ECA Certified QA Manager Course*

Every participant will get a CD with various contract examples

Pharmaceutical Contracts: GMP and Legal Compliance

20 – 21 March 2012, Barcelona, Spain

SPEAKERS:

Dr Carsten Coors
Qualified Person, Vetter Pharma-Fertigung GmbH, Germany

Ian Holloway
Medicines & Healthcare Products Regulatory Agency (MHRA), U.K.

Silke Mainka
Lawyer, 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

ECA
EUROPEAN COMPLIANCE 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

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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. Get to know possibilities and tools to realise compliant contracts which can be deployed in your daily work.

Background

Not only caused by increasing contract manufacture and analysis, every pharmaceutical company establishes business connections with a number of suppliers and service providers. The regulating authorities call for correctly defined, agreed and controlled contracted services. **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 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

The European Compliance Academy (ECA) and CONCEPT HEIDELBERG cordially invite you for a social event on Tuesday evening in Barcelona. 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 Regulating Authority
- Regulatory background
- Duties and responsibilities
- Expectations of the authorities
- Minimum content

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
- How should the company document their contacting activities
- Challenges of the globalisation
- Common Inspection Findings
- Regulatory actions

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

Workshop

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

Every participant 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).

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.

Ian Holloway

Medicines & Healthcare Products Regulatory Agency (MHRA), U.K.

Ian Holloway has long experience in worldwide GMP inspections. He is currently Head of the Defective Medicines Report Centre at MHRA.

Silke Mainka

Lawyer, Germany

As a self-employed lawyer, Silke Mainka has been working for the pharmaceutical industry for more than 10 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 still working as an attorney in the field of international contracting.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?

First benefit:

During the membership, you enjoy a 200 € discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:

The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website **www.gmp-compliance.org.**

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

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☐ 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)

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)!

Date

Tuesday, 20 March 2012, 9.30 – 18.00 h
(Registration and Coffee 9.00 – 9.30 h)
Wednesday, 21 March 2012, 8.30 – 15.30 h

Venue

nh-Hotel Constanza
C/Deu i Mata, 69-99
08029 Barcelona, Spain
Phone +34 93 2811500
Fax +34 93 2811525

Fees

ECA Members € 1,490.- per delegate plus VAT
QP Association Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
(does not include ECA membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
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. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention "ECA7227" to receive the specially negotiated rate (single room € 143,- per night incl. breakfast, excl. VAT) for the duration of your stay. Reservation should be made directly with the hotel not later than 20 February 2012. 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

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.

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