Elemental and mutagenic impurities – What's new?

Exchange of knowledge and experiences after implementation of the regulatory requirements

Course no. 6641

08 to 09 November 2016
Mannheim, Germany

Drug RegulatoryAffairs

Quality Control/Analytics

APV
MAKING SCIENCE WORK

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

Drug RegulatoryAffairs
Quality Control/Analytics

A seminar organised by the APV focus group Drug Regulatory Affairs

Target Group

The seminar addresses pharmaceutical professionals in R&D as well as in quality control/assurance and regulatory affairs departments of pharmaceutical, API and raw material manufacturers.

Outline

The ICH guidelines Q3D and M7 have been implemented and are/will become applicable for new as well as for marketed products. The seminar will provide analytical background information as well as regulatory requirements and expectations of health authorities. The speakers will present case studies and give practical recommendations for implementation of the guidelines with regard to Marketing Authorization Applications and Lifecycle Management.
In this context the following topics will be addressed:

- Relationship between raw material/API and pharmaceutical manufacturers
- Relationship between quality, toxicology and regulatory functions
- Development of risk assessments and control strategies
- What is the link with the pharmacopoeial monographs?
- How does Module 3 look like?
- How and when to file variations?

Programm

Tuesday, 08 November 2016 09:00 to 17:30

ICH Q3D

Welcome and introduction
Dr. Philipp Huber, Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany

ICH Q3D from a Regulatory Point of View

- Risk assessment according to Q3D:
  - o Identification Step
    - Acceptable approaches to include/exclude elements
    - Which sources of data can be used
    - How much data is enough
    - Active substance: ASMF and CEP
  - o Converting PDEs
  - o Output of the risk assessment
- Strategies for other routes of administration
- Required information in module 3 (summary of risk assessment)

Markus Savsek, Bonn, Germany

Implementation of ICH Q3D

- Practical implementation principles including changes in Pharmacopoeias
- Overview on training materials ICH and case studies
- Relationship between quality and regulatory functions
- Lifecycle Management

Dr. Christophe Girault, Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany

ICH Q3D – Developement, validation and application of analytical methods

- Available analytical techniques – a short overview
- Development and validation of a screening method
- Product specific methods
- Practical aspects and experiences

Dr. Hans-Christian Mans, Currenta GmbH & Co. OHG, Leverkusen, Germany

Raw material manufacturer

- BASF's approach towards ICH Q3D
- USP <233> and the BASF methodology
- Risk assessment

Dr. Wolf-Rüdiger Schlag, BASF SE, Lampertheim, Germany

Workshop:

Developing control strategy and module 3 documentation based on risk assessment for Marketing Authorization Application and Lifecycle Management
Dr. Christophe Girault
Dr. Philipp Huber
Dr. Hans-Christian Mans
Markus Savsek
Dr. Wolf-Rüdiger Schlag

Panel discussion

Get-together

Elemental and mutagenic impurities – What's new?

Wednesday, 09 November 2016 09:00 to 17:30

ICH M7

Regulatory approach for mutagenic impurities – Quality perspective
- Impurity and hazard assessment
- Risk characterization
- Control strategies and life cycle management

Dr. Corina Nachtsheim, Bonn, Germany

Mutagenic Impurities – practical aspects during development
- Strategies in development
- Analytical challenges
- Practical examples and case studies

Dr. Michael Finkam, Grünenthal GmbH, Aachen, Germany

The safety aspects: hazard assessment and (cancer) risk characterization
- Literature search, (Q)SAR analysis for mutagenicity and classification
- Bacterial reverse mutation assay (Ames) test and possible follow-up toxicity assays
- Toxicity testing or control: interaction between Toxicology and CMC
- Acceptable intakes: special issues (treatment duration and indication)

Dr. Esther Vock, Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany

Implementation of ICH M7 for marketed products
- Practical implementation principles for marketed products and life cycle management
- Relationship between quality, toxicology and regulatory functions
- Required information for variation to Module 3

Dr. Christophe Girault, Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany

Mutagenic Case studies – Quality approach to ICH M7
- Low levels
- Multiple mutagenic impurities
- ICH M7 control options

Dr. Corina Nachtsheim, Bonn, Germany

Workshop:

Developing control strategy and module 3 documentation based on risk assessment for Marketing Authorization Application and Lifecycle Management
Dr. Christophe Girault
Dr. Philipp Huber
Dr. Corina Nachtsheim
Dr. Michael Finkam
Dr. Esther Vock

Panel discussion

Programme is subject to change

Elemental and mutagenic impurities – What's new?

