ONLINE TRAINING

Variations in Europe

Practical Guidance on Classification, Submission and Current Regulatory Updates

TOPICS

- Variation Regulation (inlcuding new features since 01.01.25)
- Classification and submission
- Type IA Notification, Type IB and II Variations
- Grouping and worksharing
- Variation submission (eAF, CESP)
- Quality-related variations: Changes in the production process, analytics, formulation and packaging

YOUR SPEAKERS

Kora Doorduyn-van der Stoep
Medicines Evaluation Board MEB), Utrecht, THE NETHERLANDS

Pablo López Bajo
ASPHALION S.L., Barcelona

Dr Regina Heckenberger
Bayer AG, Wuppertal, Germany

Dr Elke Löber
Senior CMC Regulatory Affairs Manager at Boehringer Ingelheim International GmbH.

8 - 9 SEPTEMBER 2025 - ONLINE

Aims and objectives

This training will bring you the latest information in the planning, classification and submission of variations. All relevant changes related to the new Variation Regulation (applicable since 01.01.25) will be discussed.

Day 1 addresses regulatory requirements in detail, particularly guidance documents, variation classification, use of the variation (e-)application form and organisation of grouping and worksharing.

Day 2 addresses the classification and handling of quality-related changes. Case studies on how to work with the classification guideline and the Q&A paper will reinforce your knowledge.

Who should attend?

This practical seminar is aimed at anyone involved in planning, creating or submitting variations.

Employees in the following departments will particularly benefit from the seminar:

- regulatory affairs
- quality assurance
- production

YOUR SPEAKERS

Kora Doorduyn-van der Stoep
Medicines Evaluation Board MEB), Utrecht, THE NETHERLANDS
Chairperson CMDh
EU representative at the MEB

Pablo López Bajo
ASPHALION S.L., Barcelona

Dr Regina Heckenberger
Bayer AG, Wuppertal, GERMANY
Head of Regulatory CMC Wuppertal

Dr Elke Löber
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Booking options: e-Learning - EU Variation System & Procedures

Do you lack basic knowledge about variation procedures? Then we recommend the English-language e-learning ‘EU Variation System and Procedures’. If you register for both the seminar and the e-Learning the price of the e-Learning is reduced by €100 (€390 instead of €490 plus VAT).

Officially certified according to ISO 9001 and ISO 21001

Your programme for both days (each 9:00 am - 5:00 pm)

Day 1

Basics, fundamentals & classification
- Variation regulation, classification guideline

Type IA-notification
- Type IA-changes according to the classification guideline
- Annual report
- Immediate notification (Type IAIN)

Type IB-variations
- Type IB-changes according to the classification guideline
- Type IB by default

Type II-variations
- Processing of type II variations
- Timelines, submission and validation

Grouping, super-grouping and worksharing
- Grouping of different types of variations
- (Super-)grouping IA variations and worksharing according to new variation regulation

Variation submission
- Variation (e)-application form
- SPOR; Web-based e-AF; PLM Portals

Special notification of change

Day 2

Changes in the production process
- Notification or variation
- Batch size change
- Change in the manufacturing flow
- Site transfer

Changes in the formulation
- API and excipient new suppliers
  How to assess a change and build a submission plan
- Challenges

Changes in the analytics - changes of:
- Contract laboratories
- Analytical methods
- Acceptance criteria/specifications
- Regulatory change control management

Packaging and production changes
- Primary/secondary packaging (specification, testing)
- Change of packaging sites
- Labelling impact

Practical examples and case studies

Variations in Europe

REGISTRATION UNDER

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REGISTRATION FORM

Yes, I will attend

☐ Complete training course (8-9 September 2025)

☐ the additional e-Learning 'EU Variation System & Procedures'

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

Name

Position, department

Company

Street

Post code, city, country

Tel. no./Fax no.

E-mail

Contact person at office

Date, signature

Date
8 - 9 September 2025 - online
Both days from 9:00 am to 5:00 pm online training
You may dial in 30 min. before the session starts

Fee
€ 1990.00 (+ German VAT)
The fee includes high-quality course material for download, a participation certificate, access to the Learning Space as well as technical support including a test meeting.

Fee e-Learning (25122643)
€ 390.00 (+ VAT) - The fee is only valid when booking the seminar at the same time.

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.

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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