US

Online Masterclass

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LIVE

CERTIFIED

CASE STUDY

Ongoing Monitoring within the Analytical Procedure Lifecycle

Dr. Joachim Ermer

29th - 30th April 2025

09.00am – 1.00pm EDT (UTC- 4)

Participants of this masterclass will

- Get an overview on the analytical lifecycle concept
- Learn about the importance of developing appropriate controls to ensure routine analytical performance (Analytical Procedure Control Strategy)
- Understand the sources of information and data on analytical performance (conformity, validity, analytical control parameters)
- Learn how to develop risk-based monitoring plans
- Receive background information about the fundamentals of trend analysis to identify adverse trends and suspect data (Control Charts)
- Learn how to calculate reliable, long-term performance parameters (e.g. precisions) to better assess suspect data as well as out-of-specification (OOS) results, and to ensure the compatibility with acceptance limits of the specification

COMPANIES REPRESENTED BY OUR PARTICIPANTS

Lonza, ADPT a Mylan company, Halozyme, ProQR Therapeutics, LTS, Jubilant Radiopharma, aldevron, MacroGenics, Algorithm, Bayer

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Course outline

The hallmark of the lifecycle concept is a comprehensive and enhanced understanding of the analytical procedure performance (ICH guideline Q14 “Analytical procedure development” and ICH Q2(Revision 2) guideline “Validation of analytical procedures” (both published in December 2023), USP General Information Chapter <1220> “The analytical procedure lifecycle” (valid since May 1, 2022)).

The analytical lifecycle starts with considering the required analytical performance to measure the respective Quality Attribute (i.e., the Analytical Target Profile, ATP) and selecting an appropriate analytical technique. In Stage 1 (Analytical Procedure Design), the method is developed and optimized by applying Quality-by-Design (QbD) principles. Stage 2 (Procedure Performance Qualification) consists of demonstrating suitability (i.e. an appropriate performance as defined in the ATP) in the intended routine environment, which includes (traditional) validation, but also verification of compendial procedures, as well as analytical transfer.

Stage 3 (Ongoing Procedure Performance Verification) continuously ensures that the analytical procedure remains suitable across the whole lifecycle. This includes an assessment of the impact of changes and an ongoing monitoring of selected procedure parameters (ICH Q14). Appropriate control of the capability is long expected for the manufacturing process (FDA and EU Process Validation guidelines), including continuous monitoring, as several FDA Warning Letters emphasize).

Of course, the most benefit will be achieved by applying QbD principles right from the start of the analytical lifecycle. However, such an enhanced understanding (ICH Q14) can also be gained for long-established legacy methods by establishing an ongoing monitoring program to extract performance data and information from routine application of the analytical procedure. Over time, a very reliable data base can be accumulated, leading to enhanced understanding and knowledge, as well as enabling to identify adverse trends and suspect results.

Because of this importance, USP has decided to develop a General Information Chapter <1221> “Ongoing Procedure Performance Verification” which is anticipated to be published for comment in the Pharmacopeial Forum in 2025 (see https://www.uspnf.com/notice/gc-1221-prospectus-20240927)

Particular emphasis is given to the practical utilisation of statistical tools to achieve the above-mentioned objectives, for example:

- Derivation of acceptable precision from the probability of the normal distribution or tolerance factors to assess performance
- Calculation of reliable average performance parameters
- Evaluation of results (out-of-expectation (control) limits, control charts, trend analysis)
- Practically relevant assessment of out-of-control situations

"Learning by doing": Participants can practice their learnings in 2 Workshops.

Target Audience

This course is designed for analysts and managers in R&D, Quality Control and Quality Assurance responsible for establishing, investigating, ensuring, and assessing analytical performance throughout the lifecycle. Manufacturing and regulatory affairs representatives can benefit from participation by improving their understanding of routine analytical performance parameters as an (potentially) important contribution to the overall batch variability (Annual Product Review), to better assess manufacturing variability and controls.

Trainer

Dr. Joachim Ermer

Following study of biochemistry and PhD thesis in enzyme kinetics, Dr. Ermer started his career in pharmaceutical analytics and industrial Quality Control in 1991. He held various positions, including head of laboratory within the analytical drug development at Hoechst AG, Frankfurt, Germany, and from 2001 to 2005 a global function as Director of Analytical Processes and Technology. This included consultation, harmonisation, trouble-shooting and training of all industrial sites of Aventis with respect to Quality Control topics. From 2005 to 2010, he served as head of Quality Control Frankfurt Chemistry, Sanofi, Germany. Between 2010 and 2018, Dr. Ermer was head of QC Services which included a reference standard group with the mission to provide company-wide management and distribution of analytical reference standards. From 2018 to 2020, he held the responsibility as head of QC Lifecycle Management Frankfurt Chemistry, and evaluated compendial and regulatory changes, supported and coordinated analytical transfers, validation and implementation projects, in particular the establishment of a quality system and routine monitoring programme for continuous performance verification of all API-methods.

Dr. Ermer is member of the Ph.Eur. Working Group “Chromatographic Separation Techniques” and of the USP Expert Committee “Measurement and Data Quality“. He authored more than 70 publications on analytical topics and is editor and author of the three editions of the book “Method Validation in Pharmaceutical Analysis. A Guide to Best Practice” (Wiley-VCH, 2005, 2015, 2025).

Agenda Day 1

09:00 am — ***Welcome & Introduction***

09:15 am — **Overview analytical procedure lifecycle management**

- USP General Information Chapter <1220>, ICH Q2(R2) & Q14, 3 stages of the lifecycle, USP General Chapter Prospectus <1221>

10:00 am — **Monitoring starting point: Analytical Procedure Development**

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10:45 am — **Tea / Coffee Break**

11:00 am — **Workshop Routine Monitoring**

- Selection of suitable analytical performance parameters

11:30 am — **Sources of information on analytical performance**

- Monitoring program, conformity, validity, performance parameters, how to focus on the analytical procedure?

12:30 pm — **Wrap-up part 1**

Agenda Day 2

09:00 am

Fundamentals of trend analysis

- (Normal) distribution of data, statistical control charts (for single results, means, ranges, standard deviations, CUSUM, EWMA), alert and control limits, out-of-control rules (WECO), statistical trend analysis, outlier tests

10:00 am 

Tea / Coffee Break

10:15 am

Assessment of monitoring data

- Understanding long-term variability, calculation of average parameters, precision from stability data, performance assessment - compatibility with specification limits

11:00 am

Workshop Control Charts

- A question of focus - selection of appropriate control charts, evaluation of example data sets

11:45 am 

Tea / Coffee Break

12:00 pm

Practical application of ongoing monitoring

- Practice check for control chart limits and rules, examples for QC data

12:45 am

Wrap-up part 2 & final discussion