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CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

The new ICH Draft Guideline Q2 Validation of Analytical Procedures (Revision 2)
Live Online Training on 5 May 2022, 14:00 – 17:00 h CEST

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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If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
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- Cancellation until 1 weeks prior to the conference 50 %
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Date of the Live Online Training
Thursday, 5 May 2022, 14.00 h – 17.00 h CEST

Technical Requirements
We use Webex Events 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
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.

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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Speaker

Dr Joachim Ermer
Ermer Quality Consulting,
Germany

The new ICH Draft Guideline Q2 Validation of Analytical Procedures (Revision 2)

Live Online Training on 05 May 2022 from 14.00 - 17.00 h CEST

Highlights

- Adjustments and additions in ICH Q2(R2)
- How much lifecycle is in ICH Q2(R2)?
- Links to ICH Q14
- Discussion of the illustrative examples in ANNEX 2 of the Guideline

Objectives

After almost 2 years of delay, the draft guidelines Q2(R2) and Q14 have been published for public consultation end of March 2022. 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 are sufficiently addressed, in particular considering the new USP General Information Chapter <1220> The Analytical Procedure Lifecycle. 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. With respect to the Q2 revision, a broader range of techniques such as NIR, Raman, NMR, hyphenated techniques, lifecycle aspects with the inclusion of post-approval (ongoing) verification and maintenance, emphasis on systematic analytical development, and multivariate models were intended to be considered.

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.

Programme

Adjustments and Additions 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
  - Demonstration via confidence intervals
- Precision
  - Compatibility to specification limits
- Combined evaluation of precision and accuracy
- Total Analytical Error
- 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, 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).