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Marketing Authorisation Procedures in the EU and the US

Marketing Authorisation Procedures in the EU
16-17 October 2012, Munich, Germany

Marketing Authorisation Procedures in the US
18-19 October 2012, Munich, Germany

SPEAKERS:

Dr Mohammed Baccouche
IPMB GmbH, Germany

Dr Josef Hofer
EXDRA GmbH, Germany

Dr Klaus Menges
Bonn, Germany

Dr Usfeya A. Muazzam
Bonn, Germany

PROGRAMME:

Marketing Authorisation in the EU
- Authorisation procedures in the EU
- Structure of the dossier according to the CTD
- How to qualify quality of APIs in the dossier
- Electronic submissions
- Handling changes and variations – Experiences with the new EU variations regulation

Marketing Authorisation in the US
- Organisation of the FDA
- Drug Regulations in the US
- Structure of the CMC Dossier
- Drug Master File Procedure
- Efficient Change Control Management

ECA
EUROPEAN COMPLIANCE ACADEMY

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

Marketing Authorisation Procedures in the EU

16-17 October 2012

Objectives

During these courses you will get to know the relevant aspects of marketing authorisation procedures in Europe and USA. You will learn about

- the basic requirements to get drug approved in Europe and the US,
- the structure of the marketing authorisation dossier according to the CTD,
- the possibilities of electronic submissions,
- the peculiarities of the Drug Master File Procedure for drug approval in the US,
- handling changes and variations in the EU and the USA.

Background

Before a drug can be marketed it is required to demonstrate its quality, efficiency and safety. In Europe there are the following procedures for getting a marketing authorisation for a medicinal product: the national procedure, the decentralised procedure and the centralised procedure and the mutual recognition procedure.

Since 1 July 2003 the CTD (Common Technical Document) is the mandatory format for the dossier and has to be used for all marketing authorisation procedures in Europe. Since 1 January 2010 the new variations regulation Directive (EC) No. 1234/2008 and two other guidelines which describe the details of the various categories of variations are binding and directly applicable in all EU member states.

It is of increasing importance to have systems in place for electronic dossier submissions to national authorities. Already since January 2010 only electronic submissions are accepted by the EMA and in the near future it will be mandatory in all European member states to submit marketing authorisation applications electronically.
For getting drugs approved in the US it is important to be familiar with the relevant laws and guidelines. In particular the requirements for CMC dossier have to be watched narrowly. Moreover the US Drug Master File Procedure is different from the respective procedures in Europe and should be well understood. The same applies to the rules for handling changes and variations. Dealing with changes in a way that a loss of time can be avoided is quite often a challenge for all departments involved.

Target Audience

These education courses are designed for all persons involved in the compilation of pharmaceutical dossiers for marketing authorisations in the EU and USA. Furthermore the courses will be of interest to personnel from Regulatory Affairs, Quality Assurance, Quality Control and Production.

Programme

Marketing Authorisation Procedures in Europe

- The Centralised Procedure
- The Mutual Recognition (MRP) and Decentralised Procedure
- National Procedures
- Specific Dossier requirements
- Structure of the CTD
- Best practices for MRP for Industry

Structure of the CTD: Module 1 – National Requirements

- MA application form
- Types of application
- Marketing Authorisation Application particulars
- Quality related aspects – the summary of product characteristics (SmPC)
- Herbal and homeopathic applications
- Paediatric applications

Structure of the CTD: Module 2 – Quality Overall Summary – and Module 3 - Quality

- 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)
- 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

Structure of the CTD: Module 4 and 5 – Clinical and Non-clinical Documentation

- 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

Elecronic submissions

- The eCTD as a Standard for die electronic submissions
- Procedure of submitting an eCTD
- Non-eCTD electronic Submissions (NeeS)
- Pros and Cons of eCTD und NeeS
- Validation of an electronic submission
- Validation criteria of eCTD und NeeS
- The pathway to a harmonised standard for electronic submissions – current developments

Certificate of Suitability (CEP) and Active Substance Master File (ASMF)

- CEP and ASMF procedure – how they work in principle
- ASMF – purpose, types and format
- Contents of the applicants part and the restricted part
- Generation and update of an ASMF
- CEP application
- Dossier Content
  - Chemical substance
  - Sterile drug substance
  - Substance for TSE risk assessment
- CEP assessment and CEP inspections

Handling Variations and Changes During Marketing Authorisation Procedures

- Variation procedures and classifications
- Time scales
- Extensions of marketing authorisations
- Variations within centralised procedure
- Best practice guide for variations
- The new variations regulation

Marketing Authorisation Procedures in the US

18-19 October 2012

Programme

The US Food and Drug Administration (FDA) – Structure and Tasks

- US drug regulations
- Organisational structure, mission and current initiatives of the FDA
- CDER, CBER, CDRH - what drugs do they regulate?

