



Speakers



Marieke van Dalen
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Gerd Jilge
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API Regulatory Starting Materials



Live Online Training on 22/23 February 2024



Definition, Manufacture, Assessment and handling post-approval Changes

Highlights

- Defining an API Starting Material
- Starting Materials in the CEP Application Procedure
- Risk Assessment and Criticality Analyses
- Do all Authorities expect the Same?
- Changes in Regulatory Starting Material Supply/Suppliers
- Appropriate Controls for Starting Materials Manufacturers
- Auditing Starting Material Manufacturers

Objectives

During this Live Online Training 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 case studies 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 Live Online Training 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 – 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

Changes in Regulatory Starting Material Supply/Suppliers

- What kind of changes could occur?
- How to classify these changes?
- What information to submit?

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



Case Studies

- 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 APIs, with over 35 years of experience in the regulatory field. She is a board member of APIC, the European API Industry organization, and she actively participates and/or (co-)chairs in a number of task forces. She frequently represents APIC in meetings and conferences organized by EMA, EDQM, CPhI etc



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 Cornelia Nopitsch-Mai
Formerly Quality Assessor, Germany

Dr Cornelia Nopitsch-Mai was scientist at the Federal Institute for Drugs and Medical Devices in the assessment of the quality part of the dossier since 1991. Since 2000 she was assessor for the Certification Procedure (EDQM) in Strasbourg. She was member of the Technical Advisory Board (EDQM) from 2001 until 2010; in that time she was chairperson from 2005 until 2010. From 2007 until 2011 she was a member of the EMA Quality Working Party.



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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Reservation Form (Please complete in full)



API Regulatory Starting Materials, Live Online Training on 22/23 February 2024

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Date of the Live Online Training

Thursday, 22 February 2024, 08.30 – 16.45 h CET

Friday, 23 February 2024, 08.30– 13.30 h CET

Technical Requirements

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Fees (per delegate, plus VAT)

ECA Members € 1,690

APIC Members € 1,790

Non-ECA Members € 1,890

EU GMP Inspectorates € 945

The conference fee is payable in advance after receipt of invoice.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

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.

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Organisation and Contact

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

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