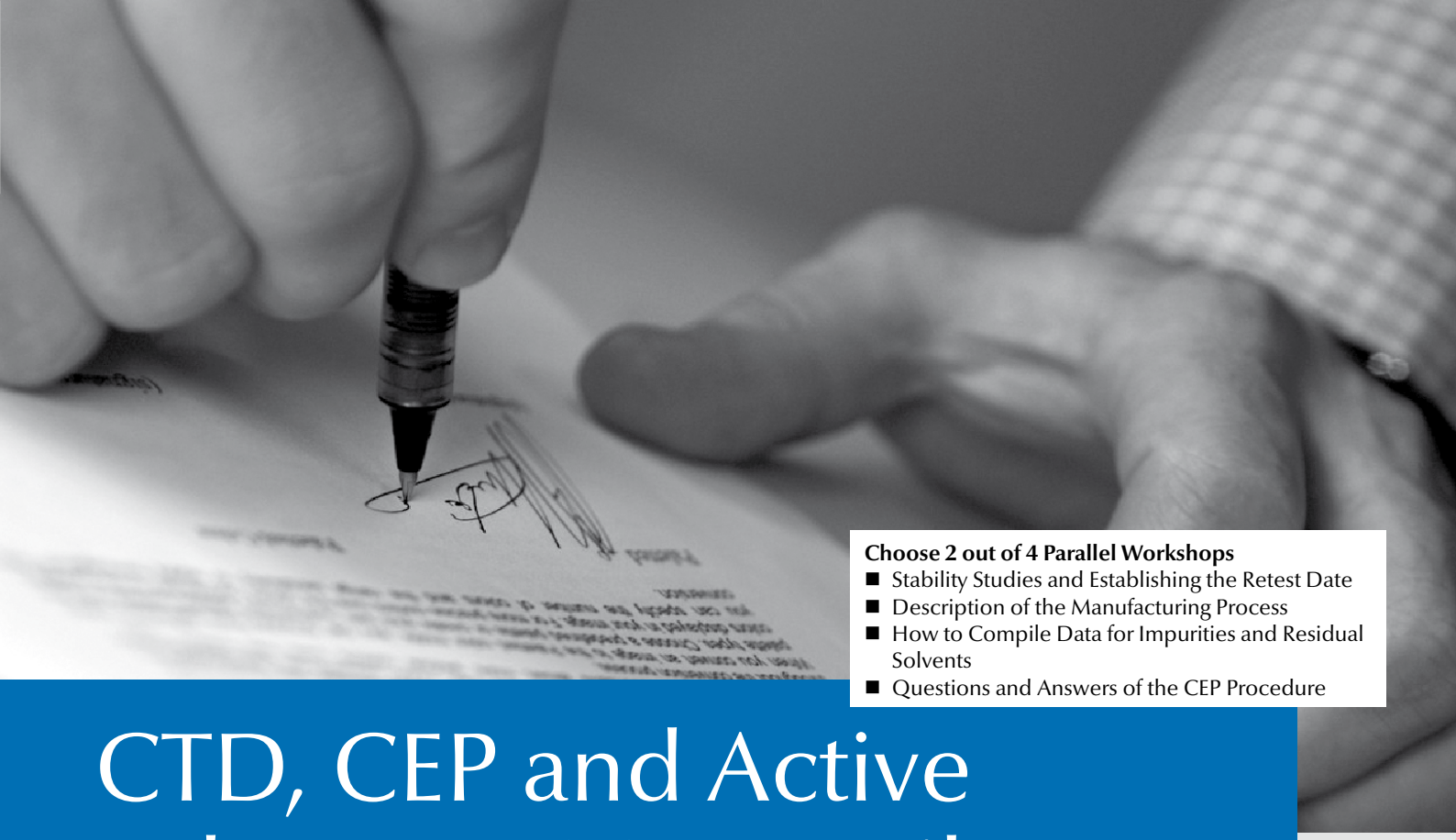

Choose 2 out of 4 Parallel Workshops

- 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

20-21 May 2014, Berlin, Germany

SPEAKERS:

