



Advanced course

Navigating Regulatory Variations: From Change to Approval

2 June 2026

Member: € 300,-
Non-Members: € 450,-
(excl. BTW)

Strengthen your expertise in EU regulatory variations with this advanced, practice-driven course led by experienced regulatory professionals. Our advanced course, "Navigating Regulatory Variations: From Change to Approval" offers an in-depth exploration of the EU Variation Guideline, with strong focus on CMC and safety-related changes. The programme combines regulatory background and guideline interpretation with real-world examples and hands-on case studies.

This course is organised by RegNed, a division of NVFG.

Why attend?

Advance your regulatory skills through a one-day, practical course that bridges variations and successful approvals. This course is structured into four focused parts, guiding you from the regulatory foundation and recent guideline updates to real-world documentation requirements, safety assessments and CMC troubleshooting. Case-based learning is embedded to reinforce understanding and application.

What will be covered?

- **Regulatory foundation:**

An overview of the regulatory history of the EU Variation Guideline, general principles for post-approval changes and a guided walkthrough of the latest Guideline updates, including hands-on regulatory experiences.

- **In-depth focus on key variation types:**

- o **Safety variations:** the link between variations and pharmacovigilance including how outcomes relate to the Pharmacovigilance Risk Assessment Committee (PRAC).
- o **CMC variations:** Assessing the impact of changes to Module 3 aspects, complemented by a practical case study, reflecting submission challenges and regulators' feedback.

- **Practical regulatory strategies:**

Clear guidance on grouping and work-sharing procedures, how to select the correct pathway and what documentation authorities expect in different scenarios.

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Who Should Attend?

This course is intended for **Regulatory Affairs professionals**, and all others involved in the **preparation and submission of EU Variations** who wishes to deepen their practical and strategic understanding.

Course Practicalities

- Date: **Tuesday 2 June 2026** | 9:00h to 17:00h
- Location: **Postillion Hotel Bunnik**, Bunnik
- Format: **One-day course** with presentations and interactive sessions. Lunch is included
- Language: Presentations and course materials **will be in English**
- Materials: Bring your laptop. Course materials will be provided (where possible).

Registration

- Register via: <https://www.nvfg.nl/evenementen/>
- **Maximum of 30 participants: register now!**
- Fee: € 300,- (excl. BTW) for NVFG members, € 450,- (excl. BTW) for non-members.
- Note: the fee to become a member of NVFG is € 135,- in the first year and € 185,- annually thereafter

We look forward to seeing you there!

Speakers

Azhar Al Nassan (Astellas Pharma Europe B.V.)

Experienced CMC Regulatory Affairs professional with 30 years in the pharmaceutical industry, spanning innovator products and branded generics. Currently working at Astellas as global CMC RA Lead focusing on strategy development across U.S. FDA, EMA (CP/DCP/MRP), PMDA, CDE, MENA, Latin America, and Asia. Member of TOPRA and Astellas representative at EFPIA manufacturing quality expert group (MQEG).

Desiree Bergamin-Egenberger (Eurocept Pharmaceuticals)

Desiree has more than 30 years of experience within Regulatory Affairs. She has worked as an RA product/project manager at both pharmaceutical companies (Synthon and Novartis Netherlands) and at the Medicines Evaluation Board. She is currently working at Eurocept Pharmaceuticals in the position of Regulatory Intelligence & Compliance Manager. Desiree is a member of the NVFG and the RegNed training group.

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David Evans (Sanofi B.V.)

David has more than 20 years of experience in Regulatory Affairs. Before his RA career, he gained extensive experience in laboratory work. He has completed thousands of CMC submissions and is currently working at Sanofi as CMC Team Lead, bringing his deep expertise in CMC to support regulatory strategies.

Elisabeth Krosveld (Sanofi B.V.)

Elisabeth has more than 15 years of experience in Regulatory Affairs. She has been working on products from different therapeutic areas including valproate, rare diseases and vaccines. Elisabeth currently works at Sanofi as Regulatory Affairs Manager for Belgium/The Netherlands. Elisabeth is also a member of the NVFG and is participating in several project groups of the VIG and RSNN.

Layla Fitoury (Sanofi B.V.)

Layla has more than 17 years of experience in Regulatory Affairs, working across both local and global levels. She is currently working at Sanofi as Head of Regulatory Affairs NL, bringing her broad regulatory expertise and international perspectives. Layla is member of the NVFG and has a seat in several VIG and RSNN Working Groups.

Marissa Benne (DADA Consultancy)

Regulatory Affairs Consultant working at DADA Consultancy, Nijmegen for 10+ years. Responsible for managing registration and variation procedures and advising pharmaceutical companies worldwide on their regulatory strategies in Europe. Specialised in the national regulations of Benelux countries and in the preparation of product information texts and artworks. Additional expertise includes compassionate use programs, market access activities, and drug-device combination products.

NVFG and RegNed

NVFG is the abbreviation for "Nederlandse Vereniging voor Farmaceutische Geneeskunde" (Dutch association for Pharmaceutical Medicine) and supports its members to perform their roles in this particular working field. RegNed, a division of NVFG, is a network of professionals in Regulatory Affairs and platform for knowledge sharing focused on daily practice and future perspectives of Regulatory Affairs.

[Click here to register](#)