



## Speakers



Marieke van Dalen  
MARA Consultancy, The Netherlands



Gerd Jilge  
Boehringer Ingelheim, Germany



Cornelia Nopitsch-Mai  
Bonn, Germany



Matthias Schneider  
BASF, Germany



Francois Vandeweyer  
VDWcGMP Consultancy, Belgium

# API Regulatory Starting Materials

18/19 February 2025 | Munich, Germany



*Definition, Manufacture, Assessment and handling post-approval Changes*

## Highlights

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

With 2 Workshops

## 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?

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- 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?

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

### Changes in Regulatory Starting Material Supply/Suppliers

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

### Starting Materials and the CEP Application Procedure

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- 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

### From Starting Materials to APIs: Risk Assessments and Criticality Analyses

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- 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 Manufacturers

- 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,  
MARA Consultancy, The Netherlands

Ms van Dalen is a global API regulatory specialist leading her own small consultancy in the Netherlands. She has 38 years of experience in the API industry, always in the regulatory field. Her latest position was with Aspen API in the Netherlands, as Global Regulatory Specialist. She was for a long time a Board member of APIC (the European API organisation) and represented APIC often in meetings and symposia with health Authorities all around the world.



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 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.

## 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.

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Reservation Form (Please complete in full)

API Regulatory Starting Materials, 18/19 February 2025, Munich, Germany

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

CONCEPT HEIDELBERG

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**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 until 4 weeks prior to the conference 10 %
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    - Cancellation until 2 weeks prior to the conference 50 %
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German law shall apply. Court of jurisdiction is Heidelberg.

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I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

## Date

Tuesday, 18 February 2025, 09.00 – 17.00 h

(Registration and coffee 08.30 – 09.00 h)

Wednesday, 19 February 2025, 08.30– 15.00 h

## Venue

H4 Hotel München Messe

Konrad-Zuse-Platz 14

81829 Munich, Germany

Phone +49 89 9400830

Email : [muenchen.messe@h-hotels.com](mailto:muenchen.messe@h-hotels.com)

## Fees (per delegate, plus VAT)

ECA Members € 1,890

APIC Members € 1,990

Non-ECA Members € 2,090

EU GMP Inspectorates € 1,045

The conference fee is payable in advance after receipt of invoice and includes dinner on the first day, 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

Via the attached reservation form, by e-mail or by fax – **or search and register directly at [www.gmp-compliance.org](http://www.gmp-compliance.org) under the number 21661.**

## 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

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