Speaker

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Dr Ermer worked for almost 30 years in various positions in industrial Quality Control at Hoechst AG, Aventis, and Sanofi. Since December 2020, he serves as consultant for topics of pharmaceutical analytics and Quality Control.

Transfer of Analytical Procedures

Live Online Training on 01 October 2025

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

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.

Target Audience

This Live Online 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

Date of the Live Online Training

Wednesday, 01 October 2025,
13.00 h – 17.00 h CEST

Technical Requirements

We use WebEx 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

By e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21851.

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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