EU

Online Masterclass

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LIVE

CERTIFIED

CASE STUDY

Analytical Method Transfer

8th - 7th August 2025

9.00am – 1.00pm EDT (UTC- 4)

Dr. Joachim Ermer

Course outline

Transfer of analytical procedures, either as part of manufacturing technology transfer, or stand-alone, plays an important role in the lifecycle of a drug substance or finished product. Consequently, it is regularly in the focus of audits and inspections. Besides the legal regulatory requirements (US CFR, EU GMP Guide), there have been several Guidelines over the last 20 years providing more details on (regulatory) expectations, for example from USP, WHO, and ISPE.

Analytical transfer can be considered as the ultimate robustness test, as deficiencies in method development, for examples missed critical performance parameters (which are then not sufficiently controlled) will likely become obvious and lead to issues or failures during transfer.

A systematic (Quality-by-Design) approach as discussed in the new ICH guideline Q14 "Analytical procedure development" (published in December 2023), as well as in the USP General Information Chapter <1220> "The analytical procedure lifecycle" (valid since May 1, 2022), will therefore facilitate transfer of analytical procedures, which is regarded as part of stage 2 of the analytical lifecycle, Analytical Procedure Performance Qualification (USP <1220>), because the suitable performance is demonstrated in the (new) routine environment in the receiving laboratory. In case of long-established analytical procedures, the lifecycle concept will include the compilation of knowledge from routine application and thus achieve such an "enhanced understanding" too.

Both approaches can provide the knowledge to facilitate an efficient planning of the whole transfer process, as well as a suitable and appropriate design of experimental transfer studies.

COMPANIES REPRESENTED BY OUR PARTICIPANTS

Pfizer | Halozyme | aldevron | Jubilant Radiopharma | almirall | MacroGenics

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Participants of this masterclass will

- Get an overview on the analytical procedure lifecycle management and the role of analytical transfer in this concept
- Receive information on regulatory requirements and expectations on analytical transfer
- Learn about different types of transfer (comparison, co-validation, re-validation, waiver) and their appropriate application
- Learn how a transfer project can be divided into individual steps (for better "digestion"), e.g. building an Analytical Transfer Team, review of documentation and knowledge, familiarisation and training of the receiving unit (RU), designing a transfer strategy, transfer plan and report, post transfer activities
- Learn how to deal with deviations, issues, and out-of-specification results in transfer, as well as how to avoid them
- Improve their understanding of statistical fundamentals impacting the assessment of transfer results (comparison approach, design of transfer studies, impact on acceptance criteria)
- Learn how a lifecycle-approach can facilitate a "lean" transfer study and improve the assurance of a successful transfer.

Participants can "experience" the impact of the design of comparison studies on the expected spread of results by statistical simulations using a provided Excel™ worksheet ("Learning by doing").

Target Audience

This course is designed for analysts and managers in Quality Control, Quality Assurance, Regulatory Affairs, and production who want to gain a better understanding of regulatory and GMP requirements concerning analytical transfer, who are responsible for transfer management, for designing transfer studies, establishing transfer acceptance criteria, and for evaluating analytical transfer results. The statistical principles for the design of transfer studies can as well be applied for other types of comparison, e.g. old vs. alternative analytical procedures, batches before and after changes, etc.

Trainer

Dr. Helmut Vigenschow

Following study of biochemistry and PhD thesis in enzyme kinetics, Dr. Ermer started his career in pharmaceutical analytics and industrial Quality Control in 1991. He held various positions, including head of laboratory within the analytical drug development at Hoechst AG, Frankfurt, Germany, and from 2001 to 2005 a global function as Director of Analytical Processes and Technology. This included consultation, harmonisation, trouble-shooting and training of all industrial sites of Aventis with respect to Quality Control topics. From 2005 to 2010, he served as head of Quality Control Frankfurt Chemistry, Sanofi, Germany. Between 2010 and 2018, Dr. Ermer was head of QC Services which included a reference standard group with the mission to provide company-wide management and distribution of analytical reference standards. From 2018 to 2020, he held the responsibility as head of QC Lifecycle Management Frankfurt Chemistry, and evaluated compendial and regulatory changes, supported and coordinated analytical transfers, validation and implementation projects, in particular the establishment of a quality system and routine monitoring programme for continuous performance verification of all API-methods.

Dr. Ermer is member of the Ph.Eur. Working Group “Chromatographic Separation Techniques” and of the USP Expert Committee “Measurement and Data Quality“. He authored more than 70 publications on analytical topics and is editor and author of the three editions of the book “Method Validation in Pharmaceutical Analysis. A Guide to Best Practice” (Wiley-VCH, 2005, 2015, and 2025).

Agenda Day 1

09:00 AM — **Introduction**

09:15 AM — **Transfer as part of the analytical lifecycle management**

- Overview on lifecycle management, USP Chapter <1220> & ICH guideline Q14, 3 Stages (Analytical Procedure Design, Performance Qualification, Ongoing Performance Verification), Analytical Target Profile (ATP), continual improvements

10:00 AM — **Guidelines and regulatory expectations regarding analytical transfer**

- US, EU, ISPE, USP, WHO, ANVISA Guidelines
- ICH Q14: risk assessment and bridging studies

10:45 AM — **Refreshment break**

11:00 AM — **Overview on the analytical transfer process**

- Transfer team, review of documentation, knowledge transfer, familiarisation and training, transfer types and when to apply them (risk assessment), transfer strategy with examples, protocol and report, documentation

11:45 AM — **Obstacles and pitfalls**

- Management of deviations, root causes of issues during transfer, OOS during transfer?

12:30 PM — **Final discussion**

Agenda Day 2

09:00 AM

Comparison of data

- Distribution of analytical data, Significance (F- and t-test) and equivalence tests, statistical significance versus practical relevance, differences caused by random variability (observed and true bias), evaluation of results: simple and statistical comparison (confidence intervals)

10:00 AM

Refreshment break

10:15 AM

Workshop Comparison (statistical simulations)

- Simple comparison, significance, and equivalence tests, impact of design of transfer studies (number of series/runs and determinations)

11:15 AM

Appropriate design of transfer studies and establishment of acceptance criteria

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

12:00 PM

Enhanced (lifecycle) approach to analytical transfer

- Based on knowledge and data from continuous monitoring in the sending unit, initial transfer study by receiving unit only (“lean” design), post-transfer control by means of the monitoring program, chance to identify and evaluate small differences

12:30 PM

Final discussion