

Lifecycle Management in Pharmaceutical Analysis

...including examples for bioanalytical methods!

- With practical oriented workshop case studies
- New ECA APLM Guide: Every participant will receive the ECA Guide on Analytical Procedure Lifecycle Management!

SPEAKERS:



Dr Joachim Ermer
Sanofi, Germany



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VelaLabs, Austria



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GSK, United Kingdom



18-19 June 2019, Berlin, Germany

HIGHLIGHTS:

- 3 Stages of Analytical Lifecycle validation: Method design, method performance qualification, continued method performance verification (new USP draft chapter <1220>)
- Application of QbD principles in analytical lifecycle management
- Understanding the Analytical Target Profile (ATP)
- Risk-based method development
- Establishment of a rational and efficient Analytical Control Strategy
- Continued analytical performance monitoring and change management
- Application of appropriate statistical tools
- Small molecules and biopharmaceuticals
- **More than four hours of interactive workshops**



Lifecycle Management in Pharmaceutical Analysis

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Objectives

The aim of this two day course is to provide guidance to apply the principles of the modern concept of lifecycle management to analytical methods, as initiated by the PhRMA/EFPIA Position Paper [QbD Analytics. Implications and Opportunities of Applying QbD Principles to Analytical Measurements, Pharmaceutical Technology, Feb. 2010, 2-8] and further elaborated by USP's Validation and Verification Expert Panel in a Stimuli Article for a proposed USP General Information Chapter [1220 The Analytical Procedure Lifecycle. Pharm. Forum 43(1)]. The application of Quality-by-Design principles during the whole analytical lifecycle provides opportunities, not only for new development products, but also for drugs already marketed, for small molecules as well as biopharmaceuticals. This course will deal among others with the following questions:

- What is the content of the three stages of analytical lifecycle aligned with current process validation concepts?
- What are the opportunities of applying QbD principles to analytical lifecycle management?
- How can the Analytical Target Profile (ATP) help to define the measurement requirements and increase regulatory flexibility?
- Why is it important to have a clear understanding and expectation of method performance?
- What is the benefit of a risk-based method development and establishment of an appropriate Analytical Control Strategy?
- What is the impact and benefit of an integrated lifecycle approach on method verification, transfer, and changes?
- Why is a continued method performance monitoring important, and how can it be achieved?

Five interactive workshops will be provided throughout the two days which will enable delegates to understand and discuss the concepts in more detail, and to be able to apply what they have learned. Delegates will have the opportunity to work through the whole analytical lifecycle by gaining "hands-on experience" with examples for small molecules and biopharmaceuticals.

Background

During the course an overview of the PhRMA/EFPIA Position Paper and the Stimuli Article for a proposed USP General Information Chapter <1210> will be provided which are based on the Analytical Target Profile (ATP) concept. The ATP defines the objective of the test and quality requirements for the reportable value. It therefore aligns with the ICH definition of QbD as "a systematic approach that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management" [ICH Q8].

Besides serving as focal point throughout the analytical lifecycle, the ATP has the potential to facilitate continuous improvement if regulatory authorities would approve the requirement-based ATP instead of specific methods.

Each method conforming to the ATP requirements could be implemented by the company's internal change control management system, thus providing regulatory flexibility. First steps into this direction can be seen in the draft ICH Q12 guideline *Pharmaceutical Product Lifecycle Management*, as, for example, the concept of "Established Conditions".

The three stages of the analytical lifecycle align with current process validation concepts. In Stage 1, the ATP is used to drive method design and development activities. Risk assessment tools and statistical methods used to facilitate understanding of the method (e.g. robustness, design of experiments) and its performance characteristics (e.g. accuracy and precision) will be discussed in the course, as well as how to establish their acceptance criteria.

Stage 2, Method Performance Qualification, confirms that the analytical procedure, operated in the routine environment is capable of delivering reproducible data which consistently meet the ATP. This includes the finalisation of the Analytical Control Strategy, e.g. a science-based definition of the replication level of the reportable value. This stage includes also holistically analytical transfer and implementation of compendial procedures.

An important aspect in the lifecycle approach is Stage 3, the Continued Method Performance Verification, i.e. the ongoing assurance that the analytical procedure remains continuously in a state of control. This includes an ongoing program for routine monitoring of analytical performance data, as discussed in the FDA Method Validation Guideline from July 2015, and the systematic evaluation of changes.

These three stages are also reflected in the new ICH topic agreed in June 2018, Analytical Procedure Development (Q14), and to revise the Analytical Validation Guideline (Q2). In Q14, the concept and strategy of enhanced approaches for analytical procedures will be discussed, as well as performance criteria needed for analytical validation. In line with ICH Q8 and ICH Q11, a greater understanding of analytical procedure can create the basis for more flexible regulatory approaches. The terms Analytical Target Profile (ATP), Critical Method Attributes, Method Operable Design Region, Analytical Control Strategy are also mentioned. The revision of Q2(R1) will include validation approaches for modern analytical technology such as NIR or ICP-MS, as well as statistical methods and on-going performance verification.

