



Choose 2 out of 4 Parallel Workshops

- Stability Studies and Establishing the Retest Date
- Description of the Manufacturing Process
- How to Compile Data for Impurities and Residual Solvents
- Questions and Answers of the CEP Procedure

CTD, CEP and Active Substance Master File

Quality of Drug Substance

1-2 March 2016, Prague, Czech Republic

SPEAKERS:

Boris Pimentel
Pi-Consulting, Switzerland

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

Wilhelm Schlumbohm
Berlin, Germany

Jan Smeets
DSM Sinochem Pharmaceuticals, The Netherlands

PROGRAMME:

- Dossier Requirements for the Drug Substance
- How to Compile an ASMF
- Requirements for the Certificate of Suitability
- Drug Substance - Setting Specifications
- Stability Data
- Description of the Manufacturing Process and Process Controls
- Impurities and Residual Solvents
- Handling of Variations/Changes in Europe and the US
- Registration Requirements in Emerging Countries
- Comparison of CEP and ASMF Procedure



CTD, CEP and Active Substance Master File

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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 and the US-DMF. Furthermore, the impact of the variations regulations will be discussed.

Participants will have the opportunity to choose 2 out of 4 parallel workshops:

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- Description of the manufacturing process
- How to compile data for impurities and residual solvents
- Questions and answers of the CEP procedure

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 Group

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.

Social Event

On 1 March, 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

General Part

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

How to Compile an ASMF Using the CTD Format

- Structure of the ASMF
- Compilation of an ASMF; how to start
- Compilation steps and technical approaches
- ASMF and eCTD
- eCTD vs. NEES
- DMF systems in the US, Japan and Latin America

Requirements for the Certificate of Suitability

- 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

Special Part

Stability Data

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

Description of the Manufacturing Process and Process Controls

- The regulatory framework for manufacturing APIs
- Most frequent issues on manufacturing process description
- Format and content of the MP Chapter CTD-3.2.S-2
- The CTD Module 3– Quality: 3.2.S.2
- Critical issues in the process description
- CEP specific requirements

Impurities and Residual Solvents

- CPMP/ICH Guidelines *Impurities and Residual Solvents*
- Specifying Impurities
- Classifying solvents, setting and proving limits
- Justification of Specification

Registration requirements in emerging countries

Regulatory Compliance

Handling of Variations/Changes in Europe and the US

- The EU Variations Regulation and detailed Guidelines
- Types of Changes
- Remaining problems of changes for the API Industry
- Change system for APIs in EU
- Change System for APIs in USA
- New FDA initiatives to facilitate changes
- Preferred options for Bulk Pharmaceutical Industry to solve post-approval change problems
- How to handle variations in the ASMF and the CEP procedure

Comparison of CEP and ASMF Procedure

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

Parallel Workshops

Please choose two out of four parallel workshops

Stability Studies and Establishing the Retest Date

Dr Jan Smeets

Description of the Manufacturing Process

Dr Wilhelm Schlumbohm

How to Compile Data for Impurities and Residual Solvents

Dr Boris Pimentel

Questions and Answers of the CEP Procedure

Fiona McLeod

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, email: becker@concept-heidelberg.de. He will forward your questions to the responsible speaker. Thank you in advance for your cooperation.

Speakers



Dr Boris Pimentel

Pi-Consulting, Switzerland

Dr Pimentel is manager of the consulting company for global regulatory services – Pi-Consulting in Switzerland. Until June 2014 he worked on the Dutch company DSM Nutritional Products in Switzerland, focusing in Pharma and Food regulations. Since 2010 as a member of the APIC board he was involved in several task forces like ASMFs, Variations and Changes, and participated in the discussions with EMA, WHO and EDQM. He also chaired the task force for Japan regulations, and Emerging Market Regulations.

Cristian Sampaolesi

Certification Division, European Directorate for the Quality of Medicines (EDQM & Health Care), France



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 Smeets

*DSM Sinochem Pharmaceuticals,
The Netherlands*

10 years with Gist-brocades, 12 years with DSM and now with DSM Sinochem Pharmaceuticals with different positions in Research & Development, Regulatory Affairs and Technical Sales Services for APIs and intermediates. Currently Director Regulatory Affairs & Technical Sales Services. Responsible for worldwide submissions and regulatory approvals. Dutch representative in group 7 (antibiotics) of the European Pharmacopoeia.

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Easy Registration



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CTD, CEP and Active Substance Master File,
1-2 March 2016, Prague, Czech Republic
 Mr. Ms.

Title, first name, surname

Company Department
Important: Please indicate your company's VAT ID Number

Street/P.O. Box

City Zip Code Country

Phone/Fax

E-Mail (please fill in)

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Date
Tuesday, 1 March 2016, 9.00 h– 18.15 h
(Registration and coffee 8.30 h – 9.00)
Wednesday, 2 March 2016, 8.30 h– 16.00 h

Venue
Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 (261) 191 111
Fax +420 (261) 225 011

Fees (per delegate plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The fee is payable in advance after receipt of invoice and includes conference documentation, social event and dinner on the first day, lunch on both 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 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.

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