With an optional pre-course Session on 26 February: Contracting in China

Pharmaceutical Contracts: GMP and Legal Compliance

27-28 February 2014, Berlin, Germany

SPEAKERS:

Dr Carsten Coors
Qualified Person,
Vetter Pharma-Fertigung GmbH

Silke Mainka
Lawyer, Pharmaceutical Industry

Dr Rainer Gnibl
EU-GMP Inspector, Bavarian Government

Dr Thomas Pattloch
Lawyer, Taylor Wessing

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

- **Every participant will get a CD with various contract examples**
- **Optional pre-course Session on 26 February: Contracting in China**

ECA ACADEMY

This course is supported by:

QP ASSOCIATION

This education course is recognised for the ECA GMP Certification Programme „Certified QA Manager". Please find details at www.gmp-certification.eu

Pharmaceutical Contracts: GMP and Legal Compliance

27-28 February 2014, 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.

The pre-course session is dealing with general and particular aspects when contracting in China.

Background

Not only caused by increasing contract manufacture 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 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 a substantial knowledge in the design and implementation of contracts in the pharmaceutical industry.

You will get first hand practical information.

Target Group

This course and its pre-session are 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

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

Programme

GMP Requirements and Expectations of the Regulatory Authority

- Outsourcing of activities
- Which external activities require technical agreements?
- Regulatory requirements and legal basis for pharmaceutical technical agreements
- How to create a technical agreement
- Technical 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
- 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 Agreement
- Table of content
- Clear responsibilities
- Product life cycle and Technical 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 of the 2-day Education Course will get a CD 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)

Programme pre-course Session "Contracting in China", 26 February 2014

Legal Background

- Chinese law and jurisdiction
- General terms and conditions
- Applicable law

Contracts and Supply Agreements - Risks and Particularities

- Contract negotiation
- Contractual clauses
- Stipulation
- Language
- Signatures
- Possible pitfalls
- Practical experience

Research, Development an IP-Protection - what you need to know

- Possibilities
- Strategy
- Costs
- Trade secrets
- Ownership and filing for IP rights
- Confidentiality agreements

When Things go wrong

- Enforceability
- Place of jurisdiction
- Conduct of a case in China
- Arbitration

Speakers

Dr Carsten Coors,
Vetter Pharma-Fertigung GmbH, Germany
Carsten Coors worked for more than 10 years in research and development at 3M in Germany and the USA. Since 1992, Carsten Coors has been working as Qualified Person in different areas of responsibility at 3M and, from 1999, at Vetter Pharma Fertigung GmbH, Ravensburg, Germany.

Silke Mainka, Lawyer
Silke Mainka has been working for the pharmaceutical industry for many years. Amongst others, she is involved in the preparation and completion of Commercial and Technical Agreements. Silke Mainka gained experience in international law from working in the USA and is also working as a self-employed lawyer in the field of international contracting.

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 Thomas Pattloch, Taylor Wessing
Thomas Pattloch is Senior Counsel and Partner at Taylor Wessing, specialising in industrial property rights and technology transfer with a particular focus on China. He studied in Munich, Germany and at the Shifan Daxue in Taibei, Taiwan and did his doctoral thesis about Chinese intellectual property and private international law in Beijing. In his career, Thomas Pattloch worked for the Asian department of the Max-Planck-Institute, a Hamburg based German law firm in Shanghai and for the EU Commission as the Intellectual Property Officer in the EU Delegation in Beijing.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ **Pharmaceutical Contracts: GMP and Legal Compliance,** 27-28 February 2014, Berlin, Germany
☐ Pre-course Session on 26 February 2014: Contracting in China

☐ 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

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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

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 %
- until 1 weeks prior to the conference 50 %
- within 1 week 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 January 2012)

Date Pre-course Session: Contracting in China

Wednesday, 26 February 2014, 13.30 – 18.00 h
(Registration and welcome snack 13.00 – 13.30 h)

Date GMP Education Course: Pharmaceutical Contracts

Thursday, 27 February 2014, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Friday, 28 February 2014, 8.30 – 15.45 h

Venue for both events:

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0, Fax +49 (0)30 212 7-117

Fees (per delegate plus VAT)

Pre-course Session:
Contracting in China
ECA Members € 590.-
QP Association Members
€ 590.-
APIC Members € 645.-
Non-ECA Members € 690.-
EU GMP Inspectorates € 350.-

GMP Education Course:
Pharmaceutical Contracts
ECA Members € 1,490.-
QP Association Members
€ 1,490.-
APIC Members € 1,590.-
Non-ECA Members € 1,690.
EU GMP Inspectorates € 845.-

Save money when booking both events
If you book the GMP Education Course "Pharmaceutical Contracts" TOGETHER WITH the Pre-course Session "Contracting in China", the fees will be as follows:
ECA Members € 1,790.-
QP Association Members
€ 1,790.-
APIC Members € 1,890.-
Non-ECA Members € 1,990.-
EU GMP Inspectorates € 995.-

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. 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

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