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.

Programme

The three Stages of Analytical Lifecycle Management

- Overview on EFPIA/PhRMA Paper and the proposed USP Chapter <1220>
- Analytical Target Profile
 - To Reportable value
 - As focal point during the lifecycle
 - Potential regulatory flexibility
- Regulatory situation, ICH Q12
- Stage 1 – Method Design
- Stage 2 – Method Performance Qualification
- Stage 3 – Continued Method Performance Verification

Analytical Target Profile – Performance requirements

- Accuracy and Precision, Target Measurement Uncertainty (TMU)
- Point estimate or statistical acceptance criteria?
- Combined or separate evaluation of accuracy and precision?
- Derivation of acceptable TMU based on probability distributions

Analytical Target Profile – Small Molecules

- Design intent of the analytical measurement
- Linkage with process control strategy (critical quality attributes)
- Business requirements of method

Analytical Target Profile – Biopharmaceuticals

- Design Intent of the Method
- Business Requirements
- Decision Rules

Workshop Variability

- Application of statistical simulations
- Gain experience (“feeling”) for the consequences of variability
- Variability of RSD determinations
- Probability of OOS results

Stage 1: Method Design – Small Molecules

- Method design and understanding
- Method selection
- Risk assessment
- Analytical Method Control Strategy
- Knowledge management
- “Translation” of ATP into specific method requirements

Stage 1: Method Design – Biopharmaceuticals

- Development and understanding
- Risk assessment
- Knowledge management
- Method Control Strategy

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)
- For drug substance assay, degradation products in a tablet formulation, methods applied to biopharmaceuticals

Stage 1: Robustness investigations – Small Molecules

- Design of experiments (DoE)
- Identification of experimental parameters
- Establishment of the Method Operable Design Region (MODR)

Stage 1: Robustness investigations – Biopharmaceuticals

- DoE
- Significance and Equivalence tests

Stage 2: Method Performance Qualification

- Precision of the reportable value
- Precision study for the definition of a science-based replication strategy: to average or not to average?
- Experimental confirmation of performance or reference to stage 1 investigations?
- Establishment of appropriate acceptance criteria

Workshop Replication strategy

- Optimization of precision of the reportable value
- For LC assays and methods applied to biopharmaceuticals

Workshop Method Selection, Lifecycle and change management

- Selection of a method/technique likely to meet the ATP requirements for example attributes (drug substance assay, degradation products in a tablet formulation, methods applied to biopharmaceuticals)
- Consideration of business needs
- Examples for Methods and Changes
- Evaluation of impact
- Risk assessment
- Definition of appropriate actions

Stage 3: Continued Method Performance Verification - Small Molecules

- FDA Method Validation Guidance
- Routine monitoring, evaluation of ongoing performance, suitable parameter and data
- Program for routine monitoring, control charts

Stage 3: Continued Method Performance Verification - Biopharmaceuticals

- Examples for monitoring of Biopharmaceuticals
- Program for routine monitoring

Workshop Routine Monitoring

- Identification of suitable performance parameters for example methods
- Establishment of a monitoring program

Wrap up & Final Discussion

The concepts and tools used over the two days will be summarised and future implications and opportunities of the analytical lifecycle approach 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 Analytical Lifecycle Management Chemistry and Global Sanofi Reference Standards Coordinator, Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany. He studied biochemistry at University of Halle and has more than 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 Analytical Lifecycle Management working group (which has recently been transformed into the support team for the update/establishment of ICH Q2/Q14) and of the USP Expert Panel Validation & Verification.



DR MARKUS FIDO

CEO and Founder of Vela Laboratories. Markus was Head of Quality Control at Igeneon / Aphton Biopharma AG where he was in charge for all QC aspects of pre-clinical and clinical projects such as stability studies, specifications, method validation, and product release. Before that, he was working as a Group Leader of Immunology and Product Development at Biomin GmbH, Head of Biochemical Control at Baxter AG and Head of Quality Operations at Octapharma GmbH.



PATRICK JACKSON

Patrick Jackson is an analyst at GSK within Product Development, Stevenage, UK with around 15 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:**
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Date

Tuesday, 18 June 2019, 9.00 – 18.00
(Registration and coffee 8.30 – 9.00)
Wednesday, 19 June 2019, 8.45 – 16.30

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Email berlin@steigenberger.de

Fees (per delegate plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
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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

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

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For questions regarding content please contact:

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For questions regarding reservation, hotel, organisation etc. please contact:

Ms Jessica Stürmer (Organisation Manager)
at +49-62 21/84 44 60, or per e-mail at stuermer@concept-heidelberg.de.

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Lifecycle Management in Pharmaceutical Analysis
18-19 June 2019, Berlin, Germany

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