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

Live Online Training on 01/02 March 2023

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

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 in**ternational 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

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

Design and Layout of Contracts – Evaluation of the Content

- Basic principles – contractual obligations and responsibilities towards third parties
- Structure of agreements
- Contents of agreements – examples:
  - Subject Matter
  - Timelines and Milestones
  - Intellectual Property
  - Term and Termination
  - Warranties and Liabilities
  - Applicable Law and Dispute Resolution
  - Miscellaneous (Force Majeure, assignment, severability, etc.)
- Practical examples

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)

Case Studies: Evaluation of Contract Examples and Cases

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):

- Agreement on Contract Manufacturing of
  - Medicinal Products
  - Medical Devices
  - Foodstuffs
- Contract Testing of Medicinal Products
- Agreement on Quality Assurance concerning
  - Starting Materials
  - Transport of Medicinal Products

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
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:

"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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Reservation Form (Please complete in full)

Pharmaceutical Contracts: GMP and Legal Compliance
Live Online Training on 01/02 March 2023

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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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 January 2012).
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

Wednesday, 01 March 2023, 9.00 – 17.00 h
Thursday, 02 March 2023, 09.00 – 15.30 h
All times mentioned are CET.

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 € 1,490
QP Association Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
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 message. Or you register online at www.gmp-compliance.org.

Conference language

The official conference language will be English.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

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

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