ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Regulatory Affairs Manager

Speakers

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

Alma Kiso
European Directorate for the Quality of Medicines (EDQM & Health Care), France

Dr Wilhelm Schlumbohm
Berlin, Germany

Dr Jan Smeets
The Netherlands

Global Registration and Life Cycle Management of APIs

Live Online Training on 23 – 25 March 2021

Contents of the regulatory information in the ASMF and CEP

Highlights

- Dossier Requirements for the Drug Substance
- Requirements for the Certificate of Suitability
- Drug Substance - Setting Specifications
- Synthesis derived impurities, genotoxic impurities, elemental impurities and residual solvents
- Stability Data
- How to read and use a CEP
- Choice and justification of the API starting material in a submission
- Variations/Changes and life cycle management: in the EU, US and rest of the world
- Registration procedures in the US, Japan and in emerging countries
- Regulatory procedures in Brazil and China

Three Case Studies
1. Stability Studies and Establishing the Retest Date
2. Description of the Manufacturing Process
3. Top 10 deficiencies in new applications for Certificates of Suitability for chemical purity

Objectives

This Live Online Training is intended to provide guidance on the format, content and submission procedures for the pharmaceutical documentation of the quality of the drug substance for different types of dossiers, the CTD, the CEP and the European ASMF.

In this context the consequences of the guidelines on Elemental Impurities (ICH Q3D (R1)) and genotoxic impurities (ICH M7) will be considered. Furthermore, the impact of the variations regulations will be discussed.

Background

In Europe there are several ways to document the quality of the drug substance for the purpose of marketing authorisation:

- Certificate of Suitability of the pharmacopoeial monograph (CEP)
- Full details of manufacture (according to CTD Module 3 Quality of Drug Substance)
- European Active Substance Master File (ASMF; former Drug Master File, DMF)
- Other evidence of suitability of the pharmacopoeial monograph

In the US, the quality of the drug substance can be documented as part of the CMC Dossier or in a US-DMF.

Target Audience

The Live Online Training is designed for all persons involved in the compilation of pharmaceutical dossiers for marketing authorisations who want to become familiar with the different ways to document the quality of the drug substance for the purpose of marketing authorisation in Europe. Furthermore, the course will be of interest to personnel from Quality Units of the medicinal products and the API industry.

Programme

Dossier Requirements for the Drug Substance – An Introduction

- Chemical pharmaceutical documentation for active substance(s) – Regulatory requirements in EU and USA
- Types of active substances – types of documentation
- CTD Module 3, CEP and ASMF (former DMF)
- CEP for a substance for TSE risk assessment

Requirements for the Certificate of Suitability to the European Pharmacopoeia

- Regulatory basis: Resolution AP-CSP (99)4 of the Council of Europe
- CEP Procedure
- Content of the CEP dossier with practical examples
- Administrative minor and major changes, 5-year's revision

The European Active Substance Master File Procedure

- Regulatory background and scope
- The revised European ASMF guideline
- Applicant's and restricted parts - points to consider
- Questions & Answers on the ASMF procedure
- Recent European developments: Sharing of assessment reports, data bases ....

Pharmaceutical Impurities: Residual Solvents, Synthesis-derived and Genotoxic and Elemental Impurities

- CPMP-/ICH-Guidelines on Impurities and Residual Solvents
- ICH M7 Guideline on genotoxic impurities
- ICH Q3D(R1) Guideline on elemental impurities
- Specifying Impurities
- Classifying solvents, setting and proving limits
- Justification of Specification

Stability Data

- CPMP/ICH Guidelines
- Stability Summary and Conclusions, stability commitment
- Documentation of Stability Data
- Necessity for documentation of raw data?

How to Read and Use a CEP

API Regulatory Starting Materials: how to Defend their Choice in a Submission

- Why is this such a hot topic
- What guidelines to consider
- How to define a suitable starting material
- How to defend your choice in the submission
- What is different for generics
- Consequences of a redefinition

Comparison of the CEP and DMF Procedure

- Advantages of the CEP procedure
- Handling Changes
- In which countries is the CEP being accepted?
- Cost Considerations
- Practical examples

Registration Procedures in the US and Japan – what are the Differences?

- Overview of the procedures
- Specifics for US and Japan

The EDQM Inspection Program

Stability Studies and Establishing the Retest Date
Dr Jan Smeets

Description of the Manufacturing Process
Dr Wilhelm Schlumbohm

Top ten Deficiencies in new Applications for Certificates of Suitability for Chemical Purity
Dr Alma Kiso

Important:
In order to prepare the lectures and the Case Studies in an optimal way, please send your questions to special topics **prior to the Live Online Training** to Ms Anne Günster, guenster@concept-heidelberg.de
She will forward your questions to the responsible speaker. Thank you in advance for your co-operation.

Registration Requirements for APIs in Emerging Countries

- General remarks on API registrations in Emerging Countries
- Details of API registration in:
  - Taiwan
  - India
  - CIS countries: Russia, Belarus, Ukraine
  - GCC countries
- APIC Emerging Countries Interest Group

Variations/Changes and Life Cycle Management: in the EU, US and Rest of the World

- Types and categories of API changes
- EU: the variation regulation and CEP revisions
- Handling API changes in the US
- Handling API changes in Japan
- Handling API changes outside these regions
- Initiatives to facilitate changes

Regulatory Procedures in Brazil and China

- Overview of the procedures
- Specifics for Brazil and China
- Experiences

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.

Alma Kiso
Certification of Substances Department, European Directorate for the Quality of Medicines and Healthcare (EDQM), France

Alma Kiso, BSc, MSc, is a Scientific Officer in the Certification Department of the EDQM. Before joining the EDQM, she was in charge of assessment of new applications for marketing authorisation for medicinal products for human use with the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina. Alma Kiso was also member of the European Pharmacopoeia Commission and expert group P4 within Ph. Eur. Commission. Since October 2016, she is in charge of the evaluation of new applications for Certificate of Suitability (CEP) in the Certification Department.

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.

Dr Jan W. H. Smeets,
The Netherlands

Dr Smeets worked for about 32 years in different positions in the pharmaceutical industry for the companies Gist-brocades, DSM, DSM Sinochem and Centrient Pharmaceuticals. The last 15 years of his career he acted as a Director Regulatory Affairs in which he was globally responsible for registrations of the whole portfolio of drug substances and drug products of the company. Moreover Dr Smeets was Dutch representative in Expert Group 7 (antibiotics) of the European Pharmacopoeia for about 20 years. He is author of multiple scientific papers and patents and was member of several interest groups of CEFIC/APIC.

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Reservation Form (Please complete in full)

Global Registration and Life Cycle Management of APIs, Live Online Training on 23 – 25 March 2021

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)

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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, 23 March 2021, 9.00 – 17.00 CET
Wednesday, 24 March 2021, 9.00 – 17.15 CET
Thursday, 25 March 2021, 9.00 – 16.30 CET

Technical Requirements

For our Live Online Training Courses, 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 e-mail 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 € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The 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.

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.

Organisation and Contact

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