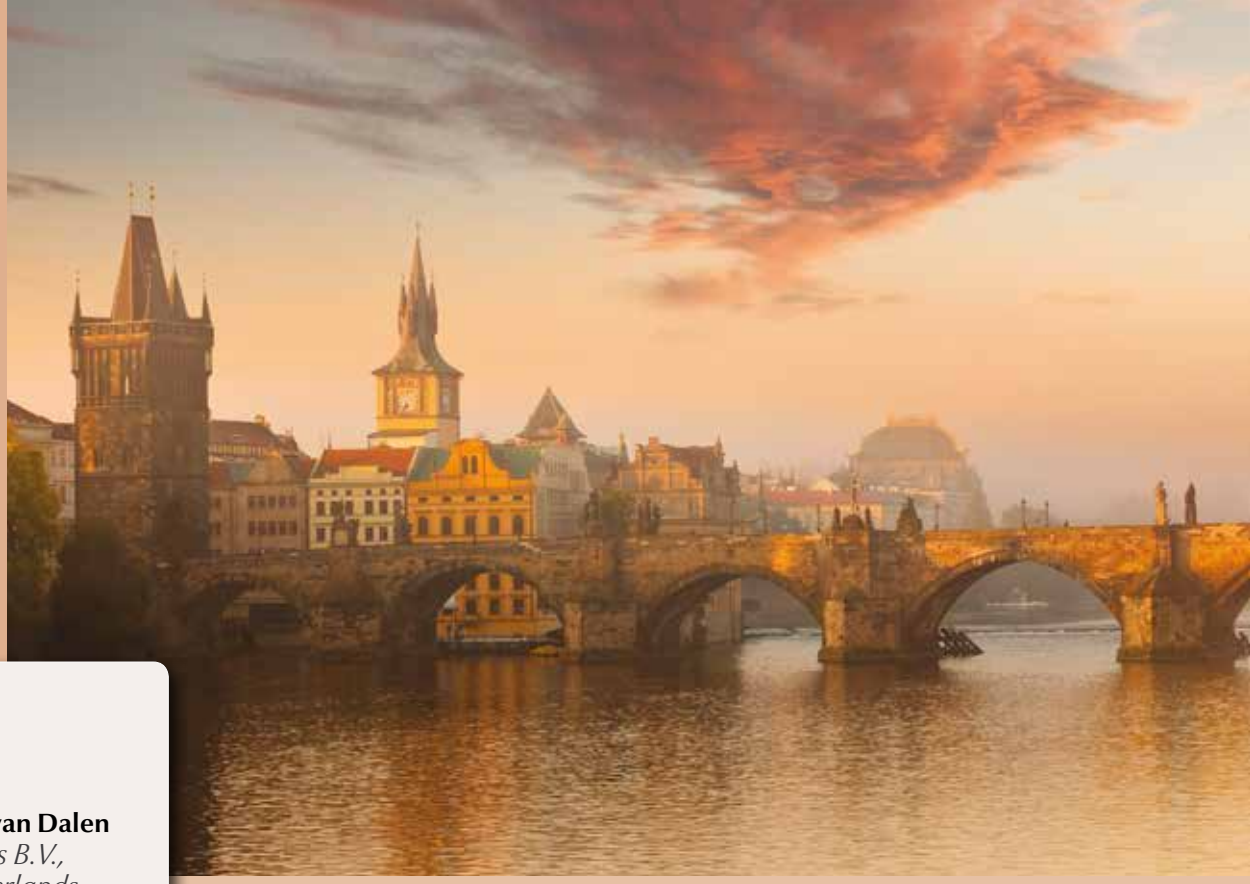
ECA ACADEMY



Speakers:

Marieke van Dalen
Aspen Oss B.V., The Netherlands

Dr Josef Hofer
EXDRA GmbH, Germany

Dr Usfeya A Muazzam
Bonn, Germany

Dr Rainer Gnibl
EU-GMP Inspector, Bavarian Government

GMP meets Regulatory Affairs

Applying for and maintaining marketing authorisations: What you need to know from a GMP perspective

24 – 25 September 2015, Prague, Czech Republic

Highlights

- Drug approvals in the ICH countries: prerequisites and procedures
- Structure of the CTD: Module 1-5
- Relevant GMP documents for a marketing authorisation application
- Peculiarities of drug approvals in Japan: GMP and quality related aspects
- Certificate of Suitability (CEP) and Drug Master Files/Active Substance Master Files
- Regulatory Compliance and Authority Inspections
- Handling variations and changes in a global environment

