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Speaker

Dr Joachim Ermer
Ermer Quality Consulting, Germany

Book the course "ICH Q2 Revision, Lifcycle Concept, Precision and Accuracy" together with the course "Specificity/Selectivity, Response (Calibration Model), Impurities and Quantitation Limit" and save € 100,-!

Validation in Pharmaceutical Analysis

ICH Q2 Revision, Lifecycle Concept, Precision, and Accuracy, Live Online Training on 13 March 2024

Specificity/Selectivity, Response (Calibration Model), Impurities and Quantitation Limit, Live Online Training on 14 March 2024

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, in particular the new ones in Q2(R2), this Live Online Training provides 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 trainings 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 from November 2023 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(R2). However, its degree of detail is rather low, and the examples provided in Annex 2 often lack orientation beyond the guideline text. The lifecycle aspect of validation is treated in Q2(R2) rather as the "poor stepchild", but covered better in the new ICH Guideline Q14 Analytical Procedure Development, and – in a true holistic way - in 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, in particular the new aspects and requirements of the revised ICH guideline Q2(R2), and who are interested in practical recommendations for an efficient design, execution, and evaluation of a successful analytical validation.

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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
- Non-linear response functions

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). The third edition is in preparation and scheduled for publication mid-2024.


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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Reservation Form (Please complete in full)

Validation in Pharmaceutical Analysis:
☐ ICH Q2 Revision, Lifecycle Concept, Precision, and Accuracy, Live Online Training on 13 March 2024
☐ Specificity/Selectivity, Response (Calibration Model), Impurities and Quantitation Limit, Live Online Training on 14 March 2024

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

Wednesday, 13 March 2024, 14.00 h – 18.00 h CET

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

Thursday, 14 March 2024, 14.00 h – 18.00 h CET

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 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
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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.

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