ECA ACADEMY

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

SPEAKERS

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Berlin, Germany

22 – 23 October 2015, Hamburg, Germany

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
- Comparison of ASMF and CEP procedure

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

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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
- which are the major differences and advantages of the ASMF and CEP procedure

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

Comparison of the CEP and ASMF Procedure

- The certification scheme of the PhEur
- Advantages and disadvantages of the CEP procedure compared to the ASMF procedure
- Handling of variations in the CEP procedure
- Coutries accepting CEPs

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 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, Pi-Consulting, Switzerland
Dr Pimentel is manager of the consulting company for global regulatory services –Pi-Consulting in Switzerland. Until June 2014 he worked on the Dutch company DSM Nutritional Products in Switzerland, focusing in Pharma and Food regulations. Since 2010 as a member of the APIC board he was involved in several task forces like ASMFs, Variations and Changes, and participated in the discussions with EMA, WHO and EDQM. He also chaired the task force for Japan regulations, and Emerging Market Regulations.

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:
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69007 Heidelberg, Germany

Reservation Form:
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info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Thursday, 22 October 2015, 9.00 h– 17.45 h
(Registration and coffee 8.30 h – 9.00)
Friday, 23 October 2015, 8.30 h– 15.30 h

Venue
Barceló Hamburg
Ferdinandstraße 15
20095 Hamburg, Germany
Phone +49 (0)40 226362-0
Fax +49 (0)40 226362 999

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/POG 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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D-69007 Heidelberg, Germany
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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 22 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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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**

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1. We are happy to welcome a substitute colleague at any time.
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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).

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