Live Online Training

Speaker/Moderator

Dr Joachim Ermer
Ermer Quality Consulting, Germany

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Transfer of Analytical Procedures

Live Online Training on 13 April 2021, 14:00 – 17:30 h

Highlights

- Management of the Transfer Process
- Root Causes of Issues during Transfer
- Risk-based Design of Transfer Studies
- Evaluation of Results
- Life Cycle Approach
- Post-transfer Control

Programme

Objectives

This Live Online Training provides regulatory requirements and recommendations with respect to the transfer of analytical procedures, e.g. from USP, WHO, and ISPE. Transfer can be regarded as the ultimate robustness check of the analytical procedure. Aspects neglected or missed during method development will often become evident. Therefore, a meticulous planning and a prudent management of issues during the transfer are vital. A thorough Quality-by-Design method development or otherwise retrieved knowledge on the performance of the analytical procedure will facilitate an efficient planning of the transfer as well as increase the probability of success.

Background

The transfer of analytical procedures is a frequent activity during the lifecycle of a drug substance or drug product. Thus, it is regularly in the focus of audits and inspections. According to the EU GMP guide part 1, chapter 6, Quality Control, and US 21 CFR 211.194, QC laboratories which did not perform the original validation should verify the appropriateness of the testing method. The EU GMP guide (6.38 – 6.40) requires a protocol for this analytical transfer. The General Information Chapter of USP <1224> „Transfer of analytical procedures“ provides some detailed discussion of the process, including various transfer strategies such as comparative testing, co-validation, re-validation, and waiver.

Target Audience

This Training is aimed at executives and employees from Quality Control, Quality Assurance, and Production who want to gain a better understanding of the GMP requirements, as well as an efficient planning, execution, and evaluation of a successful method transfer.

Programme

Regulatory Requirements and Expectations

- Guidelines for transfer of analytical procedures
- Analytical transfer as part of the lifecycle management
- Management of deviations, suspect and out-of-specification results

Management of the Transfer Process

- Transfer team
- Transfer strategy
- Protocol and report, documentation
- Training
- Root causes of issues during transfer

Rational and Efficient Design of Transfer Studies

- Evaluation of results (simple and statistical comparison)
- Risk-based design of effort
- Acceptance criteria (accuracy and precision)
  - Capability-based (empirical, from validation, from monitoring)
  - Requirement-based (statistical derivation from specification limits, acceptable OOS rate)
- Design of experimental studies (required number of series and determinations, dependent on acceptance limits and evaluation)

Lifecycle Approach

- Based on knowledge and data from continuous monitoring in the sending unit
- Initial transfer study by receiving unit only
  - “Lean” design, risk limitation for larger errors/ differences
- Post-transfer control by means of the monitoring program
  - Chance to identify and evaluate small differences

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).

Moderator

Dr Gerhard Becker, CONCEPT Heidelberg, Germany

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Reservation Form (Please complete in full)

Transfer of Analytical Procedures
Live Online Training on 13 April 2021, 14:00 – 17:30 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

Phone / Fax

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Date of the Live Online Training
Tuesday, 13 April 2021, 14:00 h – 17:30 h CEST

Technical Requirements
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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.

Ordering a Recording
Independent from the Live Online Training Courses, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

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

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