

Quality & GMP Essentials for Regulatory Affairs/CMC

Managing the interface between Quality and Regulatory Affairs (RA)

TOPICS

- GMP Know-how: The essentials
- Specifications and Impurities
- Change Control
- Stability testing/data
- Interface between Quality and Regulatory Affairs
- Validations

YOUR SPEAKERS

Raimund Brett

gempex GmbH,
Mannheim, GERMANY

Dr Ralph Nussbaum

Omega Pharma Manufacturing GmbH & Co KG,
Herrenberg, GERMANY

Dr Rainer Ilg

Boehringer Ingelheim Pharma GmbH & Co. KG,
Ingelheim, GERMANY

Quality & GMP Essentials for RA/CMC

Aims and objectives

As an employee in Regulatory Affairs/CMC, do you want to master collaboration and communication at the interface with the quality department in a confident, efficient, and sustainable manner?

Essential for this is knowledge of quality-relevant facts, GMP fundamentals, as well as understanding of the processes at the interface.

After participating in the seminar, you will have gained insight into the requirements and workflows in the GMP-regulated area. Your understanding of the daily challenges faced by the quality department will be enhanced. You will know the data basis for your CMC documents and will have discussed approaches for transferring this knowledge to the regulatory area. Realistic examples will strengthen the implementation of efficient communication at the interface between Quality and RA/CMC in your daily work.

Who should attend?

This seminar is aimed at employees in Regulatory Affairs/CMC. Both, beginners and professionals from departments that work interdisciplinarily with the quality department will benefit from participation.

Prior knowledge of pharmaceutical quality is not required.

YOUR SPEAKERS



Raimund Brett
gempex GmbH,
Mannheim, GERMANY

Principal Consultant

Raimund Brett gained experience in the manufacture of sterile drugs/trial samples, the galenic development of oral drug forms and as an auditor for a manufacturer of vaccines and diagnostics.

In 2015, he moved into consulting, advising clients on compliance issues for quality assurance systems in the areas of small molecule, biological drugs as well as combination products.



Dr Rainer Ilg
Boehringer Ingelheim Pharma
GmbH & Co. KG,
Ingelheim, GERMANY

Senior Associate Director, Global Technical RA

Dr R. Ilg has been working at Boehringer Ingelheim since 2007. He spent his first years in analytical development before moving to CMC RA for Small Molecules (2009). Since 2013, he has been working as team leader in the biopharmaceutical division.



Dr Ralph Nussbaum
Omega Pharma Manufacturing
GmbH & Co KG,
Herrenberg, GERMANY

Head Quality & Qualified Person

Dr R. Nussbaum has been Head of Quality & Qualified Person at Omega Pharma Manufacturing GmbH & Co KG since August 2024. Over the past 30 years, he has held senior QC/QA positions at various pharmaceutical companies, incl. AuregenBiotherapeutics, Synlab, Analytical Services, Carbogen-Amcis, and Grünenthal.

Managing the interface between Quality and RA

Your program from 9:00 am until 5:00 pm CET

Welcome, introduction, expectations

GMP Know-how

Raimund Brett and Dr Rainer Ilg

- Definition, objectives, guidelines
- GMP and PQS in practice
- Audits and inspektions
- Dokuments in the Quality/RA area
- PQR
- Supply chains: Oversight overview
- Interfaces in Manufacturing and Distribution of Pharmaceuticals

Specifications and impurities

Dr Ralph Nussbaum

- ICH Q6A, Q6B, Pharmacopoeias
- ICH Q14: Analytical Lifecycle Management and ATP
- ICH Impurity Guidelines
- Mutagenic impurities and nitrosamines
- Specification limits

Change Control

Raimund Brett

- Management of changes in the GMP-regulated environment
- Causes of changes
- Impact on and involvement of RA

Stability testing/data

Dr Ralph Nussbaum

- Conducting stability tests
- Shelf life, storage instructions
- Procedure for OOS results

Interface between Quality and RA

Dr Rainer Ilg

- How does data get into the dossier?
- Who has which responsibility?
- Traceability

Validations

All speakers

- The basics
- Process and cleaning validation
- Method validation, including outlook on changes due to (Draft) ICH Q1 and (Draft) ICH M4Q(R2)
- Which validation data is relevant for regulatory documents?

Recap and outstanding questions

Quality & GMP Essentials for Regulatory Affairs/CMC

REGISTRATION UNDER

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REGISTRATION FORM

Yes, I will attend

Quality & GMP Essentials for RA/CMC

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

Date

Friday, 3 July 2026 - Online training
from 9:00 am - 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.

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Contact person at office

Date, signature

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.
- Continuous support during the online event guarantees that you concentrate entirely on the training.
- We guarantee the highest quality according to ISO 9001 and ISO 21001.

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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