ECA Certified Technical Operations Manager Course*

Industrial Pharmacy for Non-Pharmacists

Processes and Requirements in the Pharmaceutical Industry

8-9 November 2011, Berlin, Germany

SPEAKERS:

Dr Jean-Denis Mallet
ECA & Former Head of Pharmaceutical Inspection Dpt, Afssaps

Dr Josef Hofer
EXDRA

Dr Afshin Hosseiny
Tabriz Consulting Limited

Dr Harald Stahl
GEA Pharma Systems

PROGRAMME:

- Principles of the Pharmaceutical Industry
- Quality Systems and Regulatory Affairs
- The starting point of GMP:
- Chemical & biotechnological API synthesis
- Dosage forms and action of drugs
- Manufacture of solid dosage forms
- Manufacture of semi-solid dosage forms
- Manufacture of sterile drugs
- Packaging of medicinal products

ECA
EUROPEAN COMPLIANCE ACADEMY

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

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Objectives

This education course aims at clearly explaining the interrelationship in pharmaceutical production – from authorisation to drug production and release. It will focus on **illustrating the various production processes** and their demands on equipment and facilities. Requirements from the GMP perspective as well as the way the different dosage forms work will complete the seminar.

Background

In addition to staff in the pharmaceutical industry there are many service providers and suppliers connected with the industry. They also have to deal with their customers' requirements – from the view of regulations as well as from processes. However, how many are pharmacists or know the different pharmaceutical processing steps?

Even within pharmaceutical companies the high specialisation makes it difficult to take a look beyond the own area. An understanding for the interrelationships in the production of medicinal products facilitates communication and increases **efficiency of your own work**. We would like to pose important questions and provide the answers for:

- Where does GMP start?
- How does the pharmaceutical quality management system work?
- What is stated in the authorisation and how does this affect production?
- How are tablets and other dosage forms produced?
- What are the critical process parameters and the critical equipment components?
- How do the various dosage forms work?
- Who is responsible for what and who decides?

Target Audience

This seminar addresses all areas working for or with pharmaceutical companies, as well as staff within the pharmaceutical industry working in areas adjacent to production:

- Staff in engineering, sales, logistics, business development etc.
- Consultants and service providers
- Prospective heads of production and quality assurance without pharmaceutical background

Programme

The Pharmaceutical Industry

- Development of drug
- Finding the right galenical form
- Clinical trials - from phase I to III
- From launch to routine production
- Batch to batch vs. continuous processing
- End of patent and Generics

Dr Afshin Hosseiny

Important QA Systems in the Pharmaceutical Environment

- CAPA, Change Control, ...
- Validation and Qualification
- GMP Audits and Inspections
- Responsibilities and functions (QP, Head of ..)
- Batch documentation and release, QA & QC
- Supplier Qualification

Dr Afshin Hosseiny

Regulatory Affairs

- GMP compliance vs. regulatory compliance
- Submissions/Applications in EU and US
- Required data for submissions
  - Quality (main part)
  - Efficacy
  - Safety
- Changes and variations in EU and US
- Influence of registration documents on daily business

Dr Josef Hofer

Dosage Forms & Actions of Drugs

- Different dosage forms and their applications
- Resorption, distribution, biotransformation
- Kinetics and mechanism of action
- Therapeutic index & Adverse effects
- Influence of finished dosage parameters on action of drugs

Dr Josef Hofer

Chemical and biological API Production

- Difference between API and final dosage form production
- Where does GMP start?
- Fundamentals of API production: From raw material to the final intermediate and the API
- Fundamentals of biotechnological API production: microorganisms as mini plants

Dr Afshin Hosseiny

Semi-Solid Dosage Forms

- Basics of oil/water mixtures
- Importance of raw materials
- Clean Room an equipment requirements
- Clean room concepts: Class C, D, E, ...
- Production process
- Filling of non-sterile liquid and semi-solid forms

Dr Jean-Denis Mallet

Fundamentals of Solida Production

- Fundamentals of
  - Granulation
  - Spray Drying
  - Compaction
- Critical Process Parameters (CPQs)
- Equipment requirements

Dr Harald Stahl

Sterile Manufacturing Operations

- Prerequisites for aseptic processing
- Requirements for equipment and premises
- Clean room concepts: Class A, B, C, D
- Typical material and personal flows
- Media fill
- Filling of vials, ampoules and prefilled syringes
- 100% inspection

Dr Jean-Denis Mallet

Primary and Secondary Packaging

- Primary packing
- Secondary packaging
- Room classification for primary and secondary packaging
- Specific requirements in the pharmaceutical packaging process
- Packaging as the main reason for recalls

Dr Afshin Hosseiny

Social Event

On 8 November 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.

Speakers

Dr Josef M. Hofer

Exdra GmbH, Germany

Dr Josef Hofer is Managing Director of exdra GmbH (excellence in drug regulatory affairs.). Since1999, Dr Hofer is assistant lecturer at the University in Bonn (Germany) for Regulatory Affairs.

Dr Afshin Hosseiny

Tabriz Consulting Limited, Great Britain

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 Jean-Denis Mallet

ECA, former head of the French Inspection Department, SNC LAVALIN, France

Jean-Denis Mallet is a pharmacist. He was previously the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps). He also used to work in or with the pharmaceutical industry during many years at various positions including Quality Assurance, Production Management, Engineering and GMP Consulting. He has also been auditor of the International Red Cross Now he is member of the ECA advisory board and works for SNC LAVALIN.

Dr Harald Stahl

GEA Pharma Systems, Germany

Dr Harald Stahl worked for 3 years in the Pharmaceutical Development of Schering AG in Germany. At that time his main interest was the aseptic production of pellets. Since 1995 he served within GEA Process Technology in various positions. Presently he owns the position of a Senior Pharmaceutical Technologist of GEA Pharma Systems. He has published more than 20 papers on various aspects of pharmaceutical production.

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

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

Reservation Form (Please complete in full)

Industrial Pharmacy for Non-Pharmacists
8-9 November 2011, 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

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If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
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- until 2 weeks prior to the conference 10 %,
- until 1 week prior to the conference 50 %
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Date

Tuesday, 8 November 2011, 10.00 to approx. 18.15 h
(Registration and coffee 09.30 – 10.00 h)
Wednesday, 9 November 2011, 09.00 to approx. 16.15 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Germany
Phone +49(0) 30 2127 0
Fax +49(0)30 2127 117

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 event. Please use this form for your room reservation or be sure to mention "VA 6892 ECA Course" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 7 October 2011. 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
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Robert Eicher (Operations Director) at
+49-62 21 / 84 44 12, or per e-mail at
eicher@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Jessica Stürmer (Organisation Manager)
at +49-62 21 / 84 44 43, or per e-mail at
stuermer@concept-heidelberg.de.

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