ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Regulatory Affairs Manager

Speakers

Marieke van Dalen
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Drug Master File Procedures in the EU, the US and Japan

Live Online Training on 14/15 October 2025

With updates on the CEP 2.0!

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
- CEP 2.0: What is new?

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.

NEWS

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To subscribe, simply scan the QR code or visit www.gmp-compliance.org/gmp-newsletter

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
- The worksharing procedure for assessments of ASMFs
- Upcoming European developments: Potential implications of the pharma package

Drug Master File Procedures in the US

- 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

- 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

Handling Changes in the US

- 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

- 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.
- The CEP 2.0: What is new?
- Handling of variations in the CEP procedure
- Advantages and disadvantages of the CEP procedure compared to the ASMF procedure
- When to use a CEP or an ASMF in an MAA

Managing Changes in Drug Master Files – Case Studies

Speakers

Marieke van Dalen
MARA Consultancy, The Netherlands

Ms van Dalen is a global API regulatory specialist leading her own small consultancy in the Netherlands. She has 38 years of experience in the API industry, always in the regulatory field. Her latest position was with Aspen API in the Netherlands, as Global Regulatory Specialist. She was for a long time a Board member of APIC (the European API organisation) and represented APIC often in meetings and symposia with health Authorities all around the world.

Dr Cornelia Nopitsch-Mai,
formerly Quality Assessor, Germany

Dr Nopitsch-Mai was 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 was 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.

Your Benefit

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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.

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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 14/15 October 2025

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.
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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.

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, 14 October 2025,
9.00 h – 16.30 h, CEST
Wednesday, 15 October 2025,
9.00 h – 16.30 h, CEST

Technical Requirements

We use WebEx for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21925.

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.

You cannot attend the live online event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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

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