



Quality and Risk Management
throughout the Pharmaceutical
Supply Chain

GMP meets GDP

Storage - Transportation - Cold Chain

14 – 15 February 2013, Barcelona, Spain

SPEAKERS:

Ian Holloway
MHRA, U.K.

Dr Afshin Hosseiny
Tabriz Consulting, U.K.

Dr Andreas König
Aenova Holding, Germany

LEARNING OBJECTIVES:

- Global GMP and GDP 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 Risk Management
- Tracking and Tracing
- 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



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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 borders 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

Social Event

On 14 February, you are cordially invited to a social event in Barcelona. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



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
- The revised EU Guideline on Good Distribution Practice
- Who needs a Responsible Person (RP)?

“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, Distribution 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 Holloway is currently Head of the Defective Medicines Report Centre at MHRA. He 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 Manufacturing & Quality 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.

Lufthansa is Mobility Partner for all ECA Events



As an ECA course or conference attendee, you will receive **up to 20% discounted travel fares**

(according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – otherwise the booking platform window will not open.

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



+ 49 6221 84 44 34

Reservation Form (Please complete in full)

GMP meets GDP, 14 – 15 February 2013, Barcelona, Spain

Please choose ONE workshop in each Session:

Workshop Session 1:

- Understand your Supply Chain
- Deviations in the Supply Chain

- Mr Ms

Workshop Session 2

- The selection of the best Supply Route
- Contracts in the Supply Chain

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

P.O. Number (if applicable)

Street/P.O. Box

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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 week prior to the conference 50 %
 - 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.

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

Thursday, 14 February 2013, 9.00 h - 18.00 h
(Registration and coffee 8.30 h - 9.00 h)
Friday, 15 February 2013, 8.30 h - 16.00 h

Venue

nh-Hotel Constanza
C/Deu i Mata, 66-699
08029 Barcelona, Spain
Phone +34 93 2811500
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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. You will receive a room reservation form when you have registered for the conference. Please use this form for your room reservation or be sure to mention "ECA7657" to receive the specially negotiated rate (single room € 143,- per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 16 January 2013. 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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