ECA Academy
Your GMP/GDP Information Source

Speaker

Dr Joachim Ermer
Ermer Quality Consulting, Germany

Book the course "ICH Q2 Revision, Lifcycle Concept, Precision and Accuracy" together with the course "Specificity, Linearity, Impurities and Quantitation Limit" and save € 100,-!

Validation in Pharmaceutical Analysis

ICH Q2 Revision, Lifecycle Concept, Precision, and Accuracy,
Live Online Training on 22 March 2022

Specificity, Linearity, Impurities and Quantitation Limit,
Live Online Training on 23 March 2022

Highlights

ICH Q2 Revision, Lifecycle Concept, Precision, and Accuracy

- Revision of ICH Q2-Guideline and Q14 Analytical Procedure Development – Mission accomplished?
- The Analytical Procedure Lifecycle – USP General Information Chapter <1220> (valid May 1, 2022)
- Analytical Target Profile – Performance requirements (acceptance criteria for suitability)
- Validation Characteristics and Error Types
- Aspects of an efficient Validation
- Design of Precision Studies, calculation and optimisation of Precision
- Accuracy by comparison, recovery, combined with precision
- Appropriate application of significance and equivalence tests
- How to avoid Mistakes in Validation

Specificity, Linearity, Impurities and Quantitation Limit

- Specificity – Peak Purity Investigations
  - Samples for Investigation of Specificity
- Linearity – Requirements to Calibration Models
  - StatisticalCalculations
- Validation of Impurities
- Quantitation Limit (blank procedures, from linearity, from precision)
- How to Avoid Mistakes in Validation

Objectives

Besides regulatory expectations, these Live Online Training Courses provide practical recommendations and orientation for demonstration of the on-going suitability of analytical procedures. A rational and efficient validation approach is ultimately based on the respective routine application, which should be reflected in the validation design. This includes the identification of the relevant performance parameters, the selection of appropriate tests and calculations and, in particular, the establishment of acceptance criteria for the evaluation.

Both training courses focus on the relevant validation characteristics, taking the - long-awaited - revision of the ICH Q2 guideline into consideration (provided a timely publication of the draft for consultation). Lifecycle aspects will be included in the discussion.

Background

According to EU GMP Guide Part 1, Chapter 6, Quality Control (6.15) and US 21 CFR 211.194, analytical procedures must be suitable for their intended purpose. The regulatory requirements to validation of analytical procedures utilised for release and stability studies of drug substances and drug products are described in the ICH guideline Q2(R1). However, its degree of detail is rather low, and the discussion is mainly focused on chromatographic methods. A broader consideration of other analytical techniques as well as alignment with lifecycle aspects is intended with the revision of Q2. The latter will also be the focus of the new ICH Guideline Q14 Analytical Procedure Development and is already content of the USP General Information Chapter <1220> The Analytical Procedure Lifecycle (valid May 1st, 2022).

Target Audience

These Live Online Training Courses are aimed at executives and employees from Quality Control, Quality Assurance, and regulatory who want to gain a better understanding of the GMP requirements for validation of analytical procedures, are interested to participate in a discussion of the revised ICH guideline Q2 (provided a timely publication), and who are interested in practical recommendations for an efficient design, execution, and evaluation of a successful analytical validation.

Programme "ICH Q2 Revision, Lifecycle Concept, and Precision, and Accuracy"

Lifecycle Concept, ICH Q2 Revision and Q14

- Revision of ICH Q2-Guideline and Q14 Analytical Procedure Development – Mission accomplished?
- The Analytical Procedure Lifecycle – USP General Information Chapter <1220> (valid May 1, 2022)

Analytical Target Profile

- Requirements to the analytical performance
- Error types
- Evaluation of performance parameters (simple, statistical)
- Aspects of an efficient validation

Precision

- Precision levels (system precision, repeatability, intermediate precision, reproducibility)
- Acceptance limits for assay
  - Derivation from probability, measurement uncertainty, tolerance factors
- Design of precision studies and calculations
  - Uncertainty of precisions: point estimators and confidence intervals
- Optimisation of precision by averaging (replication strategy)
  - Precision of the reportable value (small molecules, bioassay)
  - Assay for small molecules, bioassay

Accuracy and Range

- Comparison and recovery
- Statistical significance and equivalence tests
- Variability and expected difference between means
- Acceptance criteria for assay
- Separate and combined evaluation of accuracy and precision
- Range

Workshop: Multiple Choice Questions (from Publications)

- How to avoid mistakes in validation

Programme "Specificity, Linearity, Impurities and Quantitation Limit"

Specificity

- Comparison and (chromatographic) separation
- Samples for investigation of specificity
- Peak purity investigations

Linearity

- Changes in the revised ICH Q2 guideline
- Requirements to calibration models
  - linear single-point and multiple-point calibration,
  - weighted linear regression
  - non-linear calibration
- Statistical calculations (regression, suitable parameters)
- Acceptance criteria for calibration function
  - residual and sensitivity plot
  - ordinate intercept

Validation of Impurities

- Concentration dependency of precision (Horwitz function)
- Acceptance limits for accuracy and precision of impurities
- Recovery
- UV-response factors

Detection and Quantitation Limit

- Determination of the quantitation limit (blank procedures, from linearity, from precision)
- Is less more?
  - Capability and requirement-based quantitation limits
- Consideration of practical relevance (samples, concentration range for linearity approaches)

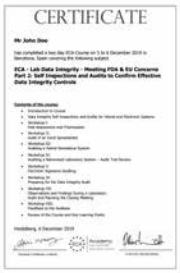
Workshop: Multiple Choice Questions (from Publications)

- How to avoid mistakes in validation

Speaker of both Training Courses

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).


CERTIFICATE

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.

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GERMANY

Reservation Form (Please complete in full)

Validation in Pharmaceutical Analysis:
☐ ICH Q2 Revision, Lifecycle Concept, Precision, and Accuracy, Live Online Training on 22 March 2022
☐ Specificity, Linearity, Impurities and Quantitation Limit, Live Online Training on 23 March 2022

Title, first name, surname

Department | Company

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

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If you cannot attend the conference you have two options:
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German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training ICH Q2 Revision, Lifecycle Concept, Precision, and Accuracy

Tuesday, 22 March 2022, 14.00 h – 18.00 h CET

Date of the Live Online Training Specificity, Linearity, Impurities and Quantitation Limit

Wednesday, 23 March 2022, 14.00 – 18.00 h CET

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (single booking, 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.

Save money and book both courses:

ECA Members € 1,080 | APIC Members € 1,180
Non-ECA Members € 1,280 | EU GMP Inspectorates € 1,080
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax 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.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

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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