APIC Active Pharmaceutical Ingredients Committee

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A pre-conference session to the
14th APIC/CEFIC European Conference
on Active Pharmaceutical Ingredients

How to comply with ICH Q11

15 November 2011, Munich, Germany

Objectives

This pre-conference session **highlights the key principles of the new ICH Q11 Guideline**. You will get to know the essential aspects and approaches of process development and drug substance understanding described in the new Guidance such as

- How to link material attributes and process parameters to drug substances CQAs
- How to apply the concept of Design Space
- How to develop a control strategy
- How to submit relevant information from manufacturing process development in the CTD format

This pre-conference session ideally complements the following 14th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients.

Target Audience

This pre-conference session is designed for all scientists, and persons involved in R&D departments of API manufacturers. Furthermore, the session will be of interest to personnel from production, quality assurance, quality control and regulatory affairs.

Programme

The new ICH Q11 Guidance on Development and Manufacture of Drug Substances – an overview

- Goals and scope of the new Guidance
- Fundamentals and key principles of API process development
- The concept of design space
- Control strategy
- Process validation and evaluation
- Submission requirements in the CTD
- ICH Q8, Q9, Q10 – how do they work together with ICH Q11?

Manufacturing Process Development – General Principles and Process Development Tools

- Drug substance quality link to drug product
- Process development tools
- Critical quality attributes (CQAs)
- Linking material attributes and process parameters to drug substance CQAs
- Design space(s) and real-time release testing

Knowledge Management and Quality Risk Management during the Lifecycle of a Product

- Quality risk management and informal risk management processes
  - Risk management
  - Risk assessment
  - Risk control
- Knowledge management/prior knowledge and development studies
- Systematic approach to manage knowledge throughout the lifecycle

Process Validation and Design Space in early development

- Points to consider regarding
  - number and complexity of the process being validated
  - level of process variability
  - process knowledge available
- Product related and process related impurities
- Process variability, variability of material attributes and the design space

How to submit process development information via the CTD

- Where and how to submit development related information in the CTD - specific suggestions for
  - quality risk management and process development
  - CQAs
  - Design Space
  - Control strategy
- Where to include summaries and detailed information

APIC Comments to the ICH Q11 Draft Guideline

Speakers

Karl Metzger, gmPlan GmbH, Germany
Karl Metzger is Managing Partner of gmPlan GmbH. He was formerly Management responsible for the Welding's integrated Management System and deputy QP for APIs.

Filipe Neves, Hovione, Portugal
Filipe Neves is Assistant Engineer in the R&D Particle Design Discipline at Hovione FarmaCiencia SA, Loures, Portugal.

Ron Ogilvie, Pfizer, UK
Ron Ogilvie is a CMC adviser in Pfizer's Global Regulatory CMC group, chair Pfizer's Impurity Council and has been involved in Q11 development as part of EFPIA EWG support team.

Luisa Paulo, Hovione, Portugal
Compliance Director at Hovione and Vice Chair of APIC's Good Manufacturing Practices & Quality Assurance Working Group.

Tom Sam, Merck Sharp & Dohme, UK
Tom Sam is Head Global CMC Regulatory Affairs Merck Sharp & Dohme, Oss, The Netherlands

Elmar Wenzel, Freelance Consultant, Germany
Mr Wenzel was formerly head of API production at the Plankstadt site of AstraZeneca, now Corden Pharma. He is now freelance consultant.

Easy Registration

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Internet:
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Date
Tuesday, 15 November 2011, 09.00 – 17.15 h
(Registration and coffee 08.30 – 09.00 h)

Venue
Leonardo Royal Hotel Munich
Moosacher Straße 90
80809 Munich, Germany
Phone: +49 (0) 089 288 538 0
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Fees
EUR 890.- per delegate plus VAT

A special fee of 690,- Euro will be granted to participants who also register for the 14th European APIC/CEFIC Conference.
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch 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 when you have registered for the event. Please use this form for your room reservation or be sure to mention "Concept Heidelberg" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 4 October 2011. Early reservation is recommended.

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

Conference language
The official conference language will be English.

Organisation and Contact
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How to comply with ICH Q11
15 November 2011, Munich, Germany

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