ECA Academy
Your GMP/GDP Information Source

API Regulatory Starting Materials

Workshops
- API synthesis: How to define suitable Starting Materials
- How to defend the choice of the Starting Material in the submission

Definition, manufacture, assessment and handling post-approval changes

20-21 September 2016, Prague, Czech Republic

SPEAKERS:

Marieke van Dalen
Aspen Oss, The Netherlands

Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

Gerd Jilge
Boehringer Ingelheim, Germany

Corina Nachtsheim
Quality Assessor, Germany

Matthias Schneider
BASF, Germany

LEARNING OBJECTIVES:

- Defining an API Starting Material
- Starting materials in the CEP application procedure
- Re-defining regulatory starting materials and how to deal with it
- Risk assessment and criticality analyses
- What is different for Generics?
- Handling post approval changes
- Pre-starting material information
- Appropriate controls for Starting Materials manufacturers

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

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Objectives

During this course **all relevant aspects** regarding API regulatory starting materials will be discussed. You will learn

- What has to be considered when a starting materials have to be defined
- How risk assessment can be applied
- Which aspects have to be taken into account when applying for a CEP
- How quality agreements should look like and
- How post approval changes can be handled.

Furthermore you will have the opportunity to participate in one of two parallel workshops about

- How to define suitable starting materials in API synthesis
- How to defend the choice of the starting material in the submission

Background

According to EU GMP Guide Part II (ICH Q7) an API starting material is a raw material, an intermediate, or an API that is used in the production of an API and is incorporated as a significant structural fragment into the structure of the final API. From this point on, appropriate GMP has to be applied to the API manufacturing steps.

In a marketing authorisation application the applicant has to describe in an ASMF the API manufacturing process. The "API regulatory starting material" has to be clearly designated and the rationale for the point at which the production of the API begins has to be documented. The same applies for a CEP application procedure.

In the last few years assessors have been more and more challenging the proposed regulatory starting materials. E.g. the definition of a starting material has been one of the top deficiencies in CEP applications. This is partly due to the fact that companies tend to describe shorter synthetic routes starting from complex starting materials. Moreover changes of critical quality attributes and the request from the authorities to re-define the starting material can create difficult situations regarding additional efforts and significant delays in the application process.

Target Audience

This course is designed for all persons involved in the manufacture of APIs. Furthermore, the seminar will be of interest to personnel from quality assurance, regulatory affairs both from API and pharmaceutical companies and to contract manufacturers.

Programme

How to define API Regulatory Starting Materials: What do the guidelines tell us?

- API Regulatory Starting Materials – overview of guidelines
- Definition according to the guidelines
- Global guidelines (ICH Q7 and Q11)
- US, EU and Japan guidance
- How to use the term "significant structural fragment"
- Distinguishing starting meterials from raw materials, reagents and solvent
- Selection of an appropriate Starting Material
- Starting Material specification

API Regulatory Starting Materials – Challenges and practical implications for a submission

- How to use the elements of the guidelines in practice
- Is a global approach the best way forward?
- What is the level of detail to be provided?
- What are the consequences of the choice?

API Regulatory Starting Materials – What is different for Generics?

- One file fits all?
- Redefinition of the RSM; practical aspects
- Practical experiences

Starting Materials and the CEP application procedure

- Regulatory background
- Scope of the CEP procedure
- Provisions of the Guideline PA/PH/CEP (14) 06 "Use of a CEP to describe a starting material in an application for another CEP"
- Important points to be considered for defining an API starting materials

How to handle post-approval changes

- Changes to the pre-starting material information
- Re-definition of the starting material: possible or not
- Handling changes/variations when multiple stakeholders are involved

From starting materials to APIs: risk assessment and criticality analyses

- Criticality analysis methods (HAZOP, FMEA etc)
- Critical quality attributes (CQA) and critical process steps (CPS)
- Linking CQA and synthesis steps
- Critical impurities
- Critical raw materials
- Process criticality analysis; example

Workshops

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APIC's position on Starting Materials

- Definition of the SM
- Risk management
- Qualification of the SM supplier
- Pre-SM information
- Handling changes/variations

Appropriate controls for Starting Materials manufacturers

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.

Speakers

Marieke van Dalen
Aspen Oss B.V., The Netherlands
Marieke van Dalen is the global regulatory specialist in the regulatory group dedicated to API's, 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.

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany
Dr Hiltrud Horn is managing director of HORN PHARMACEUTICAL CONSULTING. From 1990 to 1997, she was employed by Hoffmann-La Roche in Quality Control/Quality Assurance. From 1997 to 1999, she dealt with medical writing in the 'International Drug Regulatory Affairs and Project Management' department of the same company. In 1999, she joined Knoll AG as head of the departments 'Regulatory Compliance and CMC Documentation' and 'Dossier Production and Compliance' for international drug registration. In 2002, she started at Cap Gemini Ernst & Young, where she was the responsible consultant for questions concerning biotechnology and life sciences.

Dr Gerd Jilge
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
In 1991 Dr Gerd Jilge came to Boehringer Ingelheim working in product development where he was responsible for method development and validation for the application of analytical procedures. In 2000 Dr Jilge took a position in Drug Regulatory Affairs of Boehringer Ingelheim GmbH with the focus on CMC documentation for the submission of new and registered drug products. Since July 2007 he is working in Quality Management on method development for new drug substances.

Dr Corina Nachtsheim
Quality Assessor, Germany
Dr Nachtsheim studied chemistry at the University of Cologne and received a Ph.D. (Dr. rer. nat.) in pharmaceutical chemistry at the University of Bonn. She is working as a quality assessor at the German Federal Institute for Drugs and Medical Devices since Jan. 2001. Since Nov. 2007, she is an external expert in the framework of the certification procedure of the EDQM in Strasbourg. She became a member of the chemical Technical Advisory Board (EDQM) in Nov. 2011 and is currently chairperson.

Matthias Schneider, *BASF, Germany*
Matthias Schneider is Regulatory Affairs Manager for APIs and Excipients at BASF, Germany. Before he joined BASF, he was Regulatory Affairs Manager for APIs and Drug Products at Hoffmann-La Roche in Switzerland for 4 years. Before that he was employed by Amgen and worked in the department of Research and Development of lead structures for 7 years.

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:

Reservation Form (Please complete in full)

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Please choose ONE workshop:
☐ API synthesis: How to define suitable Starting Materials
☐ How to defend the choice of the Starting Material in the submission

☐ Mr. ☐ Ms.

Title, first name, surname

Company | Department

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

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Date

Tuesday, 20 September 2016, 9.00 – 17.15 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 21 September 2016, 9.00 – 14.30 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 / 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.

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