

## Speakers



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



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

06/07 September 2023 | Vienna, Austria



*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

1. Description of the Active Substance manufacturing process
2. 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

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- Regulatory background and scope
- The revised ASMF guideline
- Open and closed parts – points to consider
- Comparison of ASMF and CEP procedure

### Drug Master File Procedure in the US

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- How to file and use Drug Master Files in the US
- The format and the content of the US Drug Master File
- Specific points to consider for the US Drug Master File
- GDUFA question-based review: some US specifics

### How to Document Drug Substance Stability

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- 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

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- 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

## Handling Changes in the US

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- What guidance to use
- Types of changes in the US guidance and the procedures around it
- How to classify a change in the US
- Link to the FDA inspection program

## Handling Changes in the EU

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- 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

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- 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

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- Change procedures and communication with the Japanese authority
- Types of changes
- Notification of changes

## Comparison of the CEP and ASMF Procedure

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- 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

## Speakers



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

Ms van Dalen is the global regulatory specialist in the regulatory group dedicated to APIs, with over 35 years of experience in the regulatory field. She is a board member of APIC, the European API Industry organization, and she actively participates and/or (co-)chairs in a number of task forces. She frequently represents APIC in meetings and conferences organized by EMA, EDQM, CPhI etc.



Dr Cornelia Nopitsch-Mai  
Quality Assessor, Germany

Dr Nopitsch-Mai is scientist at the Federal Institute for Drugs and Medical Devices in the assessment of the quality part of the dossier since 1991. Since 2000 she is assessor for the Certification Procedure (EDQM) in Strasbourg. She was member of the Technical Advisory Board (EDQM) from 2001 until 2010; in that time, she was chairperson from 2005 until 2010. From 2007 until 2011 she was a member of the EMA Quality Working Party.



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.

## 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.

### Your Benefit Internationally Acknowledged Certificate from ECA Academy



The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“. This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

If the bill-to-address deviates from the specifications on the right, please fill out here:

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Reservation Form (Please complete in full)

Drug Master File Procedures in the EU, the US and Japan, 06/07 September 2023, Vienna, Austria

Please choose one out of two workshops:  Description of the Active Substance 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

Country

ZIP Code

Phone / Fax

E-Mail (Please fill in)

CONCEPT HEIDELBERG  
P.O. Box 101764  
Fax +49 (0) 62 21/84 44 34  
  
D-69007 Heidelberg  
GERMANY

#### 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 4 weeks prior to the conference 10 %
    - Cancellation until 3 weeks prior to the conference 25 %
    - Cancellation until 2 weeks prior to the conference 50 %
    - Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, 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 HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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 cancellation.

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 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.

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

Wednesday, 06 September 2023, 9.00 h – 17.45 h

(Registration and coffee 8.30 h – 9.00 h)

Thursday, 07 September 2023, 8.30 h – 15.15 h

## Venue

Radisson Blu

Park Royal Palace Hotel Vienna

Schlossallee 8

1140 Vienna, Austria

Phone +43/1/89110

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## 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 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](http://www.gmp-compliance.org).

## Presentations / Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

## Conference language

The official conference language will be English.

## Organisation and Contact

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

CONCEPT HEIDELBERG

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