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

Objectives

During this course you will get to know the relevant aspects of applying for and maintaining a marketing authorisation in the ICH countries. You will learn what you need to know from a GMP perspective about

- the basic requirements for drug approval in Europe, the US and Japan
- the structure of the marketing authorisation dossier according to the CTD
- the input from the GMP regulated departments
- drug approval procedures in the EU and US
- documents to be provided and timelines to be observed
- the peculiarities of drug approval procedures in Japan
- how to handle changes and variations in the EU, the US and Japan

Background

For getting a drug approved it is required to demonstrate its quality efficiency and safety. For that purpose the format of the Common Technical Document (CTD) which is mandatory in Europe since more than 10 years now has to be used. It is also used to apply for a marketing authorisation in the US and Japan.

Therefore a good understanding of the CTD structure is inevitable and a basic requirement for all persons from GMP regulated departments involved in providing and compiling documents for a marketing authorisation application.

For the maintenance of a marketing authorisation it is very important to know how to handle all the changes and variations occurring during the life cycle of a medicinal product.

The rules for handling variations in Europe are laid down in the variations regulation (EC) No. 1234/2008 – being applicable as well for national marketing authorisations from August 3rd 2013 – and supporting guidelines.

For handling changes in the US rules are provided in different guidances for industry and for approval of changes in Japan there are specific procedures in place to be followed. Maintaining marketing authorisations in a global scenario is a challenge and requires strategic planning and a good knowledge of the different regulations and timelines.

Efficient and smooth communication between GMP and Regulatory Affairs is a key factor of success.

Target Audience

This education course is designed for all persons involved in the compilation of pharmaceutical dossiers for global marketing authorisations in the EU and USA. Furthermore the course will be of interest to personnel from Regulatory Affairs, Quality Assurance, Quality Control and Production and Project Management.

Social Event

On 24 September 2015, 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.

Programme

Getting Drugs Approved – What you need to know from a GMP perspective

Drug Approvals in the ICH countries: prerequisites and procedures

- Centralized procedure
- Decentralized procedure
- Mutual recognition
- National procedures
- Specific dossier requirements for different medicinal products
- Time Lines
- Generic applications
- New Drug Application (NDA)
- IND procedure and special issues
- Abbreviated New Drug Application (ANDA) – Generics
- Pre-approval inspections
- Timelines and meetings with the FDA
- Regulatory requirements in Japan
- GMP regulations in Japan (J-GMP)

CTD Module 1: Summary of product characteristics and other national requirements

- Quality related aspects of the SmPC
  - Clinical particulars
  - Pharmacological properties
  - Pharmaceutical particulars
- Labelling
- Package leaflet
- Mock ups and specimen
- Quality experts, non-clinical and clinical experts
- Bibliographical applications
- Homeopathic applications
- Paediatric application

CTD Module 2: Quality of the Drug Substance: relevant GMP documents

- Presentation and format of the dossier
- Active Pharmaceutical Ingredient – documentation of quality in Module 2
- ASMF procedure and CEP procedure
- Impurities
- Stability data
- The Quality Overall Summary (QOS)

CTD Module 3: Quality of the Drug Product: relevant GMP documents

- Medicinal product – documentation of quality in Module 3
- Impurities
- Stability data
- Container and closure systems
- Critical parameters
- Optimising the submission
- Risk-based approach in industry and regulatory authority

CTD Module 4 and 5: Non-clinical and clinical documentation: GMP, GCP and GLP aspects

- Clinical study reports
- Efficacy and safety
- Clinical summary and clinical overview
- Non-clinical study reports
- Toxicology
- Pharmacokinetics
- Safety studies – decision tree
- Toxicity studies to qualify impurities
- Non-clinical summary
- Critical points

How to document Drug Substance Quality: Certificate of Suitability (CEP) and Active Substance Master File (ASMF) in EU and DMF in US and Japan

- CEP and ASMF procedure – how they work in principle
- Types and format of ASMFs
- Contents of the applicants part and the restricted part
- How to apply for a CEP
- Dossier Content
- CEP assessment and CEP inspections
- DMF in US and Japan

Peculiarities of drug approvals in Japan: GMP and quality-related aspects

- Management of Japan-specific requirements in marketing authorisation procedures
- Establishment of regulatory documentation for and from Japan, international challenges
- Japanese oriented organisation and structures in drug regulatory affairs

