ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Regulatory Affairs Manager

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

Live Online Training on 20/21 April 2021

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 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 – 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

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 30 years of experience in the regulatory field. She is a board member of APIC, the European API Industry organization, and she participates in a number of task forces. She frequently represents APIC in meetings and conferences organized by EMA, EDQM, CPhI 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.

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

API Regulatory Starting Materials, Live Online Training on 20/21 April 2021

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). 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 of the Live Online Training

Tuesday, 20 April 2021, 09.00 – 17.00 h CEST
Wednesday, 21 April 2021, 09.00 – 16.30 h CEST

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

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.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

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.

Conference language

The official conference language will be English.

Your Benefit: Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,... " This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

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