ONLINE TRAINING

CMC dossier requirements: FDA vs EU

Overview on regulatory procedures for chemicals & biologicals (US)

TOPICS

- Regulatory landscape in the US
- Scientific advice
- The IND and BLA procedure
- Post-approval/maintenance: Procedures and documentation
- Requirements for the handling of quality data
- Hot topics and current challenges

YOUR SPEAKERS

Dr Christina Juli
Boehringer Ingelheim Pharma GmbH & Co. KG,
Biberach an der Riss, GERMANY

Dr Beatrix Metzner
Boehringer Ingelheim Pharma GmbH & Co. KG,
Biberach an der Riss, GERMANY

Dr Tobias Zahn
3R Pharma Consulting GmbH,
Dobel, GERMANY

6 OCTOBER 2026 - ONLINE

Aims and objectives

The purpose of this course is to provide an overview on CMC requirements for marketing authorisation (MA) of small and large molecules (chemicals & biologics) in the US.

The course aims to:

- familiarise participants with the regulatory landscape;
- explain the differences between the US and EU MA procedures;
- provide guidance on FDA specific requirements for the compilation and maintenance of CMC documents;
- give practical approaches to typical pitfalls

Take the opportunity to meet our experts Dr Juli, Dr Metzner and Dr Zahn and get first-hand information, suggestions and tips for daily business challenges.

Who should attend?

This course meets the needs of all those in the pharmaceutical industry who are involved in marketing authorisation procedures for small and large molecules (chemicals + biologics) and wish to develop their knowledge of the US regulatory environment. The specific focus is on requirements for quality data.

Both beginners and professionals that are involved in the compilation and maintenance of the CMC documentation for small and large molecules will benefit from this course.

YOUR SPEAKERS

Dr Christina Juli

Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, GERMANY
Head of CMC, CCM RA Office NBE
Dr Christina Juli studied pharmacy at the University of Würzburg, Germany. Since 2018, she is working at the manufacturing site for biopharmaceuticals of BI Pharma GmbH & Co. KG in Biberach.
In her current role, she focuses on the CMC development for biologics and is responsible for CMC regulatory topics of development projects, products, and strategic regulatory projects.

Dr Beatrix Metzner

Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, GERMANY
Global Head of CMC Management Biopharma
Dr Beatrix Metzner studied chemistry at the University of Regensburg and Freiburg, Germany.
Her professional career began at MediGene AG.
In 2005, she joined Merck KGaA, where she worked as Director Global Regulatory Oncology until November 2013.
At BI, she held various management positions. Since January 2023 she acts as Global Head of CMC Mgt. Biopharma. She has more than 20 years experience in the CMC regulatory field of NBEs and biosimilars.

Dr Tobias Zahn

3R Pharma Consulting GmbH, Dobel, GERMANY
Consultant for Drug Development
Dr Tobias Zahn studied biochemistry. In 2005 he joined The Boston Consulting Group where he was consulting primarily in projects for big pharma, biotech and medtech companies. In 2009 he moved to Birken AG where he led the clinical development. Since 2017 he works as independent consultant at 3R Pharma Consulting GmbH. He advises clients on pharmaceutical product development and assists in regulatory proceedings

Overview on regulatory procedures for chemicals + biologics

Your program at a glance from 9:00 am until 5:00 pm CET

Welcome, introduction, expectations

Regulatory landscape in the US

- Role, duties and responsibilities of the FDA: CBER, CDER, etc.
- Legislation
- US vs EU - ICH harmonisation?

Scientific advice

- Communication with the authority, additional and differing procedures FDA vs EU
- Avoiding typical mistakes

The IND and BLA procedure

- Main aspects and differences for the compilation of IND and BLA, additional and differing procedures FDA vs EU
- Dossier requirements
- Practical experiences from industry perspective

Maintenance/lifecycle management

- Post-approval changes: Standards in the ICH region, additional and differing procedures FDA vs EU

Requirements for the handling of quality data

- CMC requirements FDA vs EU
- FDA specific documentation to be included in the global dossier
- Case studies: The experts will present case studies and you as participant will work in groups on tasks referring to it. Final discussion in the plenum.

Hot topics and current challenges

- e.g. concerning inspections and audits

CMC dossier requirements: FDA vs EU

REGISTRATION UNDER

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☐ CMC dossier requirements: FDA vs EU

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Contact person at office

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Date
Tuesday, 6 October 2026 - online training
from 9:00 am until 5:00 pm CET
You may dial in 30 minutes before the lecture starts

Fee
€ 1290.00 (+ 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.

How our online events work

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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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