ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr Carsten Coors
Vetter Development Services Austria

Dr Rainer Gnibl
EU-GMP Inspector,
Local Government, Germany

Dr Monika Hupfauf
Attorney-at-Law, Austria

This course ist supported by

QP ASSOCIATION

Pharmaceutical Contracts: GMP and Legal Compliance

06/07 March 2025 | Vienna, Austria

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

Every participant will get various contract examples

Programme

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 training course you will learn how to consider all these relevant aspects.

Background

Not only caused by increasing contract manufacturing and analysis, every pharmaceutical company establishes business connexions with a number of manufacturers, suppliers and service providers worldwide. The regulating authorities call for correctly defined, agreed and controlled contracted services. The **EU-GMP Guide** and inter**national 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 training course 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

Wolfgang Schmitt, Concept Heidelberg
(On behalf of the ECA)

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 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 the German Medicines Manufacturers' Association (BAH).

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
Attorney-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 Courses:

"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

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

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Pharmaceutical Contracts: GMP and Legal Compliance
06/07 March 2025, Vienna, Austria

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 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation. 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 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
Thursday, 06 March 2025, 09.00 – 17.15 h
(Registration and coffee 08.30 – 9.00 h)
Friday, 07 March 2025, 08.30 – 14.30 h

Venue
Doubletree by Hilton Vienna Schönbrunn
Schlossallee 8 | 1140 Vienna, Austria
Phone: +43 / 1 / 89110
E-Mail: info@doubletree-schonbrunn.at

Fees (per delegate, plus VAT)
ECA Members EUR 1,890.-
QP Association Members EUR 1,890.-
APIC Members EUR 1,990.-
Non-ECA Members EUR 2,090.-
EU GMP Inspectorates EUR 1,045.-
The conference fee is payable in advance after receipt of invoice and includes lunch on both days and all 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.

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.

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 21528.

Conference language
The official conference language will be English.

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Phone +49(0) 62 21/84 44-0
Fax 49(0) 62 21/84 44 34
E-Mail: info@concept-heidelberg.de
www.concept-heidelberg.com

For questions regarding content please contact:
Mr Wolfgang Schmitt (Operations Director) at
+49-62 21/84 44 39, or per e-mail at
w.schmitt@concept-heidelberg.de

For questions regarding organisation etc. please contact:
Ms Nicole Bach (Organisation Manager) at
+49-62 21/84 44 22, or per e-mail at
nicole.bach@concept-heidelberg.de