Getting Drug approved in the USA

- Timelines and meetings with the FDA
- IND procedure and special issues
- New Drug Application (NDA)
  - Content and special issues
  - Major timelines and activities
  - Public hearing, discussion and voting
- Abbreviated New Drug Application (ANDA) – Generics
- Letters from the FDA
- Labeling – prescribing and product information
- Pre-approval inspections

Chemistry, Manufacturing, and Control (CMC) Quality Dossier in the US – general information

- Applicability of the CTD / eCTD format
- ICH Guidance - harmonised guidelines
- New initiatives in FDA's CMC review process
  - Office of New Drug Quality Assessment (ONDQA)
  - Question-based Review (QbR)
- Quality of CMC information in the IND

Chemistry, Manufacturing, and Control (CMC) Quality Dossier in the US – detailed requirements

- Contents of CMC information
- The Question-based Review (QbR) – details and benefits
- Process validation – contents and requirements
- Design aspects – Quality by Design

Drug Master File (DMF) Procedure in the US

- Types of Drug Master Files
- Submissions to DMFs
- Closure of a DMF
- US vs EU DMF – differences in the procedure

Change control and cGMP in USA

- Post approval requirements
- Changes to an approved New Drug Application
- Types of changes
- Change control procedure and reporting mechanisms
- Management based regulatory strategy
  - Quality systems and process design, validation and control

Speakers

Dr Mohamed Baccouche, *IPMB GmbH, Germany*
Dr Baccouche is CEO of the Institute for Regulatory Affairs and Pharmaceutical Services IPMB. He was head of global regulatory affairs and scientific information at Byk Gulden and Altana for 19 years. Since 1999 he is lecturer of Drug Regulatory affairs at the University of Bonn.

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 Drug Regulatory Affairs.

Dr Klaus Menges, *Federal Institute for Drugs and Medical Devices (BfArM), Bonn, Germany*
Klaus Menges is currently responsible for "Scientific Quality Assurance" at BfArM. The current responsibilities cover monitoring of the internal process organisation as well as providing his expertise in writing medical information for the public. Additionally, he is German representative in the Telematic Implementation Group for e-submission (TIGes) and their subgroups for harmonisation of the e-submission guidelines, the European Review System (EURS) and the Product Information Management System (PIM).

Dr Usfeya A. Muazzam, *Federal Institute for Drugs and Medical Devices (BfArM), Bonn, Germany*
Dr Usfeya A. Muazzam is working as Senior Assessor for Quality, Division: Quality, Department: Scientific Quality Assurance, Staff Unit: Strategy and Planning of BfArM. He is co-author of "Gute Regulatorische Praxis, Arzneimittelzulassung - Pharmazeutische Qualität", Wissenschaftliche Verlagsgesellschaft, Stuttgart, Germany.

Social Event

Participants of the Course **Marketing Authorisation Procedures in the EU** are cordially invited to a guided sightseeing tour of Munich and dinner on Tuesday evening. Participants of the Course **Marketing Authorisation Procedures in the US** are cordially invited to a dinner on Thursday evening.

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

☐ **Marketing Authorisation Procedures in the EU**
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☐ **Marketing Authorisation Procedures in the US**
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☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **Purchase Order No, if applicable**

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If you cannot attend the conference you have two options:
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Date

Marketing Authorisation Procedures in the EU
Tuesday, 16 October 2012, 14.00 – 17.30 h
(Registration and coffee 13.30 – 14.00 h)
Wednesday 17 October 2012, 8.30 – 16.45 h

Marketing Authorisation Procedures in the US
Thursday, 18 October 2012, 10.00 – 17.15 h
(Registration and coffee 9.30 – 10.00 h)
Friday, 19 October 2012, 9.00 – 17.30 h

Venue

Holiday Inn Munich – City Centre
Hochstr. 3
81669 Munich, Germany
Phone +49 (0) 89 – 48 03 - 0
Fax +49 (0) 89 – 44 87 - 170

Fees for each course

ECA Members € 1.290.- per delegate plus VAT
APIC Members € 1.390.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1.490.- per delegate plus VAT
EU GMP Inspectorates € 745.- per delegate plus VAT
The course fee is payable in advance after receipt of invoice and includes conference documentation, dinner/lunch and all refreshments. VAT is reclaimable.

Would you like to save money?
If you book the course „Marketing Authorisation Procedures in the EU" TOGETHER WITH the course "Marketing Authorisation Procedures in the US", the fee for each course reduces as follows:
ECA Members € 1,090.- per delegate plus VAT
APIC Members € 1,190.- per delegate plus VAT
Non-ECA Members € 1,290.- per delegate plus VAT
EU GMP Inspectorates € 645.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first and second day, lunch on the second and third day and all refreshments. VAT is reclaimable.

Accommodation

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 course. Please use this form for your room reservation or be sure to mention "VA 7341 ECA Course" to receive the specially negotiated rate (single room 159,- per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 18 September 2012. 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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