- With practical oriented workshop case studies

Quality by Design in Pharmaceutical Analysis

24-25 May 2016, Copenhagen, Denmark

SPEAKERS:

Dr Joachim Ermer
Sanofi, Germany

Patrick Jackson
GSK, United Kingdom

HIGHLIGHTS:

- Application of QbD and life cycle principles to pharmaceutical analysis
- Understanding the Analytical Target Profile (ATP)
- Decision rules and establishment of acceptance limits
- QbD method development
- Traditional versus QbD validation
- Life cycle and change management
- Five hours of interactive workshops

ECA 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 and life cycle approach to analytical methods?
- What is the current status and future expectations of analytical QbD and life cycle management (USP, FDA-EMA, FDA Guidance Method Validation)?
- 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?
- What is the advantage of the 3-Stage life cycle approach to validation?
- What are expectations and practical approaches to Stage 3, Continued Method Verification?
- How can QbD also benefit marketed products?

A number of interactive workshops will be provided throughout the two days which will enable delegates to apply what they have learned 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 quality and requires process performance characteristics to be 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 and of a USP Stimuli Article will be provided. These two documents use the now increasingly accepted Analytical Target Profile (ATP) concept. It parallels the Quality Target Product Profile described and defined in ICH Q8 and defines the performance requirements for the measurement of a given Quality Attribute. The ATP can be used to drive all analytical life cycle activities within the three stages (Method Design, Method Performance Qualification, Continued Method Performance Verification) including change control.

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.

Aligned with the modern approach to process validation, increasing attention is given to ensure that "the procedure should be followed during the life cycle of the product to continually assure that it remains fit for its intended purpose" (FDA Method Validation Guidance). Performance parameters as well as acceptance criteria to establish a rational and efficient monitoring and trending are closely related to a sound method understanding as part of the QbD approach.

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

Target Audience

This course is designed for analytical managers and scientists who are responsible for performing or reviewing activities like method development, validation, transfer, operation and monitoring 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 Quality-by-Design and life cycle management

- Overview on proposals of EFPIA/PhRMA Paper and USP Stimuli Article
- Analytical Target Profile
- Application of QbD principles to pharmaceutical analysis
- Change Control and regulatory flexibility
- Stages of the validation life cycle approach
  - Method Design
  - Method Qualification
  - Continued Method Verification

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
- Precision of the reportable result and impact on the analytical control strategy
- 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
- Suitable parameters for continued performance verification

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

Starting from provided ATPs for several critical quality attributes, delegates will be split into small groups in order to discuss how each ATP is translated into method specific performance characteristics and acceptance criteria. The delegates will identify suitable parameters to monitor the continued performance of the selected procedure. 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 summarized and future implications and opportunities of applying QbD and life cycle management principles to analytical measurements will be discussed. Delegates will be given time to ask questions on how they can apply what they have learned to their own analytical methods.

Speakers

DR JOACHIM ERMER

Head of Quality Control Services Chemistry, Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany and Global Reference Standards Coordinator of Sanofi Industrial Affairs. He studied biochemistry at University of Halle and has over 25 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 and of the USP Expert Panel Validation & Verification.

PATRICK JACKSON

Patrick Jackson is an analyst at GSK leading analytical quality by design application within Product Development, Stevenage, UK with more than 8 years experience in the pharmaceutical industry working on Active Pharmaceutical Ingredients and chemical route development. Pat studied at York University where he obtained a Masters in Chemistry and later obtained a Masters in Applied Statistics from Sheffield Hallam University. Pat is also an associate member of The Royal Society of Chemistry.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
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:

Reservation Form (Please complete in full)

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Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
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Date

Tuesday, 24 May 2016, 9.00 h – 18.00 h
(Registration and coffee 8.30 h – 9.00 h)
Wednesday, 25 May 2016, 9.00 h – 15.30 h

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 (0)33 96 50 00
Fax +45 (0)33 96 55 55

Fees (per delegate plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
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 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.

Social Event

On 24 May 2016, 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.

Conference Language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49-62 21/84 44-0
Fax +49-62 21/84 44 84
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Andrea Kühn-Hebecker (Operations Director)
at +49-62 21/84 44 35, or per e-mail at
kuehn@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Katja Kramer (Organisation Manager)
at +49-62 21/84 44 16, or per e-mail at
kramer@concept-heidelberg.de.

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