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

Live Online Training on 29/30 September 2020

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

Programme

Objectives

This Live Online Training 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

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 Live Online Training 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 29 September 2020

09.00 – 09.15 h Introduction

09.15 – 10.00 h
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

10.00 – 10.15 h
Q & A Session

10.15 – 10.45 h Break

10.45 – 11.30 h
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

11.30 – 11.45 h
Q & A Session

11.45 – 12.30 h
Handling Changes in the EU

- 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

12.30 – 12.45 h
Q & A Session

12.45 – 14.00 h Break

14.00 – 14.45 h
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)

14.45 – 15.00 h
Q & A Session

15.00 – 15.30 h Break

15.30 – 16.30 h
Description of the Active Substance Manufacturing Process

- Regulatory basis - relevant guidelines
- Description of the Active Substance Manufacturing process
- Active substance starting material
- Critical steps in the synthesis
- Process validation

16.30 – 16.45 h
Q & A Session

Programme 30 September 2020

08.30 – 09.15 h
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

09.15 – 09.30 h
Q & A Session

09.30 – 10.15 h
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

10.15 – 10.30 h
Q & A Session

10.30 – 11.00 h Break

11.00 – 11.45 h
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

11.45 – 12.00 h
Q & A Session

12.00 – 13.00 h Break

13.00 – 14.15 h
Requirements of the Drug Master File Procedure in Japan (Part 1 and 2)

- 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

14.15 – 14.30 h
Q & A Session

14.30 – 15.00 h Break

15.00 – 16.00 h
Workshop
Managing Changes in Drug Master Files – Case Studies

16.00 – 16.30 h
Final Q & A Session

Speakers

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

Ms 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
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 PhD in biochemistry, and is further qualified as pharmacist for drug information and for public health. Currently he gives conference lectures on various quality topics and works as external advisor to drug regulatory authorities.

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Reservation Form (Please complete in full)

Drug Master File Procedures in the EU, the US and Japan – Live Online Training on 29/30 September 2020

Title, first name, surname

Department | Company

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

City | ZIP Code | Country

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German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Tuesday, 29 September 2020, 9.00 h – 16.45 h
Wednesday, 30 September 2020, 8.30 h – 16.30 h

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

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.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can book the recording of the Live Online Training at any time at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

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