ECA Academy
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Speaker

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Following study of biochemistry and PhD thesis in enzyme kinetics at the Martin-Luther-University Halle-Wittenberg, and a post-doc scholarship in Cambridge, UK, Dr Ermer worked for almost 30 years in various positions in industrial Quality Control. His responsibilities included head of laboratory within the analytical drug development at Hoechst AG, Frankfurt, Germany, a global function as Director of Analytical Processes and Technology at Aventis, head of Quality Control and head of QC Lifecycle Management Frankfurt Chemistry, Sanofi, Germany, and Sanofi Global Reference Standard Coordinator. Since December 2020, he serves as consultant for topics of pharmaceutical analytics and Quality Control. Dr Ermer is member of the Focus Group "Analytics and Quality Assurance", International Association of Pharmaceutical Technology (APV), 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, and 2025).

Continuous/Ongoing Verification in Pharmaceutical Analysis

Live Online Training on 29 September 2025

Highlights

- Analytical Procedure Performance
- Risk-Based Identification of Suitable Performance Parameters
- Sources of Analytical Performance Data and Information
- Monitoring and Trend Analysis
- Control Charts
- Periodic Assessment of Analytical Procedures (Analytical Review)

Objectives

Besides regulatory and compendial expectations, as discussed in the just published draft of a new USP General Information Chapter <1221> "Ongoing Procedure Performance Verification" this Live Online Training provides practical recommendations and orientation for demonstration of the continual suitability of analytical procedures across the analytical procedure lifecycle. In particular, efficient approaches will be presented to extract information and data from routine analysis. This will be illustrated with examples from quality control of chemical drug substances and biopharmaceuticals. A comprehensive understanding of the real analytical performance is extremely helpful to identify, investigate and evaluate suspect (out-of-trend, OOT) or out-of specification (OOS) results as well as for a continuous process validation.

Background

According to the FDA-Guidance "Analytical Procedures and Methods Validation for Drugs and Biologics" (2015), it should be continually assured that an analytical procedure remains fit for its intended purpose throughout its application. This includes an ongoing program for routine monitoring of analytical performance data, and the systematic evaluation of changes with the objective to evaluate regularly the need for optimization and revalidation, if needed. These activities belong to stage 3 of the analytical lifecycle management as discussed in the USP General Information Chapter <1220>. The ongoing performance verification is also discussed in the ICH Guideline Q14 "Analytical Procedure Development" (2023), and in the just published ICH Training Materials (Module 4 and 5).

Target Audience

This Training is aimed at executives and employees from Quality Control, Quality Assurance, and production who want to gain a better understanding of the GMP requirements as well as current discussions with respect to the lifecycle management of analytical procedures and are interested in practical recommendations for an efficient design, execution, and evaluation of a continuous analytical performance verification.

Programme

Regulatory Requirements and the Lifecycle Concept of Analytical Procedures

- FDA validation guidance (2015)
- USP General information chapter <1220>
  - Stage 1: Procedure Design and Development
  - Stage 2: Procedure Performance Qualification
  - Stage 3: Ongoing Procedure Performance Verification
- ICH Q14 "Analytical procedure development"
- Draft USP General Information Chapter <1221> "Ongoing Procedure Performance Verification"

WORKSHOP
Sources of Data and Information on Analytical Performance

Evaluation of Procedure Performance

- Risk management: Factors related to analytical procedure criticality & risk-based performance monitoring plans
- Analytical Procedure Performance Metrics (conformity, validity, analytical control parameters)
- Risk-based identification of suitable performance parameters (SST, from sample analysis, control samples)
- Links to Analytical Procedure Control Strategy (ICH Q14, Training Module 4)
- Continued verification of ATP requirements and periodic analytical performance assessment
- Continual improvements

Monitoring and Trend Analysis

- Control charts (Shewhart, range, standard deviation, CUSUM)
- Statistical out-of-control rules
- Pragmatic establishment of trending rules and limits (statistical, empirical)
- Examples

Date of the Live Online Training

Monday, 29 September 2025,
14.00 h - 17.00 h CEST

Technical Requirements

We use WebEx for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need.

Fees (per delegate, plus VAT)

ECA Members € 590 | APIC Members € 640
Non-ECA Members € 690 | EU GMP Inspectorates € 590
The fee is payable in advance after receipt of invoice.

Registration

By e-mail to info@concept-heidelberg.de, or search and register directly at www.gmp-compliance.org under the number 22514.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

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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