ONLINE TRAINING

APIs in the dossier: Quality data, e-submission, global regulatory strategy

TOPICS

- Overview and scope of ICH guidelines
- Manufacturing processes, impurities, specifications and stability
- Structure of CTD module 3.2.S, changes according to ICH M4Q(R2)
- ASMF and CEP procedures
- e-submission requirements to active ingredients
- Global approval relevant API changes: Challenges & opportunities

YOUR SPEAKERS

Dr Federico Marighetti
- requested -
Bonn , GERMANY

Dr Helmut Vigenschow
ViPharmaService,
Burgrieden, GERMANY

Dr Henrietta Dehmlow
F. Hoffmann-La Roche AG,
Basel, SWITZERLAND

Dr Lisa Matzen
Boehringer Ingelheim International GmbH,
Ingelheim, GERMANY

29 - 30 SEPTEMBER 2026 - ONLINE

Aims and objectives

The regulatory environment for active pharmaceutical ingredients (APIs) is changing rapidly. Keeping pace requires more than just knowing the guidelines.

This seminar provides comprehensive, practice-oriented training on current and upcoming CMC documentation standards, including the revised CTD structure under ICH M4Q(R2), impurity control requirements, ASMF, CEP, as well as practical guidance on eCTD submissions and global post-approval change management. Real-world cases and expert insights support the understanding of the specific daily challenges to be mastered.

Attendees will leave with a solid understanding of EU/ICH requirements, global regulatory strategies, and emerging trends.

Who should attend?

This seminar is designed for specialists and managers in Regulatory Affairs, CMC, R&D, and GMP-Quality who are responsible for integrating API quality data into marketing authorisation dossiers or managing API-related submissions and lifecycle activities.

The focus is on small molecules and current EU regulatory requirements.

YOUR SPEAKERS

Dr Federico Marighetti
- requested -
Bonn , GERMANY
Expert for Pharmaceutical Quality

Dr Helmut Vigenschow
ViPharmaService, Burgrieden, GERMANY
Independent Consultant

Dr Henrietta Dehmlow
F. Hoffmann-La Roche AG,
Basel, SWITZERLAND
Head of Submission Management Small Molecules

Dr Lisa Matzen
Boehringer Ingelheim International GmbH,
Ingelheim, GERMANY
Head of Global CMC Regulatory Affairs

Your program on day I: Overview and scope of ICH guidelines

Dr Helmut Vigenschow

- ICH Q7 GMP for APIs
- ICH Q11 Develop. & manufacture of DS
- Revision on the EU GMP Annex 15

Development of API manufacturing processes

Dr F. Marighetti and Dr H. Vigenschow

- Synthesis procedure description
- Starting materials and intermediates
- Solvents
- Synthesis procedures: Risk assessment
- Primary packaging
- Dealing with multiple API manufacturers

Continuation of the program on day I

Impurities
Dr Federico Marighetti, Dr Helmut Vigenschow

- Impurities from synthesis/degradation
- Safety impact of impurities
- Elemental impurities
- Genotoxic impurities, including ICH M7 guideline
- Establishment of purge factors
- N-nitrosamines risk assessment update
- EMA reflection paper on the qualification of non-mutagenic impurities

EMA Guideline on the chemistry of active substances
Dr Helmut Vigenschow

- Key aspects in the draft revision

API specification and stability
Dr Helmut Vigenschow

- GMP-related specification
- API specification in the CTD
- Stability data and retest date
- Changes initiated by the new ICH Q1 stability guideline

Current structure of CTD module 3.2.S, changes according to the draft guideline ICH M4Q(R2)
Dr Federico Marighetti, Dr Helmut Vigenschow

- 3.2.S Overview
- Other CTD sections related to APIs
- Overview on fundamental changes in the CTD structure for quality data
- What will be the structure for quality data related to APIs?

ASMF and CEP
Dr Federico Marighetti

- Content and processes related to ASMF
- Proposed changes with the new draft EU directive
- Working with the CEP
- CEP 2.0
- Who is responsible for what?
- Q&A: how to use a CEP in the context of a MAA or MAV
- Procedural differences to the US FDA DMF Type II

Your program on day II: e-submission requirements to APIs
Dr Henrietta Dehmlow

- eCTD for APIs
- eCTD for CEP submission at EDQM
- E-submissions of DMF and ASMF

Global approval relevant API changes: Challenges and opportunities
Dr Lisa Matzen

- Typical regulatory changes, e.g., API manufacturers, synthesis, analytical methods and regulatory consequences
- Global regulatory strategy and country-specific requirements
- Case studies including questions from authorities
- New regulatory trends, e.g., ICH Q12, reliance and AI

Additional flexible breaks can be arranged with the speakers.

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E-mail

Contact person at office

Date, signature

Date
29 - 30 September 2026 - online training
Day 1: 9:00 until 5:00 pm CET
Day 2: 9:00 until 12:00 pm CET
You may dial in 30 minutes before the lecture starts

Fee
€ 1690.00 (+ 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.

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- Continuous support during the online event guarantees that you concentrate entirely on the training.
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