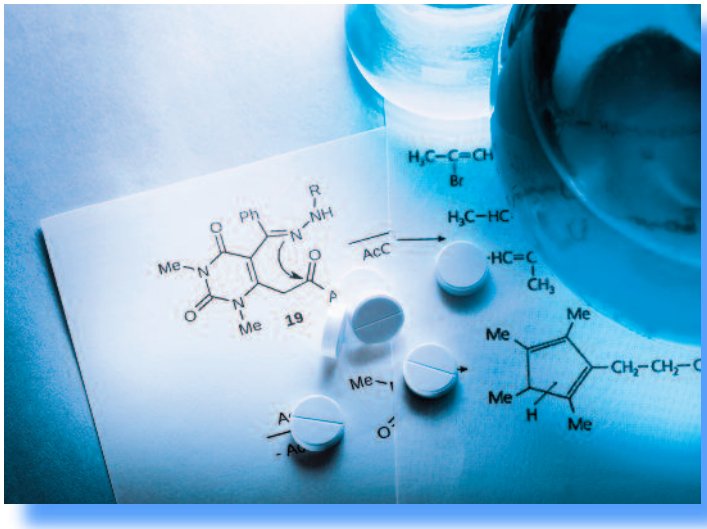
Definition of starting materials – scientific and regulatory aspects



08 November 2017
Frankfurt/Main, Germany

Course no. 6697

Drug Regulatory Affairs

Target audience

This seminar addresses pharmaceutical professionals in R&D as well as in quality control/ assurance and regulatory affairs departments of pharmaceutical industry and API manufacturers.

MAKING SCIENCE WORK

Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V.
Gemeinnütziger wissenschaftlicher Verein
International Association for Pharmaceutical Technology

Drug Regulatory Affairs

A seminar organised by the APV focus group Drug Regulatory Affairs

Objectives

This seminar covers all relevant aspects concerning the definition of starting materials:

- ICH Q11 and other relevant guidelines
- Requirements from authority's perspective
- Experiences after submissions and consequences for drug substance development and lifecycle management
- Scientific data in regulatory submissions
- Starting materials for biologicals

Take advantage to discuss with colleagues from pharmaceutical industry, API manufacturer and authorities.

Programme

Wednesday, 08 November 2017 **09:00-17:00**

Welcome and introduction

Philipp Huber, PhD
Boehringer Ingelheim Pharma GmbH & Co. KG,
Ingelheim, Germany

Definition for regulatory starting materials: ICH Q11 and other relevant guidelines

- Introduction
- Global Guidelines – ICH
- Regional requirements EMA, EDQM, FDA, PDMA
- Industry's perspective
- Examples
- Conclusion

Matthias Schneider, PhD
BASF SE
Ludwigshafen, Germany

Requirements concerning starting materials from authority's perspective

- Introduction
- Background on discussion concerning starting materials
- Guideline on chemistry of active substances
- Reflection paper
- Definition of staring materials and its consequences
- Case studies

Cornelia Nopitsch-Mai
Bundesinstitut für Arzneimittel u. Medizinprodukte (BfArM),
Bonn, Germany

Experience with API starting materials submissions and consequences for drug substance development

- Type of questions received for MAA, link with ICH Q11 guideline and related Q&A and the EMA position paper
- API SM designation during development
- Impact on development activities

Christophe Girault, PhD
Boehringer Ingelheim Pharma GmbH & Co. KG
Ingelheim, Germany
Rabea Hennig, PhD
Boehringer Ingelheim Pharma GmbH & Co. KG
Ingelheim, Germany

Using scientific data in regulatory submissions

- It's all about impurities: process understanding is the foundation of a coherent control strategy
- Risk assessment, scientific advice from HA and fallback positions for regulatory starting materials
- Design-of-Experiments, Quality-by-Design and purge calculations

Gerhard Braun
Bayer AG
Wuppertal, Germany

Starting materials for biologicals

- Starting material of biological origin
  - Expression systems
  - Characterisation of cell banks
- Definition of staring materials
  - Case studies
  - Antibody drug conjugates
- Regulatory framework to be considered

Steffen Gross, PhD
Paul-Ehrlich-Institut
Langen, Germany

Panel discussion

Programme is subject to change

Definition of starting materials – scientific and regulatory aspects

Moderator

Philipp Huber, PhD
Boehringer Ingelheim Pharma GmbH & Co. KG

Philipp Huber, PhD is pharmacist, food chemist and toxicologist. He has 15 years of experience in the area of quality control/assurance and CMC regulatory affairs. He is currently working as Head of Quality Excellence, Dept. Quality for Boehringer Ingelheim in Ingelheim, Germany.

