
LORENZ International LLC

Dr. Gabriele Wirtz
Bayer AG

17 - 18 SEPTEMBER 2026 - ONLINE

Aims and objectives

Global regulatory alignment is advancing rapidly. Joint review procedures, harmonised evidence requirements and evolving digital standards are reshaping the way pharmaceutical companies plan submissions and navigate international market access. For regulatory professionals, staying current with these developments is not a peripheral task, it is a strategic necessity.

This conference provides a consolidated, practice-oriented overview of the regulatory trends that matter most, including the convergence of regulatory and HTA requirements and the growing relevance of AI in supporting global regulatory strategies. Seven focused expert presentations deliver substantive insight across key areas of international regulatory alignment, structured to be directly applicable to strategic work and day-to-day decision-making.

Participants will leave with a sharper understanding of where global regulatory convergence stands today, where it is heading and how to position their organisation to respond effectively.

Who should attend?

This conference is designed for regulatory affairs managers and professionals operating in international contexts, particularly those with responsibility for strategic regulatory planning, global submissions and international market access for pharmaceuticals. A solid working knowledge of international regulatory frameworks and standard submission procedures is recommended.

Your speakers

Dr. Rüdiger Faust
UCB BIOSCIENCES GmbH
Policy and Intelligence Lead,
Regulatory Community Excellence

Melanie Geukes
Bayer AG
Global Regulatory Strategist

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Independent consultant in Regulatory Information Management

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ExpertFORUM Global Regulatory Affairs – Trends and Strategies

17 September 2026, 09:00 am - 04:00 pm

Joint Scientific Consultation (JSC) - aligning the needs of Regulatory agencies and HTA bodies in EU towards one global evidence program
Dr. Isabelle Stöckert

Global Reliance in Action: ACCESS, ORBIS and OPEN Review Pathways
Dr. Ulrich Granzer

Strategic Evidence Generation in a Global Regulatory Context
Andreas Lindackers

- Real-World Evidence in Global Regulatory Decision-Making: From DARWIN EU to FDA
- Implementing ICH E6(R3) and ICH M14: The Next Generation of Clinical Standards - Real-World perspective

Structured Product Data: ISO IDMP – Global Perspectives
Remco Munnik

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18 September 2026, 09:00 am - 01:00 pm

eCTD 4.0 Rollout: Preparing for the Next Era of Global Submissions
Mark A. Gray

Strategies for Global Lifecycle Management in Countries outside EU, US, Japan and China: Coordinating variations, PSURs and renewals efficiently across global markets
Melanie Geukes, Dr. Gabriele Wirtz

Exploring the Use of AI in Global Regulatory Intelligence
Dr. Rüdiger Faust

ExpertFORUM Global Regulatory Affairs

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REGISTRATION FORM

Yes, I will attend

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☐ Yes, I agree that FORUM Institut may inform me about events by:
☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

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Position, department

Company

Street address

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at office

Date, Signature

Date
17 - 18 September 2026 - online

Fee
€ 1590.00 (+ German VAT)
The fee includes high-quality course material and a participation certificate for download, access to the Learning Space as well as technical support including a test meeting

How our online events work

- Our online events are live and interactive. They can be accessed in the Learning Space, where you will also find the programme, the list of participants and all relevant documents.
- You can access the Learning Space with the same account you use for the customer portal.
- The free pre-meeting helps you resolve any technical issues before the event.
- Continuous support during the online event guarantees that you concentrate entirely on the training.
- We guarantee the highest quality according to ISO 9001 and ISO 21001.

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

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