ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr Carsten Coors
form. Vetter Pharma-Fertigung GmbH

Dr Rainer Gnibl
EU-GMP Inspector,
Local Government

Silke Mainka
Lawyer and Legal Counsel

This course ist supported by

QP Association

Pharmaceutical Contracts: GMP and Legal Compliance

11/12 February 2020 | Barcelona, Spain

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 course 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 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

Social Event

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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?

International Law: Basic juristic Knowledge for responsible Functions

- International laws and systems – how they work and fit together
- Jurisdictions and conflict of law provisions
- Contract law
- Jurisdictions law
- General product liability concepts
- Case studies

Agreements – the legal Perspective

- Confidentiality agreement
- Technical/ Quality Agreement
- Supply Agreement
- Other 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
- Contents of agreements
- Definitions
- Timelines and Targets
- Loss of Products
- Intellectual Property
- Assignment
- Term and Termination
- Arbitration
- 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)

Workshop:

Evaluate given contract examples and case studies from various points of view and discuss them with the speakers.

Every participant will get a USB stick with various contract examples:

- 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
form. Vetter Pharma-Fertigung GmbH

Until 2016, Dr Carsten Coors was Qualified Person at Vetter Pharma-Fertigung GmbH. Before that he was Qualified Person at 3M.

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).

Silke Mainka
Lawyer and Legal Counsel,
Law Firm Mainka

Silke Mainka is a generalist attorney with substantial legal experience in the pharmaceutical and biotech industry. She runs her own business since 1997 and also works as Head Legal, Integrity and Compliance at Novartis Oncology. In former roles she was General Counsel at Elanco and Head of Legal & Compliance at Novartis Animal Health in Germany and Austria

Participants' comments:

"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

"I struggled to find a course that met my needs and I am delighted to say it met my expectations. Very interesting to hear different peoples perspectives on the workshop."
Catherine Seery, Alkermes Pharma Ireland Ltd.

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

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CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Pharmaceutical Contracts: GMP and Legal Compliance | 11/12 February 2020, Barcelona, Spain

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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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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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 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, 11 February 2020, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 12 February 2020, 8.30 – 15.30 h

Venue
Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 93 503 53 00
E-Mail sants@barcelo.com

Fees (per delegate, plus VAT)
ECA Members € 1.490
QP Association Members € 1490
APIC Members € 1.590
Non-ECA Members € 1.690
EU GMP Inspectorates € 845

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments.

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 message. Or you register online at www.gmp-compliance.org.

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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