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

The Regulatory Compliance Expert

GMP meets Regulatory Affairs

22 – 23 October 2013, Budapest, Hungary

Speakers:

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

Dr Josef Hofer
EXDRA GmbH, Germany

Dr Usfeya A Muazzam
Bonn, Germany

Rico Schulze
GMP Inspectorate, Germany

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

The Regulatory Compliance Expert

22 – 23 October 2013, Budapest, Hungary

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.

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)

Programme

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

Programme

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 senior scientific project leader within the Regulatory group dedicated to API's. She is an active member of APIC, participating in the variations task force and the Japan task force, and frequently representing APIC in Interested Parties meetings organized by EMA, EDQM 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.

Rico Schulze, *GMP Inspectorate, Local Authorities Dresden, Germany*
Rico Schulze is a Pharmacist and holds a degree in Economics. Since 2003, he is GMP and GDP Inspector at the Local Inspectorate in Dresden. From 2008 to 2011 he was working at the Saxon State Ministry of Social affairs. He is also the Head of the German Authorities' Radiopharmaceuticals Working Group, and a member of the Expert Group on Medicinal Gases.

Social Event

On 22 October 2013, 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

Date
Tuesday, 22 October 2013, 9.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 23 October 2013, 09.00 – 15.45 h

Venue
Hilton Budapest WestEnd
Váci út 1-3
1062 Budapest, Hungary
Phone +36 1 288 5500
Fax +36 1 288 5588

Conference fees
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 CONCEPT 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.

*per delegate plus VAT. VAT is reclaimable.

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
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:
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.:
Mr Ronny Strohwald (Organisation Manager) at
+49-62 21/84 44 51, or per e-mail at
strohwald@concept-heidelberg.de

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

_____

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Registration form (please complete in full)

The Regulatory Compliance Expert
22 – 23 October 2013, Budapest, Hungary

☐ 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 of Business
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 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT 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 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. **You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!**

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

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 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 EUR 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 f or a conference registration.

How Do You Become 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. There are no obligations for the member! 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.

Special offer with Lufthansa

Lufthansa
Official Airline

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!