20 YEARS ECA Academy Your GMP/GDP Information Source

Global Registration and Life Cycle Management of APIs

Choose 2 out of 3 Parallel 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

SPEAKERS:

Marieke van Dalen
Aspen Oss, The Netherlands

Cristian Sampaolesi
European Directorate for the Quality of Medicines (EDQM & Health Care), France

Wilhelm Schlumbohm
Berlin, Germany

Jan Smeets
Centrient Pharmaceuticals, The Netherlands

Contents of the regulatory information in the ASMF and CEP

12 – 14 March 2019, Berlin, Germany

LEARNING OBJECTIVES:

- 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 US
- Registration procedures in the US, Japan and in emerging countries
- ICH Q3D – how to do in practice for APIs

This education course is recognised for the ECA GMP Certification Programme „Certified Regulatory Affairs Manager". Please find details at www.gmp-certification.eu

Global Registration and Life Cycle Management of APIs

12 – 14 March 2019, Berlin, Germany

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 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

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 pharmaceutical and the API industry.

Programme

Dossier Requirements for the Drug Substance – An Introduction

- Chemical pharmaceutical documentation for active substance(s) – Regulatory requirements in EU, 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

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
Cristian Sampaolesi

Important:
In order to prepare the lectures and the workshops in an optimal way, please send your questions to special topics to Dr Gerhard Becker, becker@concept-heidelberg.de

He 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

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.

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 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.

Cristian Sampaolesi
Certification Division, European Directorate for the Quality of Medicines and Healthcare (EDQM), France
Cristian Sampaolesi is a Scientific Officer in charge of the evaluation of new dossiers with the Certification Division of the EDQM since 2012. From 2003 to 2008 he held different responsibilities in the Quality Control field within the Pharmaceutical Industry in Italy. In 2009 he joined the Maltese National Competent Authority as Quality Assessor, position held for 3 years. From 2010 to 2012 he was the nominated member within the Joint CHMP/CVMP Quality Working Party at EMA.

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
Ph.D. in chemistry at the University of Utrecht, The Netherlands; 30 years with the company (Gist Brocades, DSM, DSP, Centrient Pharmaceuticals) with different positions in Research & Development, Technical Sales Services and Regulatory Affairs for intermediates, APIs and Drug Products. Currently Director Regulatory Affairs within Centrient Pharmaceuticals.and Dutch representative in Expert Group 7 (antibiotics) of the European Pharmacopoeia for 18 years. Author of multiple scientific papers and patents. Member of several interest groups of CEFIC/APIC. Speaker/lecturer in many international conferences/ courses dealing with Regulatory Affairs for APIs.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Global Registration and Life Cycle Management of APIs
12 – 14 March 2019, Berlin, Germany

Please choose **two** out of three workshops
☐ Stability Studies and Establishing the Retest Date
☐ Description of the Manufacturing Proces
☐ Top ten deficiencies in new applications for Certificates of Suitability for chemical purity

☐ Mr. ☐ Ms.

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **Purchase Order No, if applicable**

Street/P.O. Box

City | Zip Code | Country

Phone/Fax

E-Mail (please fill in)

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 http://www.gmp-compliance.org/eca_privacy.html). 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.

German law shall apply. Court of jurisdiction is Heidelberg.

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 %,
- until 1 weeks prior to the conference 50 %
- 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 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 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)

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

Date

Tuesday, 12 March 2019, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 13 March 2019, 9.00 – 17.30 h
Thursday, 14 March 2019, 9.00 – 13.30 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
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, dinner on the first day, lunch on all days and all refreshments. VAT is reclaimable

Accommodation

CONCEPT 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.

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, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Gerhard Becker (Operations Director) at +49 (0) 62 21 / 84 44 65, or per e-mail at becker@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.