Image: Chemgineering

Participate in 4 Workshops

GMP in API Development

Requirements of ICH Q7 Chapter 19 and practical implementation

4 – 5 June 2013, Berlin, Germany

SPEAKERS:

Dr Reiner Kirrstetter
Sanofi-Aventis, Germany

Peter Mungenast
Merck KGaA, Germany

Dr Jordi Ruiz-Combalia
Spain

Dr Carsten Tiegs
F. Hoffmann-La Roche, Switzerland

LEARNING GOALS:

- GMP requirements for different development phases
  - The GMP Matrix
- Qualification in development
  - Understanding the requirements and philosophies
  - How to proceed and document
- Defining the API starting materials
- Cleaning validation
  - How to establish cleaning limits
- Analytical data requirements
  - How to collect and compile analytical data
- Genotoxic Impurities
  - How to deal with them in early development phases
- Risk management in API development
  - Stage dependent approach

ECA
EUROPEAN COMPLIANCE ACADEMY

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

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Objectives

During this education course GMP requirements for a special group of APIs - 'APIs for use in clinical trials' - will be discussed in detail. The course is intended to provide guidance on

- GMP Characteristics for Phases I/IIa and IIb/III
- Principles and practices of process validation in early phases
- Practical aspects of qualification in development
- Cleaning and cleaning validation
- Defining the API Starting Materials
- How to deal with genotoxic impurities in early stages of development

In 4 Workshops the participants have the opportunity to discuss the following essential topics of the course in more detail:

- Process validation
- Qualification in development
- Cleaning validation
- Analytical data compiling

Background

Section 19 of the internationally harmonised **ICH Q7** provides specific guidance for the manufacture of APIs for investigational use during development. According to *ICH Q7 '(...) The controls used in the manufacture of APIs for use in clinical trials should be consistent with the stage of development of the drug product incorporating the API (...). Once drug development reaches the stage where the API is produced for use in drug products intended for clinical trials, manufacturers should ensure that APIs are manufactured in suitable facilities using appropriate production and control procedures to ensure the quality of the API (...)'.*

In 2006 the ICH Q8 guideline "Pharmaceutical Development" came into operation. This guideline is intended to provide guidance on the section 'Pharmaceutical Development' of Module 3 CTD (Common Technical Document). This guideline, the Clinical Trials Directive and the provisions of Section 19 of ICH Q7 form the legal and regulatory framework for API manufacturers producing APIs for use in clinical trials.

Target Audience

The course is designed for all persons involved in R&D departments of API manufacturers. Furthermore, the seminar will be of interest to personnel from quality assurance, regulatory affairs and contract research manufacturers.

Programme

Requirements for Different Development Phases – The GMP Matrix

- Process optimisation and scale-up
- Characteristics for Phases I/IIa and IIb/III
  – Requirements and recommendations
- Transfer to routine manufacture
- Handling deviations and OOS

Relevant Process Matters in Development

- Important principles for compiling documentation during development
- Development of a robust process
- Determining the operating limits: The Design Space
- Process validation and change control
- Technology transfer package and development report

Process Validation – the new FDA Guidance

- General principles and regulatory requirements
- Process Design
- Process Qualification
- Continued process verification
- Concurrent validation / concurrent release
- Documentation
- Analytical methodology

Workshop I
Identifying process parameters needed for process validation

Qualification in Development – System and Practical Aspects

- What are the basic requirements and philosophies
- What are the basic systems?
- What should be qualified?
- How to proceed and document
- What further activities are necessary

Workshop II
Qualification in development

Defining the API Starting Material – What has to be Considered

- The characteristics of an API-SM
- Definitions and key guidelines
- Selection criteria for API-SM
- Issues with existing and proposed guidelines
- Some examples for discussion

Cleaning – A Big Challenge in Process Development

- Cleaning validation versus cleaning verification
- Analytical methods (specific vs non-specific methods)
- How to establish cleaning limits
- Levels of cleaning
- Documentation
- Sampling methods

Workshop III
Collecting data necessary to set up cleaning validation

Analytical Data Requirements

- Substance chemical evidence
- Specifications
- Impurities definition
- Analytical methods
- Standards and equipment

Workshop IV
Collecting and compiling analytical data

Genotoxic Impurities in API development

- What is genotoxic – scientific background
- Regulatory requirements
- Risk assessment approaches
- Stage dependent approach for genotoxicity
- Experiences with regulatory authorities regarding data of potential genotoxic material

Risk management in API development

- Risk management philosophy
  - Potential threats and opportunities
- Risk management theory
  - Risk assessment
  - Risk control
  - Risk review
- Risk management in practice – how to do
  - QRM procedure
  - Individual risk decision

Social Event

On 4 June, 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

Dr Reiner Kirrstetter

Sanofi-Aventis Deutschland GmbH, Frankfurt/Main, Germany
Currently working in the Global Quality Organisation. Educational Background: Chemistry, Ph.D. at the University of Heidelberg in 1976. Worked for more than 30 years in pharmaceutical industry (Research, PD, Production, Quality Operations). Since 22 years experienced in GMP and Regulatory Compliance (4 years as Site Quality Head of API Frankfurt). Performed GMP audits in Europe, US, China, India, Japan. Involved in several Regulatory Inspections from FDA and German Authorities. Published 20 articles related to GMP and QM Requirements

Peter Mungenast

Merck KGaA, Darmstadt, Germany
Peter Mungenast studied Biology and Chemistry at the University in Karlsruhe. Then he worked in different functions for Merck KGaA. Since 1996 he is responsible for cleaning validation, training and different projects in the Quality Assurance department.

Dr Jordi Ruiz-Combalia

AUDIT GMP, Barcelona, Spain
Dr Ruiz Combalia has more than 40 years experience in API Industry, where he has had different responsibilities. He started with Bioiberica, Spain as R&D Director, then he moved to Quality positions. Between 1992 and 2006 he has collaborated with the Organic Chemistry Expert Group of the Real Farmacopea Espanola. Since 1994, and up to 2007 he has been member of Group of the Experts 11, Chair of the CRB Working Party, and member of the Spanish Delegation to the European Pharmacopoeia Commission. He was one of the starting members of BPCC, actually APIC. He left Bioiberica in 2012 and works now with AUDIT GMP, Barcelona.

Dr Carsten Tiegs

F. Hoffmann-La Roche AG, Basle, Switzerland
Dr Tiegs is working as a GMP compliance manager in the Process Research and Kilolaboratory Department, responsible for the SOP documentation, training, and any further GMP-related issues. He is a SHE representative and since several years ECO delegate for the pharma division.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
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69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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

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Reservation Form (Please complete in full)

GMP in API Development
4 – 5 June 2013, Berlin, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number, if applicable**

Street/P.O. Box

City Zip Code Country

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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 %,
- until 1 weeks prior to the conference 50 %
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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)

Date

Tuesday 4 June 2013, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday 5 June 2013, 8.30 – 16.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Fax +49 (0)30 212 7-117

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 conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days 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. 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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