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Speaker

Dr Joachim Ermer
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The new ICH Guideline Q2 Validation of Analytical Procedures (Revision 2)

Live Online Training on 30 January 2024

Highlights

- Adjustments and changes in ICH Q2(R2): What is new?
- How much lifecycle is in ICH Q2(R2)?
- Links to ICH Q14
- Calibration models – linear, non-linear, multivariate
- Combined evaluation of precision and accuracy
- Discussion of the illustrative examples in Annex 2 of the Guideline

Mission accomplished?

Programme

Objective

During the ICH Assembly Meeting on 31 October and 01 November 2023, the final ICH guidelines Q2(R2) and Q14 were adopted, after more than 3000 comments have been received each concerning the draft guidelines published in March 2022.
During this Live Online Training, the participants will learn what aspects have changed and what is new in the revised Q2 guideline. A critical discussion will be provided whether the gaps and uncertainties of the old guideline from 1994 are sufficiently addressed, in particular considering the new USP General Information Chapter <1220> Analytical Procedure Life Cycle. Some of the examples provided in Annex 2 will be critically discussed and evaluated.

Background

Since the implementation of the ICH Guideline Q2 Validation of Analytical Procedures in 1994, many topics emerged in the pharmaceutical area, in particular in manufacturing, towards a holistic lifecycle management, such as the ICH Guidelines Q8-12, or the FDA and EU process validation guidelines. Although ICH Q2 served its role to harmonise terminology and basic requirements with respect to analytical validation, some gaps and uncertainties remained and became more and more obvious in the light of the recent developments. For example, the major focus of Q2 on chromatographic methods, the lack of clarity what suitability means (acceptance criteria linked to the measurement requirements for the respective Critical Quality Attribute), or the confusion between the response function (calibration model) and linearity of the analyte in the sample (accuracy). Consequently, in November 2018, a concept paper was published describing the area of improvements for a revision of the Q2 Guideline as well as the introduction of a new, related ICH Guideline Q14 on Analytical Procedure Development.

Target Audience

This Live Online Training is aimed at executives and employees from Quality Control, Quality Assurance, and regulatory who want to gain an overview on the revised ICH Q2 Guideline, in order to prepare for future expectations.

Programme

Adjustments, Changes, and new Requirements in Q2(R2)

- Validation protocol and acceptance criteria
- Validation of platform analytical procedures
- Multivariate analytical procedures
- Performance characteristics
- Specificity/selectivity
  - Technology inherent justification
- Reportable/working range
  - Response (calibration) functions: linear, non-linear, multivariate
  - Lower limit (detection and quantitation limit, reporting threshold)
- Accuracy
  - Inference
  - Acceptance criteria taking the uncertainty into account (e.g. confidence intervals)
- Precision
  - Precision levels
  - Acceptance criteria taking the uncertainty into account (e.g. confidence intervals)
- Combined evaluation of precision and accuracy
  - Demonstration via prediction or tolerance intervals

How much Lifecycle is in Q2(R2)?

- Validation during the lifecycle
- Links to Q14
  - Use of data and results from development
- (Missing the) Analytical Target Profile

Discussion of the illustrative Examples in Annex 2

- Quantitative separation techniques (assay and relative area quantitation)
- Elemental impurities by ICP-OES/MS
- Dissolution for immediate release (quantitation with HPLC)
- Biological assays
- Particle size measurement

Speaker

Dr Joachim Ermer | Ermer Quality Consulting, Bensheim, 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).

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The new ICH Guideline Q2 Validation of Analytical Procedures (Revision 2)
Live Online Training on 30 January 2024

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Date of the Live Online Training

Tuesday, 30 January 2024, 14.00 h – 17.00 h
All times mentioned are CET

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Fees (per delegate, plus VAT)

ECA Members EUR 590
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The conference 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.

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Conference language

The official conference language will be English.

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Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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