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GMP Certification Programme  
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## Speakers



Dr Carsten Coors  
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EU-GMP Inspector,  
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# Pharmaceutical Contracts: GMP and Legal Compliance



Live Online Training on 04/05 March 2026



## Highlights

- GMP requirements
  - Duties and responsibilities
  - Expectations of the authorities
- Legal and juristic knowledge
  - International law
  - Structure of agreements
  - Content of agreements
- Practical perspective
  - What is needed?
  - Who is involved?
  - Challenges
  - Helpful terms

This course is supported by



Every participant will get various contract examples

## Objectives

Three prerequisites are needed to work out contracts which are legally and GMP compliant:

- Awareness of the GMP requirements
- Applicable legal and juristic knowledge
- The practical perspective.

During this Live Online Training you will learn how to cover all these relevant aspects.

## Background

Not only caused by increasing contract manufacturing and analysis, every pharmaceutical company establishes business connexions with a number of suppliers and service providers worldwide. The regulating authorities call for correctly defined, agreed and controlled contracted services. The **EU-GMP Guide** and **international legislation** require a written contract between the partners which clearly establishes the duties and responsibilities of each party.

By compiling these contracts, it is of extreme importance not only to meet the legal expectations. The company and the responsible persons need to be aware of their tasks and their liability. Not to mention that the **contents should be easily transferable into the daily work** and must be reduced to practice.

The speakers in this education course have substantial knowledge in the design and implementation of contracts in the pharmaceutical industry.

**You will get first hand practical information.**

## Target Audience

This Live Online Training is designed for all personnel involved in the realisation of contracts. It also applies to decision makers and responsible persons who must implement the subject matters of the contract. The course is addressed to both the contract giver and the contract acceptor.

## Moderator

Dr Gerhard Becker, Concept Heidelberg  
(On behalf of the ECA)



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## Programme

### GMP Requirements and Expectations of the Regulatory Authority

- Outsourcing of activities
- Which external activities require Technical/Quality Agreements?
- Regulatory requirements and legal basis
- How to create a Technical/Quality Agreement
- Is a Quality Agreement essential for QP and QA?

### What QA needs to know about Juristic Principles

- Basic juristic knowledge for responsible functions
  - International laws and systems – how they work and fit together
  - Common Law vs. Civil Law
  - International business: which law applies in the contract?
- Contract law
- Responsibilities within the company (who is signing what)
- What to do in the case of mergers and acquisitions
- Contracts with several entities within the same group of companies
- Case studies

### Different Agreements in Pharmaceutical Industry

- Confidentiality Agreements
- Research and Development (F&E) Agreements
- Master Service Agreements
- Clinical Trial Agreements
- Manufacturing and Supply Agreements
- Technical/Quality Agreements
- Distribution Agreements
- Their structure and how they fit together within the supply chain

### Pharmaceutical Contracts in the Light of Inspections

- Frequent findings
- Business contract vs. Technical/Quality Agreement
- Table of content
- Clear responsibilities
- Product life cycle and Technical/Quality Agreement
- Internal contracts
- Evaluation of a Technical Agreement (interactive session)

### The GMP Technical Agreement/ Quality Agreement

- Who is involved
- Helpful terms and arrangements
- Demands and challenges
- Quality agreements during development
- Economic limits

## The Delineation of Pharmaceutical Responsibilities and the Mutually Agreed Specifications

- Minimum content
- Who is involved?
- Helpful terms and arrangements
- Perception and supervision of agreed responsibilities
- Implementation of contractual obligations into company GMP system

## Supply and Service Agreements: What You Need to Know

- Practical aspects you need to consider when establishing contracts with
  - Suppliers of excipients and packaging materials
  - Service providers (e.g. clothing, pest control)

### Interactive Session: Evaluation of Contract Examples and Cases

- Principles
- Structure
- Content



### Question and Answer Sessions

A set of live Q&A Sessions will give you the possibility to interact with the speakers and get answers to your questions.



### Every participant will get various contract examples (for download):

- Contract Manufacturing
- Contract Testing
- Transport
- APIs

Prepared by Pharma Deutschland

## Speakers



**Dr Carsten Coors**

**Vetter Development Services Austria**

Before working in Quality Assurance at Vetter Development Services Austria, Dr Carsten Coors was Qualified Person at Vetter Pharma-Fertigung GmbH in Germany.



**Dr Rainer Gnibl**

**Government of Upper Bavaria, Germany**

Dr Rainer Gnibl is EU-GMP inspector in Germany and performs GMP inspections worldwide also on behalf of the European Medicines Agency (EMA).



**Dr Monika Hupfauf**

**Koch/Hupfauf Attorneys-at-Law, Austria**

Dr Monika Hupfauf has gained experience as an Attorney-at-Law and trainee at both national and international law firms. Amongst others her main focus is on the development of pharmaceuticals and medical products up to and including market entry.



### Participants' comments on the last live Courses:

*"Very well organized, information on point without being overwhelming"* / Eleni Kallinikou, Pharmathen

*"Good overview of different types of agreements, good to see both the GMP and the legal angle"*  
Ann Michiels, Johnson&Johnson

*"Congrats for the event!"*  
Stefan-Razvan Tataru, S.C. Antibiotice SA, Romania

*"It was definitely a very interesting & helpful course."*  
John Mekkattu, Manager Quality Assurance  
Acino Pharma AG, Switzerland

*"Experienced presenters with very good subject knowledge."*  
Paul Anderson, G R Lane Health Products, UK

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Pharmaceutical Contracts: GMP and Legal Compliance  
Live Online Training on 04/05 March 2026

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Company

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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 [http://www.gmp-compliance.org/eca\\_privacy.html](http://www.gmp-compliance.org/eca_privacy.html)). 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

Wednesday, 04 March 2026, 9.00 – 17.00 h

Thursday, 05 March 2026, 09.00 – 15.30 h

All times mentioned are CET.

Technical Requirements

We use Webex for our live online training courses and webinars. At [www.gmp-compliance.org/training/online-training-technical-information](http://www.gmp-compliance.org/training/online-training-technical-information) you will find all the information you need to participate in our events 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 € 1,890

QP Association Members € 1,890

APIC Members € 1,990

Non-ECA Members € 2,090

EU GMP Inspectorates € 1,045

The conference fee is payable in advance after receipt of invoice.

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.

Registration

Via the attached reservation form, by e-mail or by fax – or **search and register directly at [www.gmp-compliance.org](http://www.gmp-compliance.org) under the number 22163.**

Conference language

The official conference language will be English.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand“ – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at [www.gmp-compliance.org/recordings](http://www.gmp-compliance.org/recordings).

Organisation and Contact

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

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