Global Registration and Life Cycle Management of APIs

10 – 12 March 2020 | Vienna, Austria

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

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
- Handling of Variations/Changes in Europe and the USA
- Registration procedures in the US, Japan and in emerging countries
- ICH Q3D – how to do in practice for APIs

Choose 2 out of 3 Parallel 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.

Programme

Participants will have the opportunity to choose 2 out of 3 parallel 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

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?

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:
  - China  |  Taiwan  |  India  |  CIS countries: Russia, Belarus, Ukraine  |  Brazil  |  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.

ICH Q3D – how to do in practice for APIs

---

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 more than 20 years with German drug licensing authorities in the field of assessment of the CMC parts of new drug applications. He is expert for the Certification Procedure of the European Pharmacopoeia.

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.

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.
Global Registration and Life Cycle Management of APIs | 10 – 12 March 2020, Vienna, Austria

Please choose two out of three workshops

- Stability Studies and Establishing the Retest Date
- Description of the Manufacturing Process
- Top ten deficiencies in new applications for Certificates of Suitability for chemical purity

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)

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of single rooms in the conference hotel. You will receive a room reservation form in the POG. Early registration is recommended. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!

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.

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 event 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.

WA/26072019