Highlights

- 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
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 one of two parallel 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.
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

APIC’s position on Starting Materials
- Definition of the SM
- Risk management
- Qualification of the SM supplier
- Pre-SM information
- Handling changes/variations

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 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
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
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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:
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   - Cancellation until 1 week prior to the conference: 50%,
   - Cancellation within 1 week prior to the conference: 100%.

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