ECA Certified Pharmaceutical Development Manager Course*

- With practical oriented workshop case studies
- Create your own ATP!

Quality by Design in Pharmaceutical Analysis

7 – 8 December 2011, Frankfurt, Germany

SPEAKERS:

Phil Borman
GSK, United Kingdom

Dr Joachim Ermer
Sanofi-Aventis, Germany

HIGHLIGHTS:

- Application of QbD Principles to Pharmaceutical Analysis
- Understanding the Analytical Target Profile (ATP)
- Decision Rules and Establishment of Acceptance Limits
- QbD-Method Development
- Traditional Validation versus QbD Validation
- Life Cycle and Change Management
- Six Hours of Interactive Workshops

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

The aim of this two day course is to provide guidance on how QbD principles can be applied to analytical methods and identify the opportunities, not only for new development products, but also for drugs already marketed. This course will deal among others with the following questions:

- What are the opportunities of applying QbD to analytical methods?
- What is the purpose of the PhRMA/EFPIA Position Paper on analytical QbD?
- How can the Analytical Target Profile increase regulatory flexibility?
- Why is it important to have a clear understanding and expectation of method performance?
- What is the impact of QbD on method development, validation and transfer?
- How can QbD also benefit marketed products?

A number of interactive workshops will be provided throughout the two days which will enable delegates to be able to apply what they have learnt and to discuss the concepts in more detail. Delegates will have the opportunity to work through the whole QbD process by gaining "hands-on experience" using a number of case studies.

Background:

The pharmaceutical industry is currently embracing QbD concepts to help improve the robustness of manufacturing processes and to facilitate continuous improvement strategies to enhance product quality and manufacturing productivity. QbD ensures product and process performance characteristics are scientifically designed to meet specific objectives, not merely empirically derived from the performance of test batches. Key QbD concepts are described in ICH guidelines Q8 (R1) Pharmaceutical Development, Q9 Quality Risk management and Q10 Pharmaceutical Quality System. The same opportunities exist for applying QbD to analytical methods as they do for manufacturing processes.

During the course an overview of a position paper written jointly by PhRMA and EFPIA will be provided which uses a new concept called the Analytical Target Profile (ATP). The ATP is a statement that defines the method's purpose which is used to drive method selection, design and development activities. It is hoped that greater continuous improvement of methods can also be facilitated if regulatory authorities agree with and approve the ATP statement. Each method conforming to the ATP requirements would be implemented by the company's internal change control management system, thus providing regulatory flexibility. Risk assessment tools and statistical methods used to facilitate understanding of the method performance characteristics (e.g. accuracy and precision) and their acceptance criteria will also be covered. Traditional method validation will be compared to a QbD approach which includes life-cycle aspects instead of a one off validation exercise.

Note: In order to fully benefit from the workshops, attendees should preferably bring a notebook with Excel®.

Target Group

This course is designed for analytical managers and scientists who are responsible for performing or reviewing activities like method development, validation, transfer, operation of methods in a QC environment, statistical evaluation of method performance, analytical change control etc.

In addition, QA and regulatory affairs professionals will benefit from this course by gaining an understanding in future CMC trends. This will aid more effective multifunctional discussions on these topics within industry.

Programme

Introduction to Analytical QbD

- Overview on proposals of EFPIA/PhRMA Paper
- Analytical Target Profile
- Application of QbD principles to pharmaceutical analysis
- Change Control and regulatory flexibility

Design Intent of the Method – ATP and Business Requirements

- Linkage with process control strategy (critical quality attributes)
- Definition of ATP
- Method Performance Characteristics and their criteria
- Business requirements of method

Understanding the ATP – Analytical Variability

- Sources of analytical variability
- Method performance characteristics: accuracy and precision
- Method performance and expectation ranges for experimental results and statistical parameters
- Decision rules and establishment of acceptance limits

Workshop on Variability

- Application of statistical simulations
- Gain experience ("feeling") for the consequences of variability
- Method performance statistical measures for precision, accuracy, linearity
- Probability of OOS and out-of acceptance criteria situations

QbD Method Development

- Method design
- Method selection
- Risk assessment
- Control Definition of method (robustness and ruggedness testing)

Workshop Risk Assessment

- Use of fishbone diagrams
- Identification of controllable factors, noise factors and experimental parameters (CNX)
- Use of priority matrix and failure mode and effects analysis (FMEA)

Traditional Validation versus QbD Validation

- "Translation" of ATP into specific method requirements
- Identification of relevant performance parameters
- Establishment of appropriate acceptance criteria
- Life-cycle approach, on-going validation

Life-cycle and change management

- Knowledge management system
- Analytical Method Transfer
- Routine method operation
- Continuous method verification, change control and regulatory implications

Workshop Case Studies

Delegates will use background information provided on a number of critical quality attributes to construct their own ATPs. Delegates will be split into small groups in order to discuss how each ATP is applied to a given method and how each ATP can be used to switch between alternative methods. The impact of changing the method will be assessed for each ATP. Examples of Critical Quality attributes will be used such as

- Identification of an API in a tablet formulation
- Assay of drug substance
- Water content in drug substance
- Determination of degradants in drug product

Wrap up & Final Discussion

The concepts and tools used over the two days will be summarised and future implications and opportunities of applying QbD principles to analytical measurements will be discussed. Delegates will be given time to ask questions on how they can apply what they have learnt to their own analytical methods.

Speakers

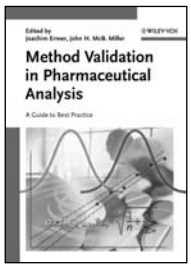
PHIL BORMAN

Manager at GSK within Analytical Sciences, Chemical Development, Stevenage, UK. Chartered Chemist with more than 13 years experience in the pharmaceutical industry working in both Chemical and Pharmaceutical Development. Phil first studied at UMIST University (Manchester) where he obtained a Masters in Chemistry and more recently obtained a Masters in Industrial Data Modelling from De Montfort University (Leicester). Phil is also a chartered member of The Royal Society of Chemistry, UK and of the EFPIA QbD working group.

DR JOACHIM ERMER

Head of Quality Control Services Chemistry, Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany. He studied biochemistry at University of Halle and has about 20 years experience in pharmaceutical analytics including development products, global responsibilities as Director of Analytical Processes and Technology, and Head of Quality Control. He is member of the EFPIA QbD working group.

Literature



Participants of this Course can purchase Dr Ermer's book "Method Validation in Pharmaceutical Analysis" (Wiley VCH, Weinheim 2005, ISBN: 3-527-31255-2) at a 15% reduced price! You will receive the order form for this book at the course.

Social Event

On 7 December 2011, 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.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **PO Number if applicable**

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Easy Registration

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www.gmp-compliance.org

Date

Wednesday, 7 December 2011, 9.00 – 18.15
(Registration and coffee 8.30 – 9.00)
Thursday, 8 December 2011, 9.00 – 15.30

Venue

Welcome Hotel Frankfurt
Leonardo-da-Vinci-Allee 2
60486 Frankfurt
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Phone: + 49 (0) 69 770 670 0
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Fees

ECA Members € 1,490 per delegate plus VAT
APIC Members € 1,590 per delegate plus VAT (does not include ECA membership)
Non-ECA Members € 1,690 per delegate plus VAT
EU GMP Inspectorates € 845 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 conference. Please use this form for your room reservation or be sure to mention "VA 6978 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 9 November 2011. 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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