ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Regulatory Affairs Manager

Speakers

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

29/30 September 2021 | Berlin, Germany

Taking into account the guidance on metal impurities (ICH Q3D) and genotoxic impurities (ICH M7)

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 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

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 join one of two parallel workshops about
- Description of the manufacturing process
- Managing changes in Drug Master Files

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
- Managing changes in Drug Master Files – Case Studies

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 Ph.Eur.
- Advantages and disadvantages of the CEP procedure compared to the ASMF procedure
- Handling of variations in the CEP procedure
- Countries accepting CEPs

Social Event

In the evening of the first course day, 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.

Speakers

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

Marieke van Dalen is the global regulatory specialist in the regulatory group dedicated to APIs, with over 30 years of experience in the regulatory field. She is a board member of APIC, the European API Industry organization, and she participates in a number of task forces. She frequently represents APIC in meetings and conferences organized by EMA, EDQM, CPhI etc.

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

Dr Horn is managing director of HORN PHARMACEUTICAL CONSULTING with focus on CMC, GMP and Regulatory Affairs. She started in pharma industry in 1990 and held several managerial positions within Hoffmann-La Roche in Basel and Knoll (Abbott) with global responsibility within QC / QA / Regulatory Affairs / Project Management / Medical Writing.

Dr Usfeya A. Muazzam
Bonn, Germany

Dr 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 Wilhelm Schlumbohm
Berlin, Germany

Dr Schlumbohm worked 30 years with German drug licensing authorities. He was an expert for the Certification Procedure of the European Pharmacopoeia and a member of the TAB for several years. He was also a member of the ASMF working group, and the CVMP co-opted member for quality. He is a pharmacist, holds a Ph D in biochemistry, and is further qualified as pharmacist for drug information and for public health.

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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Drug Master File Procedures in the EU, the US and Japan, 29/30 September 2021, Berlin, Germany

Please choose one out of two workshops
☐ *Description of the Manufacturing Process*
☐ *Managing changes in Drug Master Files – Case Studies*

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
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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).
German law shall apply. Court of jurisdiction is Heidelberg.

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Date
Wednesday, 29 September 2021, 9.00 h – 17.45 h
(Registration and coffee 8.30 h – 9.00 h)
Thursday, 30 September 2021, 8.30 h – 15.15 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Email berlin@steigenberger.de

Fees (per delegate, plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
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 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 course. Reservation should be made directly with the hotel. 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
ECA has entrusted Concept Heidelberg with the organisation of this event.

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