ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Pharmaceutical Development Manager

Speakers

Dr Joachim Ermer
Ermer Quality Consulting, Germany

Dr Ulrich Kissel
European QP Association, KisselPharmaConsulting, Germany

Sue Mann
Sue Mann Consultancy, UK

Ian Pardo
Spires Quality / RareGenix, UK

Dr Ralf Schreiner
QProgress, Germany

GMP meets Development

GMP and FDA Compliance in Pharmaceutical Development and IMP Manufacturing

18–20 November 2025, Heidelberg, Germany

Highlights

- Legal Requirements and Authority Inspections
  - EU and FDA - what is really required
  - ICH Q8
  - Data Integrity
  - Pre-approval Inspections
  - GMP/GDP/GCP Interface
- GMP Issues and Best Practices
  - GMP from Phase 1 to Phase 3
  - Qualification and Validation
  - Analytical Development
  - IMP Manufacturing, Packaging and Supply
  - Change Control
  - The Role of the QP
- Case Studies and Practical Examples
  - PSF and CTD
  - Cleaning Validation
  - Deviations
  - Stability Studies
  - Data Integrity

With a View on the Detailed Commission guideline on GMP for IMPs!

Objectives

During this Course, specialists will share their **expert knowledge** about **all important GMP aspects** in Pharmaceutical Development and Investigational Medicinal Product (IMP) Manufacturing. You will be able to elaborate and discuss both **EU and FDA requirements.**

Background

Not only in the manufacturing of marketed products (c)GMP Compliance is mandatory. Also in the manufacturing of IMP supplies, compliance with the applicable GMP Guidelines is obligatory. But which GMP requirements are the applicable ones? And **do the requirements differ from clinical phase 1 to phase 3**? And what is the role of **ICH Q8, Q9, Q10 and Q12**?

With the third revision of ICH E6 (ICH E6(R3)), the GMP for IMP principles will be expanded to the following: *Adequate measures to ensure that the investigational product is handled and shipped appropriately should be implemented*.

Previously, the WHO already published two documents relating to Development and GMP for IMPs: „Good Practices for Research and Development Facilities of Pharmaceutical Products" and „GMP for IMPs".

In addition, instead of the current EU GMP Annex 13 (Manufacture of IMPs), the Detailed Commission guidelines on GMP for IMPs for human use apply.

Complex challenges have to be faced and resolved to guarantee high quality products. The safety of the drug and hence also the patient should always be the main focus. Terminated studies or studies without reliable results will lead to extensive extra costs and delays in the whole development and approval process.

This course has been designed by the ECA to broaden your knowledge and to consolidate the various GMP aspects which need to be considered in a successful development of a new pharmaceutical product.

Target Audience

This course has been designed for R&D personnel involved in Pharmaceutical Development, IMP Manufacturing, Quality Control, Quality Assurance, and Regulatory Affairs.

Participants' comments

„Very good organization and moderation! Great speakers."
Dr Teodora Ivanova, B. Braun Melsungen AG, Germany

„Very competent and good speakers, good topics, very good presentation style."
Dr Sandra Bruder, Germany

„Great course, giving good overview and also special detailed information on GMP in Development, especially IMP´s – also for me as experienced QP in Pharmaceutical Development."
Dr Simone Wengner, Catalent Pharma Solution, Germany

„Subjects interesting, speakers speak in a comprehensible way also for not mother tongue, not too fast. Good support with slides. Very available to answer questions."
Dr Maria Giammaruco, Menarini Ricerche S.p.A., Italy

Programme

Global GMP Requirements from Phase 1 to Scale-up and Transfer

- Global requirements: applicable law, directives, guides and guidelines: what is really required
- A comparison of FDA and European requirements and expectations

IMPs in the Context of ICH Q8-Q10, Q12 and Q14

- How to integrate Quality by Design (QbD)
- Risk Analysis in pharmaceutical development
- Life cycle concept

Important Documents in Pharmaceutical Development

- Early documentation
- CTD
- PSF: Style and content
- Case studies

Analytical Development (ICH Q14)

- From method development to method validation
- Quality control and IMP release
- Analytical Qualification

Packaging and Supply of Clinical Trial Materials

- GMP requirements
- Quality control of packaging and labelling
- Handling and sourcing of comparators
- Randomisation and blinding

How to handle Deviations in an R&D Environment

- Why we need a process for Deviations
- What we need to know
- How to do it

Change Control for IMPs

- What is required
- What is important
- What are the benefits
- How to implement

IMP Manufacturing: How much Qualification and Validation is needed?

