ECA Academy
Your GMP/GDP Information Source

Live Online Training

Speaker

Dr Joachim Ermer
Ermer Quality Consulting, Germany

Ongoing Verification in Pharmaceutical Analysis

Live Online Training on 24 January 2023

Highlights

- Regulatory guidance (FDA, USP, ICH Q14)
- Sources of data on analytical performance
- Risk-based implementation of a monitoring programme
- Evaluation of procedure performance
- Monitoring and trend analysis
- Control charts
- Trend analysis for stability results

Objectives

Regulatory guidelines discuss expectations for an ongoing control and evaluation of the suitability of analytical procedures, but – fortunately – do not provide details how to do this. Thus, the practical implementation is up to QC and QA. This Live Online Training provides practical recommendations and orientation for demonstration of the on-going suitability of analytical procedures. 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 investigate and evaluate suspect 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", 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 draft of the new USP information chapter <1220>. The importance of such a monitoring to identify potential failures and adverse trends as well as ensure an efficient management of changes is also discussed in the draft of the new ICH guideline Q14 "Analytical procedure development".

Target Audience

This Live Online 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 an ongoing analytical performance verification.

Programme

Regulatory Requirements and the Lifecycle Concept of Analytical Procedures

- FDA validation guidance (monitoring and trending)
- USP General information chapter <1220> (valid May 1st, 2022)
  - Stage 1: Procedure Design and Development
  - Stage 2: Procedure Performance Qualification
  - Stage 3: Ongoing Procedure Performance Verification
- ICH Q2-Revision and Q14 Analytical development

Workshop: Sources of Data and Information on Analytical Performance

Evaluation of Procedure Performance

- Indicators of performance (conformity, validity, analytical control parameters)
- Risk-based identification of suitable performance parameters (SST, from sample analysis, control samples)
- Evaluation of information and data (OOS, invalid results, control charts, average parameters)
- Continual improvements

Monitoring and Trend Analysis

- Control charts (Shewart, range, standard deviation, combined, CUSUM)
- Pragmatic establishment of rules and limits (statistical, empirical)
- Trend analysis for stability results
- Examples

Speaker

Dr. Joachim Ermer
Ermer Quality Consulting, Germany

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 50 publications on analytical topics and is editor and author of the two editions of the book "Method Validation in Pharmaceutical Analysis. A Guide to Best Practice" (Wiley-VCH, 2005 and 2015).

Your Benefit:
Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.


CERTIFICATE

Mr John Doe

ECA - Lab Data Integrity - Meeting FDA & EU Concerns
Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls

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- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings

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Reservation Form (Please complete in full)

Ongoing Verification in Pharmaceutical Analysis
Live Online Training on 24 January 2023

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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Date of the Live Online Training
Tuesday, 24 January 2023,
14.00 h – 17.00 h h CET

Technical Requirements
We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

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 message or you register online at www.gmp-compliance.org.

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.

You cannot attend the live event?
We also offer many of the training courses and conferences mentioned in this brochure as recordings. This means that you can watch the videos of the event "on demand" - whenever it suits your time - on our web server. Quite uncomplicated without software simply in the browser. Interested? You can find all recorded events at www.gmp-compliance.org/recordings.

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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