ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Pharmaceutical Development Manager

## Speakers

**Thomas Becker**
Dr Thomas Becker Pharma & Biotech Consulting

**Pascal Brendelberger**
Pharma Packaging Expert

**Patryk Jegorow**
Takeda

**Gabriela Schallmeiner**
Inspection Ready Consulting

**Gerlinde Schmitter**
CureVac

**Gabriele Schwarz**
BfArM

**Dr Lenka Taylor**
Heidelberg University Hospital

Co-sponsored by the European QP Association

ECA QP ASSOCIATION
An ECA Foundation Interest Group

# GMP meets GCP

## Management, Supply and Quality Assurance of Clinical Trials

### Live Online Training from 16 - 18 June 2026

*Get the Updates on the EU Clinical Trials Regulation 536/2014 and ICH E6!*

## Highlights

- Rules and Regulations
  - Applicable legislation and GMP/GCP interfaces
  - Duties and responsibilities
  - Data Integrity
  - Typical inspection findings
- Supply Management
  - Packaging, labelling, distribution
  - Shelf-life extensions
  - Handling of comparators
  - GMP requirements at the investigational site
  - Trials outside the EU
- Study Management
  - Key tasks and responsibilities
  - The role of the hospital pharmacy
  - IMP-related documentation
- The Role of the QP in Clinical Trials
  - When does the QP responsibility end?
  - Oversight of the supply chain
- Case Studies

# Objectives

During this Live Online Training Course, **well-experienced specialists** will share their **expert knowledge** about important aspects of IMP Supplies and the Management of Clinical Trials. Hear essential aspects about the organisation and management of the supplies, their distribution, things to consider during the study and **learn how the various regulations lead the way**. During this event, the **important interfaces between GMP and GCP** will be elaborated.

# Background

In the development of new pharmaceutical products, it is a challenge to design and initiate sound and appropriate studies. **Compliance with GMP and GCP regulations is mandatory**. A prerequisite for a successful study is the **thorough planning of the clinical trial supplies**. Beginning with the order, the manufacturing and supply of the IMPs, an efficient study management and full compliance with applicable rules and regulations will lead to satisfactory results. **GMP and GCP requirements need to be considered and understood** from all parties involved.

This Live Online Training Course has been designed by the ECA to enhance and broaden your knowledge and to **consolidate the various aspects** which need to be considered for an efficient management of clinical trials.

# Target Audience

Specialists, managers and executives from R&D dealing with the various aspects of IMP supply and clinical trial management. It addresses representatives from IMP manufacturing, packaging, QP certification and supply as well as from the study design and management and the respective Quality Assurance units. It is also directed to CROs and members of inspectorates and authorities.

# Programme Day 1

## Introduction to Revision 3 of ICH E6 GCP

- Completely revised structure
- Applicable to various trial designs and technology-friendly
- Foundational Concept „Quality by Design“ (QbD)
- Risk-Based, Proportionate Quality Management (RBQM) framework
- Clarified roles and responsibilities of sponsors and investigators
- Enhanced Data Governance requirements

## Legislation Related to Investigational Medicinal Products (IMPs)

- Legislation impacting IMP QPs
- New & upcoming regulations and guidance
- Other topics – within and outside the EU

Q&A Session 1

## Packaging and Labelling of IMPs

- Blinding aspects in packaging
- Packaging technology
- Unblinding risks during packaging
- Just-in-time labelling
- Relabeling
- Reconstitution

## Distribution of IMP Supplies

- Distribution concept and prerequisites
- IRT
- Temperature controlled shipments
- Temperature deviations
- Site transfer
- Depots
- Customs

## Challenges of Clinical Trial Material Supply

- Supply Chain planning
- Comparators: selection, procurement, pedigree
- Blinding
- NIMPs
- Shelf-life assignment
- Outsourcing

Q&A Session 2

# Programme Day 2

## Interface Between GMP and GCP

- Clinical Trial Ph I – III
- Interaction and communication between sponsor and manufacturer / QP
- Investigator Initiated trials
- Early access programme
- Compassionate use

## The Role of the QP in Clinical Trials

- QP Declaration (QPD)
- QP Obligations derived from the “new Annex 13” (C(2017) 8179 final)/ Annex 16, Annex 21 and Clinical Trials Regulation (EU) No 536/2014
- Differences between ATMPs and non-ATMPs