- Qualification vs. Validation
- What can be found in the regulations
- DQ/IQ/OQ of equipment
- How much process validation is needed?

Cleaning Validation / Verification in Pharmaceutical Development

- Cleaning validation vs. cleaning verification

The FDA Pre-Approval Inspection (PAI)

- Involvement of the R&D Department
- What the FDA will look for
- What happens at FDA during and after the PAI
- Responding to FDA after the PAI

The Role of the QP in Pharmaceutical Development and IMP Release

- Responsibilities
- Co-operation with Head of Production and Head of Quality Control
- Confirmation of Compliance, certification and batch release
- Comparators
- Complaints and recalls

The GMP/GDP/GCP Interface

- Reconstitution
- Pre-requisites for randomisation and blinding
- Distribution
- Site-to-site transfers
- Shelf life extension
- The QP: Where does the responsibility end?

Interactive Sessions:

1. Transition of GMP Requirements from Phase 1 to Phase 3 and the Interface to Development Work

- Challenges and Differences
- How to apply phase appropriate GMPs
- Managing a GMP Lifecycle

2. Stability Studies throughout the Development of a new Product

- Different types of products in CT studies (and support)
- APIs and various dosage forms
- Late stage stability strategies
- New draft ICH Q1 Guideline
- New draft ICH Q1 Guideline

3. Data Integrity

- Manufacturer's understanding of data integrity, needs and benefit
- Regulatory expectations
- Hybrid systems (paper **and** electronic records) - how to ensure data integrity?

You will be able to attend 2 of these parallel sessions. Please choose the ones you like to attend when you register for the course.

Speakers

Dr Joachim Ermer, Ermer Quality Consulting, Germany

Joachim Ermer has 30 years of experience in pharmaceutical analytics including global responsibilities as Director of Analytical Processes and Technology, Head of Quality Control, and Head of QC Lifecycle Management (Sanofi, Frankfurt). Since December 2020, he works as a consultant for topics of pharmaceutical analytics and Quality Control. He is member of the USP Expert Committee "Measurement and Data Quality", and of the Ph. Eur. Chromatographic Separation Techniques Working Party.

Dr Ulrich Kissel, European QP Association, KisselPharmaConsulting, Germany

Ulrich Kissel is Qualified Person and Member of the Board of Directors of the European Qualified Person Association (EQPA). He works as a GMP consultant and contract QP to the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

Sue Mann, Sue Mann Consultancy, UK

Sue Mann has more than 30 years experience in the Pharmaceutical Industry, mainly in Quality Assurance, Clinical Trials supply and production support. In her last position, Sue was Vice President of International Quality Assurance at Shire Pharmaceuticals.

Ian Pardo, Spires Quality / RareGenix, UK

Ian Pardo is a Consultant Senior Quality Leader and EU Pharmaceutical Qualified Person (QP). He has experience in manufacturing, testing, reviewing and certifying biological medicinal products, including vaccines, gene therapy products, cellular therapies, monoclonal antibodies and globular proteins. Ian also worked with traditional small molecule products, including sterile (anti-infectives and cytotoxics), oral liquids, oral solids, semi-solids and aerosols.

Dr Ralf Schreiner, QProgress, Germany

Dr Ralf Schreiner started his consultancy business in 2018. Prior to that, he spent 20 years in various management positions in the pharmaceutical industry, most recently as Executive Director Quality Systems at Actavis/Allergan.

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CONCEPT HEIDELBERG
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

GMP meets Development, 18–20 November 2025, Heidelberg, Germany

Please choose TWO workshop sessions:

☐ *Transition of GMP Requirements from Phase 1 to Phase 3 and the Interface to Development Work*
☐ *Stability Studies throughout the Development of a new Product*
☐ *Data Integrity*

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks prior to the conference 100 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

Tuesday, 18 November 2025, 10.00 – 17.15 h CET
(Registration and coffee 9.30 –10.00 h CET)
Wednesday, 19 November 2025, 9.00 – 17.00 h CET
Thursday, 20 November 2025, 9.00 – 13.30 h CET

Venue

NH Collection Heidelberg
Bergheimer Straße 91
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Email nhcollectionheidelberg@nh-hotels.com

Fees (per delegate, plus VAT)

ECA Members € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1,245
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on first & second day, business lunch on third day and refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22025.

Conference language

The official conference language will be English.

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
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