With Workshops on API Starting Materials, Quality Risk Assessment and Process Development

ICH Q11 Training Course

Approaches to developing process and drug substance understanding

7 – 8 May 2013, Heidelberg, Germany

SPEAKERS:

Karl Metzger
gmPlan, Germany

Filipe Neves
Hovione, Portugal

Tom Sam
MSD, The Netherlands

Márcio Temtem
Hovione, Portugal

Elmar Wenzel
Freelance Consultant, Germany

PROGRAMME:

- Key principles of the new ICH Q11 Guidance
- Manufacturing process development
- Knowledge management and quality risk management during the product lifecycle
- Process validation and design space
- Information about process development to be provided in the CTD

ECA
EUROPEAN COMPLIANCE ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified Pharmaceutical Development Manager". Please find details at www.gmp-certification.eu

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Objectives

This training course 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 assess quality risks and manage knowledge systematically throughout the lifecycle
- How to submit relevant information from manufacturing process development in the CTD format

Three practical workshops on **Definition of the API Starting Material, Quality Risk Management and Process Development** ideally complement the contents of the lectures.

Background

A company can choose to follow different **approaches in developing a drug substance**: a "traditional" or an "enhanced" approach whereas these two approaches are not mutually exclusive. The traditional approach is characterised by defined set points and operating ranges for process parameters and the drug substance control strategy is typically based on demonstrating the process reproducibility and on testing to meet established acceptance criteria.

In an **enhanced approach**, risk management and more extensive scientific knowledge are used to select process parameters and unit operations that impact critical quality attributes (CQAs) for evaluation in further studies to establish any design space(s) and control strategies applicable over the lifecycle of the drug substance.

A **greater understanding** of the drug substance and its manufacturing process can provide the basis to enhance the degree of **regulatory flexibility**.

In this way the new ICH Q11 Guideline is to be seen in connection with ICH Q8 (Pharmaceutical Development), Q9 (Quality Risk Management) and Q10 (Pharmaceutical Quality Systems).

Target Audience

This training course 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?

Workshop "Definition of the API Starting Material"

In this Workshop you will get to know the key principles of defining the API Starting Materials based on practical examples.

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

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

- Quality risk management and informal risk management processes
  - Risk management
  - Risk assessment
  - Risk control
- Quality risk management and cost saving measures
- A formal risk register as part of Quality risk management
- Key attributes of a good risk assessment
- Knowledge management/prior knowledge and development studies
- Systematic approach to manage knowledge throughout the lifecycle
- Prior Knowledge and Development Studies

Workshop "Quality Risk Management"

During this Workshop you will learn more about how to perform criticality analyses of syntheses and processes. You will receive relevant information on how to implement this concept into practice.

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

Workshop "Process Development"

In this Workshop you will discuss relevant aspects of process development considering operating limits and determining the Design Space.

Approaches to developing a Control Strategy

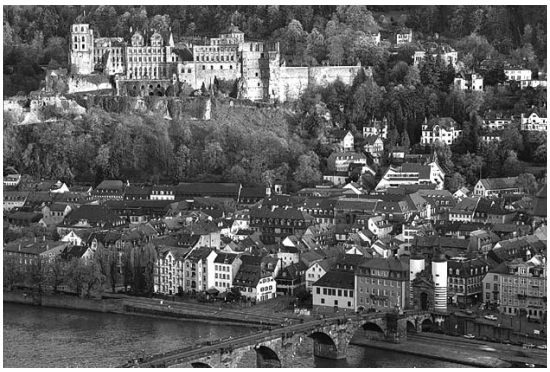
- Development of meaningful parametric, attribute and procedural controls
- Considerations in developing a control strategy
  - Possible downstream factors impacting the quality of the drug substance
  - Implementation of control points for specific CQAs
  - Submission of control strategy information

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

Social Event

On 7 May 2013, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



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 Group Leader (Inhalation department) in the R&D – Drug Product Development group at Hovione FarmaCiencia SA, Loures, Portugal.

Tom Sam, *MSD, The Netherlands*
Tom Sam is Head Global CMC Regulatory Affairs MSD, Oss, The Netherlands.

Dr Márcio Temtem, *Hovione, Portugal*
Dr Márcio Temtem holds a position as Process Development Engineer in the Particle Design Discipline at Hovione where he is technically involved in the development of Spray drying processes, Solid dispersions and milling technologies.

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.

GMP Certification Programme

This course is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

ECA Certified Validation Manager
ECA Certified QA Manager
ECA Certified API Production Manager
ECA Certified Quality Control Manager
ECA Certified Technical Operations Manager
ECA Certified Computer Validation Manager
ECA Certified Regulatory Affairs Manager
ECA Certified Microbiological Laboratory Manager
ECA Certified Sterile Production Manager
ECA Certified Biotech Manager
ECA Certified Pharmaceutical Development Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

Easy Registration

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Reservation Form:
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Reservation Form (Please complete in full)

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Date

Tuesday, 7 May 2013, 10.00 h – 18.00 h
(Registration and coffee 9.30 h – 10.00 h)
Wednesday, 8 May 2013, 09.00 h – 15.45 h

Venue

Hotel Crowne Plaza Heidelberg
Kurfürstenanlage 1
69115 Heidelberg, Germany
Phone +49 (0)6221 9170
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Fees

ECA Members € 1,590.- per delegate plus VAT
APIC Members € 1,690.- per delegate plus VAT (does not Include ECA Membership).
Non-ECA Members € 1,790.- per delegate plus VAT
EU GMP Inspectorates € 895.- per delegate plus VAT
The fee is payable in advance after receipt of invoice and includes conference documentation, social event and dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

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

Conference language

The official conference language will be English.

Organisation and Contact

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