Rabea Hennig, PhD
Boehringer Ingelheim Pharma GmbH & Co. KG

Rabea Hennig, PhD is chemist. She has 9 years of experience in the area of chemical process development. She is currently working as CRO monitor for Boehringer Ingelheim in Ingelheim, Germany.

Cornelia Nopitsch-Mai
BfArM

Cornelia Nopitsch-Mai,
Bundesinstitut für Arzneimittel u. Medizinprodukte (BfArM), Bonn, Germany.

Speaker

Gerhard Braun
Bayer AG

Gerhard Braun is chemist by training with 20 years of experience in the chemical and pharmaceutical industry. He is currently working as section head for process research and development with Bayer Pharma in Wuppertal, Germany.

Matthias Schneider, PhD
BASF SE Ludwigshafen, Germany

Matthias Schneider, PhD is chemist. He has 17 years of experience in the pharmaceutical industry – 9 of them in CMC regulatory affairs. He is currently working as Regulatory Affairs Manager BASF SE Ludwigshafen, Germany.

Christophe Girault, PhD
Boehringer Ingelheim Pharma GmbH & Co. KG

Christophe Girault, PhD is pharmacist. He has 25 years of experience in the area of Clinical Trial Supplies and CMC regulatory affairs.
He is currently working as Regulatory Affairs Manager CMC for Boehringer Ingelheim in Ingelheim, Germany.

Steffen Gross, PhD
Paul-Ehrlich-Institut

Steffen Gross, PhD has extensive experience in molecular and cell biology. Steffen Gross joined the Paul-Ehrlich Institute in 2005 and became Head of the section monoclonal and polyclonal antibodies in 2012. He is involved in the assessment of the quality and preclinical issues for marketing authorization applications, scientific advices and clinical trial applications. Until 2012 he has been laboratory head of the section monoclonal and polyclonal antibodies and has been involved in testing of immunoglobulins, immunsera and monoclonal antibodies as well as in planning and performing research projects. Due to his experience he also often supports inspections as an expert for certain products. Before joining the Paul-Ehrlich Institute he has worked in the Netherland for three years as a postdoc. During this time he has worked for several months at the National Institute of Health in Bethesda. After his return to Germany he became a research group leader at the University of Frankfurt/Main, Germany.

Registration by fax +49 6131 9769-69

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Location

Leonardo Royal Hotel Frankfurt
Mailänder Straße 1
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Telefax +49 69 6802333
www.leonardo-hotels.com

I herewith repealable authorise APV to use my e-mail address to send me APV relevant material including current programme information. My acceptance can be cancelled at any time in writing.

Date

Course no. 6697
08 November 2017
09:00-17:00

Registration fee

Industry	990 EUR
Authorities/University	495 EUR
Students[1]	178 EUR

(free of VAT according to § 4,22 UStG)
Coffee breaks, luncheon and electronic proceedings included.

[1]Limited places for full time students available; written evidence must be submitted.

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: +49 6131 9769-0
Fax: +49 6131 9769-69
e-mail: apv@apv-mainz.de

You will receive a confirmation of your registration with the invoice.

Hotel reservation

Leonardo Royal Hotel Frankfurt
Mailänder Straße 1
60598 Frankfurt/Main
Germany
Telefon +49 69 6802 0
Telefax +49 69 6802333

Participants should make their own hotel reservation referring to the APV seminar.

Deadline for special conference rate: 25 September 2017.

Special rate: Single room incl. breakfast buffet from 105 EUR per night.

Mainz, March 2017

Definition of starting materials - scientific and regulatory aspects, Course No. 6697

Registration
As soon as you have found a seminar of your interest, it is very easy to register for it via fax, e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise.

Registration confirmation
After your registration was successfully processed, you will receive a confirmation.

Before the event
A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc.

After the event
You will receive a certificate confirming your participation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time.

Follow-up
After the event, we are open to receive any suggestions and critique that might arise during the seminar and will certainly help you with further questions you may have.

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