



Academy
Your GMP/GDP
Information Source

Pharmaceutical Contracts: GMP and Legal Compliance

Every participant will get various
contract examples

SPEAKERS:



Dr Carsten Coors
*form. Vetter Pharma-
Fertigung GmbH*



Silke Mainka
*Lawyer and Legal Counsel,
Law Firm Mainka*



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



13-14 February 2019, Berlin, Germany

LEARNING OBJECTIVES:

- 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:



Pharmaceutical Contracts: GMP and Legal Compliance

13-14 February 2019, Berlin, Germany

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 **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 Group

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

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 General Counsel for the Emerging Businesses of Elanco Animal Health, a division of Eli Lilly and Company. In her former role she was heading Legal & Compliance at Novartis Animal Health in Germany and Austria. Silke Mainka has worked with different cultures and international organizations. She holds an Executive Master of European and International Business Law from the University St. Gallen, Switzerland (M.B.L.-HSG).

Social Event



The ECA Academy and CONCEPT HEIDELBERG cordially invite you for a social event in the evening of the first course day. This will be an excellent opportunity to share your experiences and discuss the hot topics of the day with your colleagues and the speakers.

Participants' comments (from the 2018/2017 courses):

"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

"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





 + 49 6221 84 44 34

Reservation Form (Please complete in full)

Pharmaceutical Contracts: GMP and Legal Compliance,
 13-14 February 2019, Berlin, Germany

Mr. Ms.

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order No. (if applicable)**

Street/P.O. Box

City

Zip Code

Country

Phone/Fax

E-Mail (please fill in)

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

 D-69007 Heidelberg
 GERMANY

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

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 7 weeks prior to the conference 10 %
 - until 1 week prior to the conference 50 %
 - within 1 week prior to the conference 100 %.
 CONCEPT HEIDELBERG reserves the right to change the materials, in-

structors, 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 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 its 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.htm). 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

Wednesday, 13 February 2019, 9.00 – 18.00 h
 (Registration and coffee 8.30 – 9.00 h)
 Thursday, 14 February 2019, 8.30 – 15.30 h

Venue

Steigenberger Hotel Berlin
 Los-Angeles-Platz 1
 10789 Berlin, Germany
 Phone +49 (0)30 212 7 - 0
 berlin@steigenberger.de

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 Inspectors € 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.
 VAT is reclaimable

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. Reservation should be made directly with the hotel. You will receive a link to the room reservation when you have registered for the event. 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.

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

For questions regarding content:
 Mr Wolfgang Schmitt (Operations Director) at +49-(0)6221/84 44 39 or per e-mail at w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
 Ms Nicole Bach (Organisation Manager) at +49-(0)62 21 / 84 44 22, or per e-mail at bach@concept-heidelberg.de.