- With practical oriented workshop case studies

Quality by Design in Pharmaceutical Analysis

1 – 2 October 2014, Barcelona, Spain

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- What is the current status of analytical QbD (USP, FDA-EMA, FDA Draft Guidance Method Validation)?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 lifecycle approach to validation?
- How can QbD also benefit marketed products?

A number of interactive workshops will be provided throughout the two days which will enable delegates to 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 and of a new USP Stimuli Article will be provided which use a new concept called the Analytical Target Profile (ATP). It parallels the concept of a 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 will 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. 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 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 QbD

- 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

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

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

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 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)

QbD Method Development

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

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, continued performance verification

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 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

Life-cycle and change management

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

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

DR PATRICK JACKSON

Patrick Jackson is an analyst at GSK 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.

DR JOACHIM ERMER

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

Social Event

On 1 October 2014, 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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Easy Registration

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Date

Wednesday, 1 October 2014, 9.00 – 18.15
(Registration and coffee 8.30 – 9.00)
Thursday, 2 October 2014, 9.00 – 15.30

Venue

Barceló Sants
Placa dels Paisos Catalans, s/n
Estació de Sants
08014 Barcelona, Spain
Phone +34 93 503 53 00
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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.

Conference Language

The official conference language will be English.

Organisation and Contact

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