



Speakers



Marieke van Dalen
Aspen Oss B.V., The Netherlands



Hiltrud Horn
Horn Pharmaceutical Consulting,
Germany



Gerd Jilge
Boehringer Ingelheim, Germany



Corina Nachtsheim
Quality Assessor, Germany



Matthias Schneider
BASF, Germany



Francois Vandeweyer
VDWcGMP Consultancy, Belgium

API Regulatory Starting Materials

10/11 February 2022 | Heidelberg, Germany



Definition, Manufacture, Assessment and handling post-approval Changes

Highlights

- Defining an API Starting Material
- Starting materials in the CEP application procedure
- Challenges and practical implications for a submission
- Risk assessment and criticality analyses
- Do all Authorities expect the same?
- Handling post approval changes
- Appropriate controls for Starting Materials
- Auditing Starting Material manufacturers

Objectives

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

- What has to be considered when 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
- How post approval changes can be handled and
- How impurities in starting materials can be controlled

Furthermore you will have the opportunity to join two workshops about

- How to define suitable starting materials in API syntheses
- 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. 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 materials 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 – Do all Authorities Expect the Same?

- Differences between the expectations of health authorities
- Consequences in case of changes
- 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 material

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 Assessments 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

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

Appropriate Controls for Starting Materials

- How to control impurities in a starting material
- Analytical techniques
- Optimisation of chromatographic methods
- Downstream experiments
- Validation of analytical procedures
- Qualification of Starting Materials

How to Audit Starting Material Manufacturers

- Impact of ICH Q7 Q&A and ICH Q11 on auditing Starting Material manufacturers
- Health Authority and Regulatory expectations
- Risk based approach on "How to " audit Starting Materials
- Development and use of the APIC guideline on auditing Starting Materials
- Practical examples and case studies

Speakers



Marieke van Dalen,
Aspen Oss B.V., The Netherlands

Ms 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 Horn is managing director of HORN PHARMACEUTICAL CONSULTING with focus on CMC, GMP and Regulatory Affairs. She started in pharma industry in 1990 and held several managerial positions within Hoffmann-La Roche in Basel and Knoll (Abbott) with global responsibility within QC / QA / Regulatory Affairs / Project Management / Medical Writing.



Dr Gerd Jilge
Boehringer Ingelheim Pharma
GmbH & Co. KG, Germany

In 1991, Dr 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, he 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 has 20 years of work experience as a quality assessor at the German Federal Institute for Drugs and Medical Devices (BfArM). She is also an external expert in the framework of the certification procedure of the EDQM in Strasbourg since 2007 and has been an active member of the chemical Technical Advisory Board (EDQM) for 9 years, which she chaired from 2013 to 2019.



Matthias Schneider,
BASF, Germany

Mr 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.



Francois Vandeweyer
VDWcGMP Consultancy, Belgium

Mr Vandeweyer joined Janssen Pharmaceutica (part of Johnson & Johnson) in 1981 in chemical development. Until 1995 increasing responsibilities within the organisation mainly in the Quality Control Unit. Starting from 1995 he joined the QA department. Several Senior Manager responsibilities. 2005 Sr Manager GMP Compliance Chemical Operations Belgium (sites Geel – Olen – Beerse). 2009 Director Global Compliance EMEA/AP for Johnson & Johnson. Since May 2019 he is a freelance consultant.

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API Regulatory Starting Materials, 10/11 February 2022, Heidelberg, Germany

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

CONCEPT HEIDELBERG

P.O. Box 101764

Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg

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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

Phone +49(0) 62 21/84 44-0 | Fax +49(0) 62 21/84 44 34

info@concept-heidelberg.de | www.concept-heidelberg.com

For questions regarding content please contact:

Ms Anne Günster (Operations Director) at
+49(0)62 21/84 44 50, or per e-mail at
guenster@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:

Mr Niklaus Thiel (Organisation Manager) at
+49(0)62 21/84 44 43, or per e-mail at
thiel@concept-heidelberg.de.

Date

Thursday, 10 February 2022, 9.00 – 18.00 h

(Registration and coffee 8.30 – 9.00 h)

Friday, 11 February 2022, 8.30 – 14.45 h

Venue

Qube Hotel Bahnstadt

Grüne Meile 21

69115 Heidelberg, Germany

Phone +49(0)6221 / 639 000

Email bahnstadt@qube-heidelberg.de



On site, we will implement the necessary and required hygiene measures in close co-operation with the hotel. If infection rates and/or travel restrictions generally do not permit an on site event, it will be conducted live online. In this case, you will be informed in due time

Fees (per delegate, plus VAT)

ECA Members € 1,590 | APIC Members € 1,690

Non-ECA Members € 1,790 | EU GMP Inspectorates € 895

The conference fee is payable in advance after receipt of invoice and includes lunch on both 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.

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.

Registration

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