Fiona McLeod
European Directorate for the Quality of Medicines (EDQM & Health Care), France

Boris Pimentel
DSM-Nutritional Products AG, Switzerland

Wilhelm Schlumbohm
Berlin, Germany

Jan Smeets
DSM Sinochem Pharmaceuticals, The Netherlands

PROGRAMME:

- Dossier Requirements for the Drug Substance – An Introduction
- 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
- Comparison of CEP and ASMF Procedure

ECA ACADEMY

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

CTD, CEP and Active Substance Master File

20-21 May 2014, 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 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:

- Stability studies and establishing a retest date
- 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 20 May, 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

Dr Wilhelm Schlumbohm
Germany

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

Dr Boris Pimentel
DSM-Nutritional Products AG, Switzerland

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

Fiona McLeod
European Directorate for the Quality of Medicines (EDQM & Health Care), France

Special Part

Drug Substance - Setting Specifications

- Definition of 'specification'
- ICH/CHMP guidelines
- Pharmacopoeial tests and acceptance criteria
- Specifications in API development
- Criteria for the specification of impurities
- Justification of specifications

Dr Wilhelm Schlumbohm
Germany

Stability Data

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

Dr Jan Smeets
DSM Sinochem Pharmaceuticals, The Netherlands

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

Dr Boris Pimentel
DSM-Nutritional Products AG, Switzerland

Impurities and Residual Solvents

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

Dr Jan Smeets
DSM Sinochem Pharmaceuticals, The Netherlands

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

Dr Jan Smeets
DSM Sinochem Pharmaceuticals, The Netherlands

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

Dr Jan Smeets
DSM Sinochem Pharmaceuticals, The Netherlands

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

Fiona McLeod
Certification Division, European Directorate for the Quality of Medicines (EDQM & Health Care), France
Graduated in Pure Chemistry. She worked for 18 years for major pharmaceutical company in various analytical chemistry roles in both QA and development activities then in regulatory affairs. She then joined the European Directorate for the Quality of Medicines & HealthCare in 2004, where she is a scientific officer with the Certification Division. She is a member of the team dealing with new dossiers and also has responsibilities for e-submissions and IT solutions for the division.

Dr Boris Pimentel
DSM-Nutritional Products AG, Switzerland
Dr Pimentel is responsible for the worldwide submissions and assessments of the API documentation (CMC, Safety) for NDAs and MAAs. He is board member of APIC, chairman of APIC's Japan task force and member of the advisory board of the European Compliance Academy.

Dr Wilhelm Schlumbohm
Berlin, Germany
More than 20 years with German drug licensing authorities, assessment of the CMC parts of new drug applications, regulatory affairs, inspections in connection with licensing applications of medicinal products (pre-approval inspections). Rapporteur and member of the Technical Advisory Board for the Certification Procedure.

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.

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

If the bill-to-address deviates from the specifications on the right, please fill out here:

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P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

CTD, CEP and Active Substance Master File, 20-21 May 2014, Berlin, Germany
Please choose **TWO** 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

☐ 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

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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 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)
   - until 2 weeks prior to the conference 10 %,
   - until 1 weeks prior to the conference 50 %
   - within 1 week 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

Date

Tuesday, 20 May 2014, 9.00 h– 18.15 h
(Registration and coffee 8.30 h – 9.00)
Wednesday, 21 May 2014, 8.30 h– 16.00 h

Venue

InterCityHotel Berlin Hauptbahnhof
Katharina-Paulus-Str. 5
10557 Berlin, Germany
Phone +49 (0)30 288 755 0
Fax +49 (0)30 288 755 900

Fees

ECA Members € 1,590.- per delegate plus VAT
APIC Members € 1,690.- per delegate plus VAT
Non-ECA Members € 1,790.- per delegate plus VAT
EU GMP Inspectorates € 895.- per delegate plus VAT
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.

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

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