## Case Study: QP Tasks and Challenges in Clinical Trials

Q&A Session 3

### GCP Aspects to Consider for IMPs

- Roles and responsibilities: sponsor, CRA, investigator
- ICH GCP
- Storage of IMPs
- Reconstitution
- Accountability and reconciliation
- Sponsor: Achieving and maintaining the blind
- IMP return and destruction
- IMP related documentation

### Risk-Based, Proportionate Quality Management in Clinical Trials

- Aligning Risk Based Quality Management (RBQM) and QbD from trial design to reporting
- Continuous, dynamic risk management
- Risk-proportionate, tailored oversight across the trial lifecycle
- Extend RBQM beyond investigator sites to central facilities, and service providers
- Effective sponsor oversight and cross-functional collaboration

Q&A Session 4

## Programme Day 3

### Data (and Study) Integrity in Clinical Trials

- Responsibilities of investigator, sponsor, and monitor
- Vendors and contractors of electronic systems: considerations and pitfalls
- Why do we need an Audit Trail (Review)?
- Inspection findings

### Handling IMPs at a Hospital Pharmacy

- The role of the hospital pharmacy: manufacturing, organisation, consultancy
- The interface of manufacturing IMPs at a hospital pharmacy and the daily work
- Investigator-Initiated Trials (IITs)
- FAQs: things you need to consider
- Challenges and problem solving

### Case Study on GCP Aspects: Handling IMPs at the Investigator's Site

### A last Case Study: How Things can go wrong

- How would you have reacted?

Q&A Session 5

### Dr Thomas Becker, Dr Thomas Becker Pharma & Biotech Consulting

Thomas has more than 25 years of experience in the pharmaceutical industry mainly collected in senior positions with Quality Assurance, Compliance and Quality Control. Since June 2024 Thomas is working as a freelance GMP consultant and QP.

### Pascal Brendelberger, Pharma Packaging Expert

Pascal works as an operational excellence and process expert in the supply chain for clinical trials. Prior to this, he was Head of Packaging Operations at STADA in Bad Vilbel, Germany.

### Patryk Jegorow, Takeda

Patryk Jegorow is Qualified Person and Head of Quality Compliance and Systems, Biologics Operating Unit (Global Quality), at Takeda.

### Mag. Gabriela Schallmeiner, Inspection Ready Consulting

Gabriela is an independent consultant and qualified person with many years of experience in leading quality and QC functions and as QP. She is Deputy Chair and founding member of the Austrian Qualified Person Association (aqpa).

### Gerlinde Schmitter, CureVac SE

Gerlinde has more than 20 years of experience in the pharmaceutical industry in both, big pharma and biotech environment. Since 2018, she is working for CureVac SE, currently as Director Clinical QA and Compliance, overseeing all GCP-related activities.

### Gabriele Schwarz, BfArM

Gabriele Schwarz, a licensed pharmacist, has been working at the Federal Institute for Drugs and Medical Devices (BfArM) in Germany since 2001. Her current focus is on the regulatory support of innovations in the field of clinical trials at European and international level.

### Dr Lenka Taylor, Heidelberg University Hospital

Lenka is a Pharmacist, working at the Clinical Trial Department within the Pharmacy of the University Hospital Heidelberg. She is managing clinical trials within InPhaSol, the production unit of the University Hospital in Heidelberg, as well as commercial clinical studies.

**Participants' comments from previous GMP meets GCP Live Online Training Courses:**

*"Very informative with lots of information. Lots of food for thought. I enjoyed participating in the questions. Good discussion was promoted."*
Dr Jennifer Bell, Ekrity Ltd., Ireland

*"Very professional set up. Different aspects in IMP were very good."*
Esmee Kester, Ecraid, The Netherlands

*"Case studies make it really interesting and interactive."*
Dr Annelies Jorritsma-Smit, Celgene Distribution B.V. - a Bristol Myers Squibb Company, The Netherlands

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Reservation Form (Please complete in full)

GMP meets GCP
Live Online Training from 16 - 18 June 2026

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.
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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 of the Live Online Training

Tuesday, 16 June 2026, 9.00 h – 17.00 h
Wednesday, 17 June 2026, 9.00 h – 17.00 h
Thursday, 18 June 2026, 9.00 h – 13.00 h
All times mentioned are CEST.

## Technical Requirements

We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

## Fees (per delegate, plus VAT)

ECA Members € 2,290
EQPA 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.

## 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 22303. To avoid incorrect information, please give us the exact address and full name of the participant.

## Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

## Conference language

The official conference language will be English.

## Organisation and Contact

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

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