ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Regulatory Affairs Manager

Speakers

Marieke van Dalen
MARA Consultancy, The Netherlands

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

Cristina Jimenez Sala
Centrient Pharmaceuticals, Spain

Dr Wilhelm Schlumbohm
Berlin, Germany

Global Registration and Life Cycle Management of APIs

08 – 10 April 2025 | Vienna, Austria

Get first-hand information about the new CEP 2.0 and how to use a CEP in marketing authorization application.

Contents of the regulatory information in the ASMF and CEP

Highlights

- Dossier Requirements for the Drug Substance
- Requirements for the Certificate of Suitability
- ASMF Procedure
- Synthesis derived Impurities, Genotoxic Impurities, Elemental Impurities and Residual Solvents
- Stability Data
- How to read and use a CEP / Implementation of CEP 2.0
- 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

- Stability Studies and Establishing the Retest Date
- Description of the Manufacturing Process
- 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 variation's regulations will be discussed.

Participants will have the opportunity to take part in 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
- CEP for a substance for TSE risk assessment

Requirements for the Certificate of Suitability to the European Pharmacopoeia

- CEP Procedure: legal framework, the role, place and scope
- How the CEP procedure works for new CEPs
- Basic principles for maintaining the CEP: administrative, minor and major changes, renewal of CEPs
- Key figures and how to communicate with EDQM

The European Active Substance Master File Procedure

- Regulatory background and scope
- The revised European ASMF guideline
- Applicants' 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 / Implementation of CEP 2.0

- How to interpret information laid down on CEP-practical examples
- Project CEP 2.0: What has changed and what are the benefits?
- CEP holders' responsibilities towards their customers
- How to use a CEP in marketing authorization application

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 Programme

- How does the EDQM inspection procedure work
- EDQM GMP Assessment tools: On-site inspections, documentation-based GMP Assessment and Real Time Remote Inspections (RTEMIS)
- Inspection facts and figures

- **Stability Studies and Establishing the Retest Date**
  - *Cristina Jimenez Sala*
- **Description of the Manufacturing Process**
  - *Dr Wilhelm Schlumbohm*
- **Top ten Deficiencies in new Applications for Certificates of Suitability for Chemical Purity**
  - *Alma Kiso*

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.

Country specific Requirements

- 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

Regulatory Procedures in Brazil and China

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

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

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.

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

Ms 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. She was also member of the European Pharmacopoeia Commission and expert group P4 within Ph. Eur. Commission. Since October 2016, Alma Kiso is in charge of the evaluation of new applications for Certificate of Suitability (CEP) in the Certification Department.

Cristina Jimenez Sala, Centrient Pharmaceuticals, Spain

Ms Jiménez is a pharmacist and holds a master's degree in Pharmaceutical Industry. She has been working on different regulatory affairs positions dedicated to the life cycle management of the dossiers for final dosage forms and active principle ingredients for internal and external customers. Additionally, she was also involved in registration procedures for different type of medical devices and in vitro diagnostic products. The last years she was specially focused on managing documentation for sterile APIs registered all over the world, including FDA, EDQM, Korea, Taiwan, India, Singapore and South Africa among others.

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.

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GERMANY

Reservation Form (Please complete in full)

Global Registration and Life Cycle Management of APIs
08 – 10 April 2025, Vienna, Austria

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks prior to the conference 100 %.

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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, 08 April 2025, 09.00 – 17.30
(Registration and coffee 08.30 – 9.00)
Wednesday, 09 April 2025, 09.00 – 17.30
Thursday, 10 April 2025, 09.00 – 15.30
All times mentioned are CEST.

Venue
Austria Trend
Parkhotel Schönbrunn
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Fees (per delegate, plus VAT)
ECA Members € 2,090
APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,145
The fee is payable in advance after receipt of invoice and includes social event on the first day, lunch on all 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 – or search and register directly at www.gmp-compliance.org under the number 21631.

Conference language
The official conference language will be English.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

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