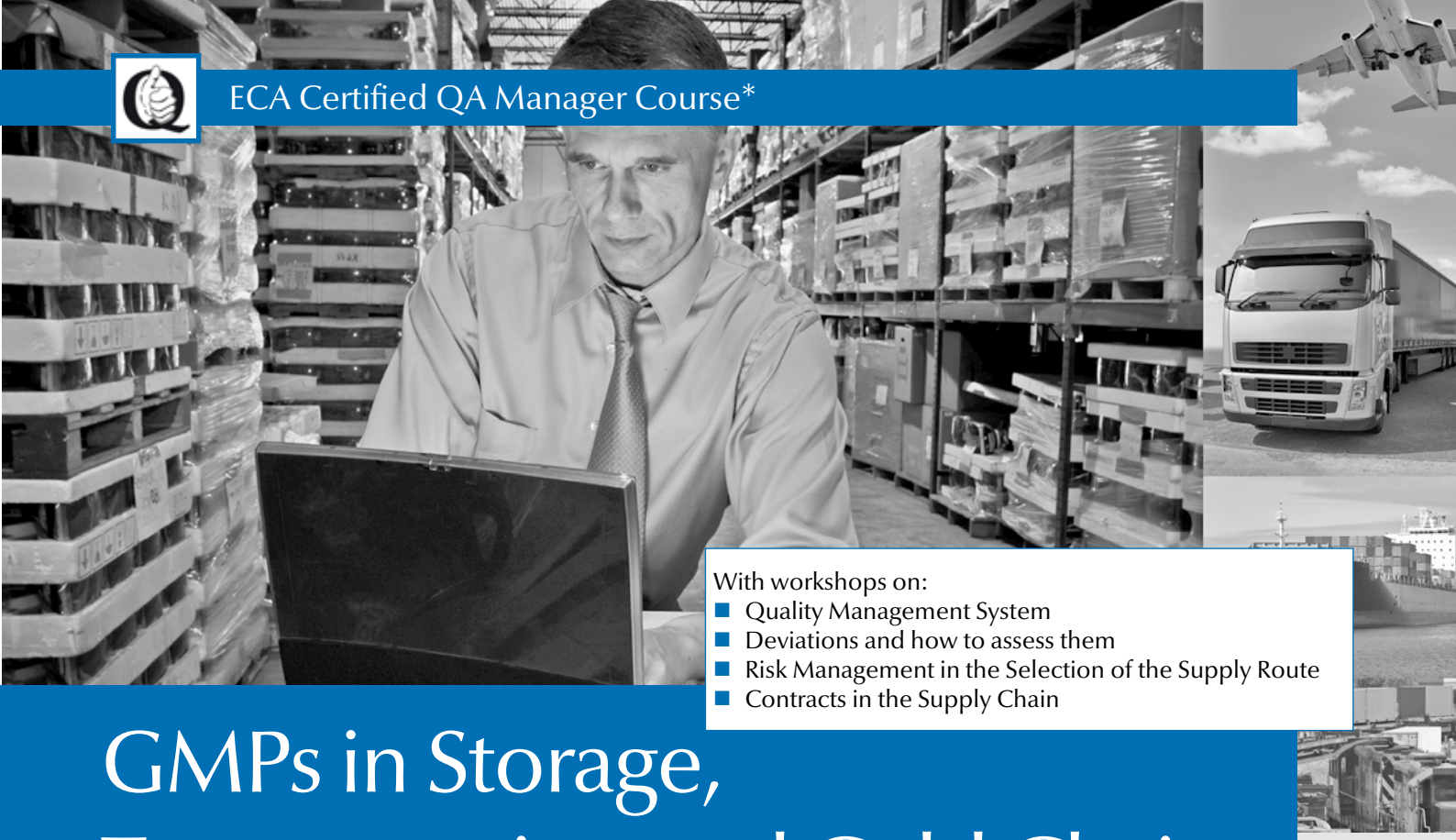

ECA Certified QA Manager Course*

With workshops on:
- Quality Management System
- Deviations and how to assess them
- Risk Management in the Selection of the Supply Route
- Contracts in the Supply Chain

GMPs in Storage, Transportation and Cold Chain

Quality and Risk Management throughout the Pharmaceutical Supply Chain

3 – 4 March 2011, Prague, Czech Republic

SPEAKERS:

Dr Afshin Hosseiny
Tabriz Consulting, U.K.

Dr Andreas König
Aenova Holding, Germany

Ian Holloway
MHRA, U.K.

LEARNING OBJECTIVES:

- Global GMP requirements and guidelines and how to implement them
- Best practices in Storage and Transportation
- Cold Chain and its Validation
- Security in the Supply Chain
- Quality and Risk Management
- Tracking and Tracing

ECA
EUROPEAN COMPLIANCE ACADEMY

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

GMPs in Storage, Transportation and Cold Chain

3 – 4 March 2011, Prague, Czech Republic

Objectives

During this course, **well experienced speakers** will share their **expert knowledge** about all relevant aspects regarding the actual **GMP requirements and current developments** in storage, transportation and Cold Chain Management. You will learn how these requirements evolve and how they can be **implemented efficiently**.

