ECA ACADEMY

SPEAKERS

MARIEKE VAN DALEN
Aspen Oss B.V.,
The Netherlands

DR HILTRUD HORN
Horn Pharmaceutical Consulting, Germany

DR USFEYA A MUAZZAM
Bonn, Germany

DR BORIS PIMENTEL
DSM-Nutritional Products AG, Switzerland

DR WILHELM SCHLUMBOHM
Berlin, Germany

Drug Master File Procedures in the EU, the US and Japan

Taking account of the guidance on elemental (ICH Q3D) and genotoxic (ICH M7) impurities

21 – 22 October 2014, Budapest, Hungary

HIGHLIGHTS:

- Requirements of the European ASMF procedure
- Different types of Drug Master Files in the US
- How to document drug substance stability
- Compiling data for residual solvents and impurities taking into account of metal and genotoxic impurities
- Special aspects of Drug Master Files in Japan
- Handling changes in European, US and Japanese Drug Master Files
- Maintaining Drug Master Files

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

Drug Master File Procedures in the EU, the US and Japan

21 – 22 October 2014, Budapest, Hungary

Objectives

This education course is intended to provide guidance on the procedures for the European ASMF, the US-DMF and the Japanese DMF. You will get to know

- how to describe manufacturing processes
- how to compile data for drug substance stability, impurities and residual solvents
- which are the important points to consider for US-DMFs
- which are the requirements for Japanese DMFs
- how to handle changes in European, US and Japanese DMFs

Participants will have the opportunity to take part in one of two parallel workshops about
1. Description of the manufacturing process **or**
2. How to compile data for Impurities and Residual Solvents

Background

Documentation of the drug substance quality is an integral part of any marketing authorisation application. In Europe the most common document for this purpose is the Active Substance Master File (ASMF) as long as the applicant has no Certificate of Suitability of the pharmacopoeial monograph (CEP). The European ASMF procedure differs significantly from the US-DMF procedure and for strategic reasons it is very important to take these differences into account. Moreover there are particular requirements for DMFs in Japan. For global acting companies it is a big challenge to handle the different procedures of compiling, submitting, changing and maintaining Drug Master Files in an efficient way.

Target Audience

The education course is designed for all persons involved in the compilation of pharmaceutical dossiers for marketing authorisations especially for Drug Master Files who want to become familiar with the different DMF procedures. Furthermore, the course will be of interest to personnel from Quality Units of the pharmaceutical and the API industry.

Programme

The European Active Substance Master File procedure – An Introduction
- Regulatory background and Scope
- The revised ASMF guideline
- Open and closed parts – points to consider
- Comparison of ASMF and CEP procedure

Drug Master File Procedures in the US
- Types of Drug Master Files
- Drug Master Files under GDUFA
- Submissions of DMFs
- Holder obligations
- Maintenance of Drug Master Files
- US vs EU DMF – differences in the procedure

How to document drug substance stability
- Stability Guidelines
- Stability Testing of new drug substances and drug products
- Storage Conditions
- Bracketing and Matrixing Designs
- Stability data from new drug dosage forms
- How to document evaluation of stability data
- Optimising the submission

Residual solvents and Impurities: synthesis derived Impurities, Metals and genotoxic Impurities
- Guidelines
- Impact of the new guidelines ICH Q3D and ICH M7
- Sources of Impurities
- Setting and justification of specifications
- Residual solvents, solvent classes
- Content and scope of data – documentation requirements
- Frequent mistakes

Parallel Workshops

Please choose one out of two Parallel Workshops:

Description of the Active Substance manufacturing process
Dr Wilhelm Schlumbohm

How to Compile Data for Impurities and Residual Solvents
Dr Usfeya A Muazzam

Post Approval Changes in the US

- Post approval activities
- Reporting requirements to the FDA (CBE 0, CBE 30, Annual Report)
- Post approval commitments and post approval reporting requirements
- Risk evaluation and mitigation strategies (REMS)

Handling Changes in European Drug Master Files

- Why is there a need for changes
- Types of changes
- How to communicate with the MA holders and how to get feed back
- Differences between ASMF and CEP
- When to implement a specific change
- Version management of the ASMF

Requirements of the Drug Master File Procedure in Japan

- Regulatory procedures in Japan:
  - Site accreditation
  - GMP paper based inspection
  - Drug Master File
- Drug Master File format
- Specific points to consider for the J-DMF
- Communication with the Japanese authorities

Changes and Maintenance of Japanese Drug Master Files

- 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 Hiltrud Horn, Managing Director of Horn Pharmaceutical Consulting, Germany
In 1990 she started her career at Hoffmann-La Roche in Quality Control/Quality Assurance. Later she was responsible for medical writing in the 'International Drug Regulatory Affaires and Project Management' department. In 1999, she joined Knoll AG as head of the departments 'Regulatory Compliance and CMC Documentation' and 'Dossier Production and Compliance' for international drug registration. In 2002 she joined Cap Gemini Ernst & Young (biotechnology and life sciences) prior to starting her own business.

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 Boris Pimentel, DSM-Nutritional Products AG, Switzerland
Dr Boris Pimentel is responsible for the worldwide submissions and assessments of the API documentation (CMC, Safety) for NDAs and MAAs. He is board member of APIC, chairman of APIC’s Japan task force and member of the advisory board of the European Compliance Academy.

Dr Wilhelm Schlumbohm, Berlin, Germany
Dr Schlumbohm worked more than 20 years with German drug licensing authorities in the field of assessment of the CMC parts of new drug applications. He is expert for the Certification Procedure of the European Pharmacopoeia.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
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69007 Heidelberg, Germany

Reservation Form:
+ 49 6221 84 44 34

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info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Tuesday, 21 October 2014, 9.00 h– 17.45 h
(Registration and coffee 8.30 h – 9.00)
Wednesday, 22 October 2014, 8.30 h– 15.30 h

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

Fees (per delegate plus VAT)
ECA Members: € 1,590
APIC Members: € 1,690
EU GMP Inspectorates: € 895
Non-ECA Members: € 1,790
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 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 for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

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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 Susanne Ludwig (Organisation Manager) at +49-62 21/84 44 44, or per e-mail at ludwig@concept-heidelberg.de.

Social Event
On 21 October 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.

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Drug Master File Procedures in the EU, the US and Japan
21 – 22 October 2014, Budapest, Hungary
Please choose ONE workshop:
☐ Description of the manufacturing process
☐ How to compile data for Impurities and Residual Solvent

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order 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 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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