Regulatory Compliance aspects during authority inspections

- Different types of inspections
- Inspections with respect to the marketing authorisation: Procedures, key aspects, typical findings
- What to do in the case of deviations from the dossier; Q.P. discretion

Maintaining a Marketing Authorisation – The interaction between GMP and Regulatory Affairs

Handling changes in the ICH countries

- Starting a change in your company
- The variations procedure in Europe
- General provisions of the Commission Regulation (EC) No 1234/2008
  - Supporting guidelines
  - Best practice guides and explanatory notes
  - Classification of variations
  - Procedural handling of variations; grouping, worksharing
- Handling Changes in the US: Changes to an approved NDA and ANDA
- Types of changes
- Change control procedure and reporting mechanisms
- Handling changes in Japan: Change procedures and communication with the Japanese authority
- Types of changes
- Notification of changes

Speakers

Marieke van Dalen, *Aspen Oss B.V., The Netherlands*
Marieke van Dalen is the global regulatory specialist in the regulatory group dedicated to API's, with almost 30 years of experience in the regulatory field. She is a board member of APIC, the European API Industry organization, and she participates in the Japan task force, Emerging markets task force and the Quality metrics task force. She frequently represents APIC in meetings and conferences organized by EMA, EDQM, ICH etc.

Dr Josef Hofer, *exdra GmbH, Germany*
Dr Josef Hofer is Managing Director of EXDRA GmbH (Excellence in Drug Regulatory Affairs.). Working for and in international pharmaceutical industry since 1980. Dr Hofer holds a lectureship at the University in Bonn for the Master Course in Drug Regulatory Affairs.

Dr Usfeya A. Muazzam, *Bonn, Germany*
Dr. Usfeya A. Muazzam worked as Senior Assessor for Quality, Division: Quality, Department: Scientific Quality Assurance, Staff Unit: Strategy and Planning of BfArM. He left the agency in 2012. He is co-author of "Gute Regulatorische Praxis, Arzneimittelzulassung - Pharmazeutische Qualität", Wissenschaftliche Verlagsgesellschaft, Stuttgart, Germany and "Guide to Drug Regulatory Affairs", Editio Cantor Verlag, Aulendorf, Germany.

Dr Rainer Gnibl, *GMP Inspector, District Government of Upper Bavaria, Germany*
Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government and the EMA and performs GMP inspections worldwide. Before that, he was also working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

GMP Certification Programme

This conference is recognised within the GMP Certification Programme Module "Regulatory Affairs Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

- Validation Manager
- QA Manager
- API (Production) Manager
- Quality Control Manager
- Pharmaceutical Engineering/Production Manager
- Computer Validation Manager
- Regulatory Affairs Manager
- Microbiological Laboratory Manager
- Sterile Production Manager
- Pharmaceutical Development Manager
- Biotech Manager
- GMP Auditor
- GDP Compliance Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to 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. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy a € 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

Use the GMP App at no costs!

The ECA Foundation has developed a GMP App which offers a comprehensive GMP Guideline database with more than 1,400 GMP Guidelines and ten thousands of pages. Check relevant Guidelines (full text versions) during internal audits, regulatory inspections or GMP compliance meetings – simply on your smartphone or tablet PC. In addition to this wealth of guideline information the GMP App also comprises features like GMP News, a comprehensive GMP Search Engine. To open the app just enter app.gmp-compliance.org in your browser and the WebApp opens immediately.

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

Date
Thursday, 24 September 2015, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Friday 25 September 2015, 09.00 – 15.45 h

Venue
Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 (261) 191 111
Fax +420 (261) 225 011

Fees (per delegate plus VAT)
ECA Members € 1,590
APIC Members € 1,690
EU GMP Inspectorates € 895
Non-ECA Members € 1,790
The course 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 to receive the specially negotiated rate. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via 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
ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
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www.concept-heidelberg.de

For questions regarding content:
Dr Gerhard Becker (Operations Director) at
+49-62 21/84 44 65, or per e-mail at
becker@concept-heidelberg.de.

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

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69007 Heidelberg
Germany

Registration form (please complete in full)

GMP meets Regulatory Affairs
24 – 25 September 2015, Prague, Czech Republic

☐ 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)

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).
Privacy Policy: By registering for this event, I accept the processing of my Personal Data.
Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.