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 14 March 2023

Specificity/Selectivity, Response (Calibration Model), Impurities and Quantitation Limit, Live Online Training on 15 March 2023

Highlights

ICH Q2 Revision, Lifecycle Concept, Precision, and Accuracy

- Important adjustments and complementations in Q2 revision 2 – Mission accomplished?
- The Analytical Procedure Lifecycle – USP General Information Chapter <1220>, ICH Q14 / Q2(R2)
- Analytical Target Profile – Performance requirements (acceptance criteria for suitability)
- Performance 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/Selectivity, Response (Calibration Model), Impurities and Quantitation Limit

- Specificity – peak purity investigations
  - Samples for investigation of specificity
- "Response" instead of "Linearity" – requirements to calibration models
  - Statistical calculations
- Validation of Impurities
- Quantitation limit (blank procedures, from linear response, 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 performance characteristics, taking the - long-awaited - revision of the ICH Q2 guideline as well as the new Q14 guideline Analytical Procedure development into consideration. 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 also in 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.

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, 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

- The Analytical Procedure Lifecycle – USP General Information Chapter <1220> and ICH Q14
- Overview on important adjustments and complementations in ICH Q2(R2)
- Reportable range

Analytical Target Profile

- Requirements to the analytical performance
- Error types
- ATP in Q2(R2) and Q14
- Evaluation of performance parameters (simple, statistical)
- Aspects of an efficient validation

Precision

- Precision levels (system precision, repeatability, intermediate precision, reproducibility)
- Precision in ICH Q2(R2)
- 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

- ICH Q2(R2): Comparison, recovery, and technology-inherent justification, combined evaluation of accuracy and precision
- Statistical significance and equivalence tests
- Variability and expected difference between means
- Acceptance criteria for assay

Workshop: Multiple Choice Questions (from Publications)

- How to avoid mistakes in validation

Programme "Specificity/Selectivity, Response (Calibration Model), Impurities and Quantitation Limit"

Specificity/Selectivity

- Adjustments in ICH Q2(R2)
- Comparison and (chromatographic) separation
- Samples for investigation of specificity
- Peak purity investigations

Response (Calibration Model)

- 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

Lower Range Limit Verification

- ICH Q2(R2): Quantitation limit and reporting threshold
- Capability and requirement-based quantitation limits
- Determination of the quantitation limit (blank procedures, from response (calibration model), from precision)
- Consideration of practical relevance (samples, concentration range for linearity approaches)

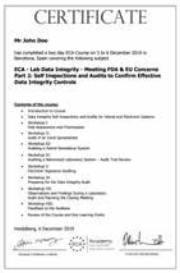
Workshop: Multiple Choice Questions (from Publications)

- 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.

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Validation in Pharmaceutical Analysis:
☐ ICH Q2 Revision, Lifecycle Concept, Precision, and Accuracy, Live Online Training on 14 March 2023
☐ Specificity/Selectivity, Response (Calibration Model), Impurities and Quantitation Limit, Live Online Training on 15 March 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

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
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, 14 March 2023, 14.00 h – 18.00 h CET

Date of the Live Online Training Specificity/Selectivity, Response (Calibration Model), Impurities and Quantitation Limit

Wednesday, 15 March 2023, 14.00 – 18.00 h CET

Technical Requirements

We use Webex Events 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 to participate in our events 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 (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.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. 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.

CONCEPT HEIDELBERG
P.O. Box 10 17 64 | D-69007 Heidelberg
Phone +49(0) 62 21/84 44-0 | Fax +49(0) 62 21/84 44 34
info@concept-heidelberg.de | www.concept-heidelberg.com

For questions regarding content please contact:
Dr Markus Funk (Operations Director) at
+49(0)62 21/84 44 40, or at funk@concept-heidelberg.de

For questions regarding organisation please contact:
Ms Marion Grimm (Organisation Manager) at
+49(0)62 21/84 44 18, or at grimm@concept-heidelberg.de