

Speakers



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GMP Certification Programme Certified Regulatory Affairs Manager

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

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

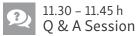
09.15 – 10.00 h The European Active Substance Master File Procedure – An Introduction

- 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

10.45 – 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



11.45 – 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

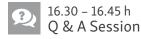
- Post approval activities
- Reporting requirements to the FDA (CBE 0, CBE 30, Annual Report)
- Post approval commitments and post approval reporting requirements
- Risk evaluation and mitigation strategies (REMS)

22 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



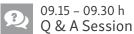
10.15 – 10.45 h Break

Programme 30 September 2020

08.30 - 09.15 h

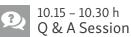
Comparison of the CEP and ASMF Procedure

- 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



09.30 – 10.15 h How to document Drug Substance Stability

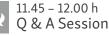
- Stability Guidelines
- Stability Testing of new drug substances and drug products
- Storage Conditions
- Bracketing and Matrixing Designs
- . Stability data from new drug dosage forms
- How to document evaluation of stability data
- Optimising the submission



10.30 – 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



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



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 PHARMACEUTI-

CAL 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 Certifica-

tion 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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.a 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		Company	Number Purchase Order Number, if applicable	de Country			cellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event writhout 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 con- ference (receipt of payment will not be confirmed)! (As of January 2012). German law shall apply. Court of jurisdiction is Heidelberg.
		Title, first name, surname	Department	Important: Please indicate your company's VAT ID Number	City ZIP Code	Phone / Fax	E-Mail (Please fill in)	or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be re- sponsible for discount airfare penalties or other costs incurred due to a cancel- lation. Terms of payment: Payable without deductions within 10 days after receipt of invoice. Important: This is a binding registration and above fees are due in case of can- Important:
If the bill-to-address deviates from the specifica- tions on the right, please fill out here:					CONCEPT HEIDELBERG P.O. Box 101764 Fax +49 (0) 62 21/84 44 34	D-69007 Heidelberg GERMANY		Seneral terms and conditions fyou cannot attend the conference you have two options: I. We are happy to welcome a substitute colleague at any time. 2. If you have to cancel entirlej we must charge the following processing fees: Cancellation until 2 weeks prior to the conference 10 %, Cancellation within 1 week prior to the conference 50 % Cancellation within 1 week prior to the conference 100 %. CONCEPT HEIDELBERG reserves the right to change the materials, instructors,

Reservation Form (Please complete in full)



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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