ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Regulatory Affairs Manager

Speakers

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

Marta Miquel
European Directorate for the Quality of Medicines (EDQM & Health Care), France

Dr Wilhelm Schlumbohm
Berlin, Germany

Dr Jan Smeets
Centrient Pharmaceuticals, The Netherlands

Global Registration and Life Cycle Management of APIs

23 – 25 March 2021 | Berlin, Germany

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 Workshops
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 education course 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.

Participants will have the opportunity to join 3 workshops:

- Stability studies and establishing a retest date
- Description of the manufacturing process
- Top ten deficiencies in new applications for Certificates of Suitability for chemical purity

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 education course 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.

Social Event

On the evening of the first 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.

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

- Marta Miquel

Important:
In order to prepare the lectures and the workshops in an optimal way, please send your questions to special topics to Ms Anne Günster, guenster@concept-heidelberg.de. She will forward your questions to the responsible speaker.
Thank you in advance for your cooperation.

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

Ms van Dalen is the global regulatory specialist in the regulatory group dedicated to APIs, 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.

Marta Miquel
Certification Division, European Directorate for the Quality of Medicines and Healthcare (EDQM), France

Ms Miquel is a Scientific Officer in the Certification Department of the EDQM. After 8 years working in the Pharmaceutical Industry in Spain and Belgium (Regulatory Affairs and Quality Assurance fields), she joined the EDQM in 2004 as Quality Assurance officer and Quality auditor. Since 2011, she is in charge of the evaluation of new applications for Certificates 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. Currently he gives conference lectures on various quality topics and works as external advisor to drug regulatory authorities.

Dr Jan W. H. Smeets
Centrient Pharmaceuticals, The Netherlands

Dr Smeets is Director Regulatory Affairs within Centrient Pharmaceuticals and Dutch representative in Expert Group 7 (antibiotics) of the European Pharmacopoeia for 18 years. He is author of multiple scientific papers and patents and Member of several interest groups of CEFIC/APIC.

If the bill-to-address deviates from the specifications 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

Reservation Form (Please complete in full)

Global Registration and Life Cycle Management of APIs, 23 – 25 March 2021, Berlin, Germany

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.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week 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 HEIDELBERGwill 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 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
Tuesday, 23 March 2021, 9.00 – 17.30
(Registration and coffee 8.30 – 9.00)
Wednesday, 24 March 2021, 8.30 – 18.00
Thursday, 25 March 2021, 9.00 – 14.30

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Email berlin@steigenberger.de

Fees (per delegate, plus VAT)
ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The conference fee is payable in advance after receipt of invoice and includes conference documentation, social event on the first day, lunch on three 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.

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
P.O. Box 10 17 64
D-69007 Heidelberg
Telefon +49(0) 62 21/84 44-0
Telefax +49(0) 62 21/84 44 34
E-Mail: info@concept-heidelberg.de
www.concept-heidelberg.com

For questions regarding content:
Ms Anne Günster (Operations Director) at
+49(0)62 21/84 44 50, or per e-mail at
guenster@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Marion Grimm (Organisation Manager) at
+49(0)62 21/84 44 18, or per e-mail at
grimm@concept-heidelberg.de.