Moderator

Philipp Huber, PhD is pharmacist, food chemist and toxicologist. He has 14 years of experience in the area of quality control/assurance and CMC regulatory affairs. He is currently working as Senior Regulatory Affairs Manager CMC for Boehringer Ingelheim in Ingelheim, Germany.

Speaker

Michael Finkam, PhD graduated in chemistry at the university of RWTH Aachen and received a PhD degree in organic chemistry from the RWTH Aachen in 1993. He has more than 20 years of experience working in the pharmaceutical industry.
He joined Grünenthal GmbH as lab head in Medicinal Chemistry, followed by various positions in project management as preclinical and CMC project lead. Currently, Michael is acting as head of analytical development being responsible for the analytical development of R&D projects at early and late stage development phases.

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.

Dr. Hans-Christian Mans, PhD is heading the Department of Element Analytics at CURRENTA GmbH & Co. OHG in Leverkusen, Germany, for more than 5 years. He studied Chemical Engineering at the University of Applied Sciences Münster followed by PhD-studies at the TU Bergakademie Freiberg, both focused on Analytical Chemistry. Dr. Hans-Christian Mans has more than 10 years of experience in Analytical Chemistry and especially in Element Analytics applying different quality systems (GMP, GLP, ISO 17025).

Corina Nachtsheim, PhD 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 2001. As 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 2011 and is currently chairperson. Regulatory handling of mutagenic impurities is an important aspect of her work.

Marcus Savsek is pharmacist. After his graduation he has begun his professional career at Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), where he has started as Pharmaceutical Quality Assessor. His work focuses on the evaluation of drug dossiers and the preparation of expert reports in the context of national and European approval procedures. He acts as a speaker at training with focusing on regulatory practices, pharmaceutical analysis, IVIVC and elemental impurities and has published as a co-author on the subject of pharmacopoeia analysis.

Wolf-Rüdiger Schlag, PhD. In 1994, after being awarded his Ph.D. in Organic Chemistry from the University of Kaiserslautern, Wolf-Rüdiger Schlag became shift supervisor in cosmetical/pharmaceutical production at Chantal Pharmaceutical GmbH. After studying MBA at the City University, Seattle (USA)/Frankfurt a.M., he was responsible for product development/international drug regulatory affairs at Hermal Kurt Herrmann GmbH & Co. In 2002 Wolf-Rüdiger Schlag received a Master degree in Drug Regulatory Affairs at the Rheinische Friedrich-Wilhelm-University, Bonn. From 2000 to 2011 he was Head of Regulatory Affairs and since 2007 Head of Product Development. Since 2011 he has been Regulatory Affairs Manager "Pharma Ingredients & Services" at BASF SE.

Dr. Esther Vock, PhD graduated in 1992 with a diploma in Biology at the ETH in Zürich, Switzerland, and received her PhD degree in 1995 under the supervision of Prof. Werner Lutz and Christian Schlatter. Esther Vock was Postdoctoral Fellow at the University of Würzburg, Germany, the University of California, San Francisco, USA and University of Vermont, Burlington, USA before she became laboratory leader in Genetic Toxicology at Boehringer Ingelheim Pharma GmbH& Co. KG, Biberach/Riss, Germany in 2000. Esther Vock is currently Director of the Special Toxicology Group. She acts as project toxicologist and is regularly involved in mutagenic impurities and metabolite strategies and testing.

Registration by fax +49 6131 9769-69

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Location

Leonardo Royal Hotel Mannheim
Augustaanlage 4-8
68165 Mannheim
Germany
T: +49 (0)621 - 400 50
F: +49 (0)621 - 400 519 0
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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. 6641
from 08 Nov. 2016 09:00
to 09 Nov. 2016 17:30

Registration fee

regular fee 1490 EUR
early bird fee
(until 15 Aug. 2016) 1390 EUR
student fee* 178 EUR
(free of VAT according to § 4,22 UStG)
coffee breaks, dinner and electronic proceedings included

*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.

Members of authorities pay half of the registration fee.

Hotel reservation

T: +49 (0)6221 - 508 671
F: +49 (0)6221 - 508 680
res.royalmannheim@leonardo-hotels.com

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

Deadline for special conference rate: 25 September 2016.

Special rate:
Single room incl. breakfast buffet from 120 EUR per night.

Mainz, May 2016

Elemental and mutagenic impurities, Course no. 6641

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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www.apv-mainz.de

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