Background

Globalisation, counterfeiting problems and the expectations regarding pharmaceutical **storage, transport and cold chain management** are forcing the pharmaceutical industry to challenge their current practices. Companies have to increase their effort and validation activities as one prerequisite for safe and secure storage and transportation of their medical products over boarders and through various climatic conditions.

Guides, Guidelines and initiatives from various agencies like EMA, FDA, WHO and USP lead the way in this development and define expectations and requirements.

WHO Guide to good storage practices for pharmaceuticals
7. Dispatch and transport

7.1 Materials and pharmaceutical products should be transported in such a way that their integrity is not impaired and that storage conditions are maintained.

Target Audience

This education course is designed for all managers, supervisors and other staff members who are involved in pharmaceutical storage , transportation and cold chain activities and the control of those activities.

Moderator

Afshin Hosseiny

Programme

European Regulatory Requirements and Guidance

- What are the rules and regulations?
- Who is responsible for maintaining product quality in the Supply Chain
- Key challenges and criteria to consider
- Cold Chain and ambient storage and transportation
- New guideline proposals

"Control of storage and transportation temperatures is essential in maintaining the quality of medicines and in helping to protect patients from sub-standard or ineffective medicines that may result from inadequate control"
[J Taylor, TCS&D, March 2002]

International Regulations/ Requirements related to Storage, Transportation and Cold Chain

- FDA
- WHO
- ICH
- Health Canada
- USP

Best practices in Storage (how to implement requirements and stay efficient)

- How to set up an adequate storage facility
- 15-25°C and 1-8°C storage
- Practical approach to temperature mapping your warehouses (from project planning to ongoing monitoring)

WHO Guide to Good Storage Practices for Pharmaceuticals; 4.18:
"Temperature mapping should show uniformity of the temperature across the storage facility."

Workshop Session 1:

1. Understand your Supply Chain

- Process mapping of a supply chain
- Developing a QMS for supply chain (Policies, SOPs, documentation & Training)

This workshop has been designed for delegates who are new in this area or are having less experience.

2. Deviations in the Supply Chain

- What are the data telling us?
- How to assess deviations
- What CAPAs are effective?

This workshop has been designed for more experienced delegates.

You can choose one of these 2 workshops offered. Please give your choice when you register for this course.

Cold Chain Management and its Validation
- Validation of transport and hold time
- Validation vs. monitoring
- How to record temperature
- Qualification of various transport routes
- Data collection and evaluation
- How to handle deviations

Best Practices in Transport and Logistics
- How to implement the Requirements and stay efficient
- Managing 15-25°C and 2-8°C transportation
- Challenges that different modes of transportation introduce to pharmaceuticals

Security in the Supply Chain
- Anti-counterfeiting strategies
- What the agencies can do
- What industry can do
- Compliance issues

Track and Trace and anti-counterfeiting Devices
- What is track and trace?
- Current technologies and best practices
- Anti-counterfeiting devices and management

Workshop Session 2

1. The selection of the best Supply Route
- Process design
- Risk assessment
- Management plans

2. Contracts in the Supply Chain
- GxP contents of Contracts
- How to transfer contents in actions

You can choose one of these 2 workshops offered. Please give your choice when you register for this course.

Speakers

Ian Holloway
Medicines & Healthcare Products Regulatory Agency (MHRA), U.K.
Ian is currently Head of the Defective Medicines Report Centre at MHRA and Holloway has a long experience in worldwide GMP- and GDP inspections.

Afshin Hosseiny, Ph.D.
Tabriz Consulting Ltd., U.K.
Dr Afshin Hosseiny is Managing Director of Tabriz Consulting Ltd. Before working as a consultant, he was Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline.

Dr Andreas König
Aenova Holding, Germany
Dr Andreas König is Director Quality Management at Aenova Holding GmbH. Until 2009 he was Vice President Global Quality Operations Animal Health at Schering Plough. Before that he was head of QC and QA Fresenius Kabi. and later Global Quality Director at Intervet.

Social Event

On 3 March, 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.

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

GMPs in Storage, Transportation and Cold Chain, 3 – 4 March 2011, Prague, Czech Republic

Please choose ONE workshop in each Session:

Workshop Session 1:
- ☐ Understand your Supply Chain.
- ☐ Deviations in the Supply Chain

Workshop Session 2
- ☐ The selection of the best Supply Route
- ☐ Contracts in the Supply Chain

☐ Mr ☐ Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **P.O. Number (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

Thursday, 3 March 2011, 9.00 h - 18.00 h
(Registration and coffee 8.30 h – 9.00 h)
Friday, 4 March 2011, 8.30 h – 16.00 h

Venue

Dorint Novotel Don Giovanni Prague
Vinohradská 157A
130 20 Prague 3
Czech Republic
Phone +42(0) 2 6703 1111
Fax +42(0) 2 6703 6717

Fees

ECA 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. Reservation should be made directly with the hotel not later than 11 February 2011. 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 "VA 6713 ECA Event" to receive the specially negotiated rate for the duration of your stay. 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 ++49-62 21/84 44-0
Fax ++49-62 21/84 44 84
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Wolfgang Schmitt (Operations Director)
at ++49-62 21 / 84 44 41 or at
w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Marion Weidemaier (Organisation Manager)
at ++49-62 21 / 84 44 46 or per e-mail at
weidemaier@concept-heidelberg.de.

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