This course provides a practical overview of the European regulatory system, covering main EU licensing routes — centralized, decentralized, mutual recognition, and national — plus pathways for orphan drugs, pediatrics, and advanced therapies. Participants will learn about the roles of the European Commission, EMA, and National Authorities, and key topics such as pharmacovigilance, clinical trials, and market exclusivity.

Designed to simplify complex EU regulatory processes, the program helps professionals master essential steps before and after marketing authorization. It includes a 4-hour self-learning module on EU fundamentals and a 4-hour live online session featuring case studies and fast-to-market strategies including ATMPs.

EU Fundamentals Online Learning Module:

The Online Learning Module will be available from 10 December.

Introduction to the EU
- EU countries/ EU languages
- Roles and Responsibilities of European Institutions
- EU legislative framework concerning medicinal products

EU Licensing Procedures – Part 1
- Marketing Authorizations in the EU – the basics
- National Procedures / Mutual Recognition Procedure/ Decentralized Procedure

EU Licensing Procedures – Part 2
- Centralised Procedure
- Conditional Approval
- Approval under exceptional circumstances
- Accelerated Assessment
- Post-Marketing Requirements
- Comparison to US and PMDA procedure

Case Studies

Live Virtual Training:

The live virtual training will be held on 14 and 16 January 2026.

Live Training (14 Jan, 2026 4:00-6:00 PM (KST/JST), 3:00-5:00 PM (SGT/CST)

- Life Cycle of a Medicinal Product: From early development to market access and post-marketing + Case studies
- Specific Medicinal Products + Case studies

Live Training (16 Jan, 2026 4:00-6:00 PM (KST/JST), 3:00-5:00 PM (SGT/CST)

- Variations/Post-Approval Changes
- Pharmacovigilance

Additional live sessions may be opened depending on the number of registrants

For more details and registration, please visit the link below.

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SESSION FACULTY

Peter Bachmann

Retired from Head International Liaison Office and Conferences, Executive Depart, Federal Institute for Drugs and Medical Devices (BfArM), Germany
30+ years in EU regulatory science; former BfArM Head and IPRP Chair (2021–2023), served on key EMA & ICH committees.

Anna Silke Hammerbacher

Vice President, SSI Strategy, Germany
Over 15 years in global regulatory strategy, led approvals for multiple blockbusters and advised EMA and FDA as an industry leader.

TARGET AUDIENCE
This program is ideal for professionals involved in global drug development, regulatory strategy, and market authorization, particularly those seeking to expand their understanding of the European regulatory framework.

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DIA volunteers, members, and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications, and educational materials, throughout the year, all around the world.

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European Medicines Regulation Training
From 10 December 2025 Access available to the online learning module
14 and 16 January 2026 from 4:00 to 6:00 PM (KST) Live virtual training.

REGISTRATION

Register online at the link below or complete this registration form and email to our Korea Office

DIA will send participants a confirmation letter within 10 business days after receipt of their registration.

Registration Fee   If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes full admission to virtual course, electronic access to training course materials. Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material. US

			REGISTRATION FEE (USD)
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		After 10 December, 2025	❑ 170
	Government	Early Bird	❑ 120
		After 10 December, 2025	❑ 145
	Industry	Early Bird	❑ 200
		After 10 December, 2025	❑ 240
NON-MEMBER	Academia	Early Bird	❑ 175
		After 10 December, 2025	❑ 210
	Government	Early Bird	❑ 150
		After 10 December, 2025	❑ 180
	Industry	Early Bird	❑ 250
		After 10 December, 2025	❑ 300
Students/ Patient / Patient Advocacy Groups			❑ 50

Please check the applicable category:
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