US

Online Masterclass

METAMORPH

LIVE

CERTIFIED

CASE STUDY

Validation & Verification of Analytical Procedures

24th - 26th June 2025

09.00am – 1.00pm EDT (UTC- 4)

Dr. Joachim Ermer

Participants of this masterclass will

- Receive an overview on the performance characteristics (precision, accuracy, specificity, calibration model, detection and quantitation limit), including changes and new recommendations in ICH Q2(revision 2)
- Gain a deeper understanding for practically relevant performance parameters
- Learn how to design efficient and practically relevant experimental studies to calculate performance parameters, for example with respect to precision levels (system/measurement precision, repeatability, intermediate precision, precision of the reportable result), combined assessment of accuracy and precision, justification of calibration models by regression analysis, comparison or recovery studies for accuracy, or determination / verification of detection and quantitation limit
- Learn how to optimise the precision of the reportable result by a scientifically based replication strategy
- Get a deeper understanding of basic statistical approaches (including those discussed in ICH Q2(revision 2) to assess analytical performance
- Learn how to derive validation acceptance criteria, e.g. from measurement requirements (specification limits)
- Receive proposals to use efficiently data from development for validation of analytical procedures
- Get an overview on USP and Ph.Eur. General chapters on verification of compendial procedures, including practical examples

Particular emphasis is given to examples and the practical utilisation of statistical tools to achieve the above-mentioned objectives.

COMPANIES REPRESENTED BY OUR PARTICIPANTS

Lonza · Bayer · DPT a Mylan company · Halozyme · Jubilant Radiopharma · aldevron

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Course outline

The objective of validation of an analytical procedure is to demonstrate that it is suitable for its intended purpose." The regulatory requirements for analytical procedures applied for release and stability studies of drug substances and drug products are described in the ICH guideline Q2(R2). The new revision, and the new ICH draft guideline Q14 "Analytical procedure development" (both published in December 2023), reflect much better the iterative character of method development and validation. The recommended "enhanced" approach (ICH Q14) will enable a better identification and understanding of the required analytical performance by consideration of Quality-by-Design tools and facilitate both planning of validation studies as well as efficient use of information and data from development. Of course, Q2(R2) provides only general orientation, requiring (or leaving) much room for practical interpretations, in particular how to establish acceptance criteria. In March 2025, ICH training materials are expected for both Q2(R2), and Q14.

Besides current regulatory expectations, the master class provides practical recommendations and orientation for demonstrating the suitability of analytical procedures. A rational and efficient design of validation studies should always focus on the respective routine application. This includes the identification of the relevant performance parameters, the selection of appropriate and meaningful tests and calculations and, in particular, the establishment of acceptance criteria for evaluation.

According to the lifecycle approach, verification of compendial procedures is also part of stage 2, Analytical Procedure Performance Qualification, because the same performance characteristics are relevant to demonstrate a successful implementation of compendial procedures in a laboratory.

"Learning by doing"

Participants can practice their learnings in several Workshops. For example, Excel™ worksheets are provided to illustrate the consequences of proper and improper experimental designs. Further, alternative validation designs are provided for assessment and selection of the appropriate ones, as well as a summary Quiz to check success of the learnings.

Target Audience

This course is designed for analysts and managers in Quality Control, Quality Assurance, and Regulatory Affairs responsible for planning, executing, and assessing validation and verification studies of analytical procedures and who want to gain information on current trends and practical, scientifically sound recommendations for a rational, efficient, and successful analytical validation.

Trainer

Dr. Joachim Ermer

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, 2025).

Agenda Day 1

09:00 am — ***Welcome & Introduction***

09:15 am — **Regulatory requirements and guidelines, lifecycle concept**

- cGMPs, ICHQ2/Q14, USP <1225>, FDA, USP <1220>

10:00 am — **Understanding analytical performance**

- Error types and validation (performance) characteristics, data distributions, performance requirements (Analytical Target Profile), simple and statistical evaluation

10:45 am — **Tea / Coffee Break**

11:00 am — **Workshop: Understanding Variability**

- Impact of number of determinations on the scatter of data (OOS risk) and of standard deviations, application of statistical simulations

11:45 am — **Precision**

- ICH Q2(Revision 2), precision levels and calculation (e.g. by ANOVA), uncertainty of precision (confidence intervals), appropriate design of precision studies, precision acceptance criteria, optimisation of precision of the reportable value by averaging

12:30 pm — **Wrap-up part 1**

Agenda Day 2

09:00 am

Accuracy

- ICH Q2(Revision 2), reportable range, separate evaluation and combined with precision, approaches (comparison, recovery, technology-inherent justification), acceptance criteria

10:00 am

Tea / Coffee Break

10:15 am

Specificity

- ICH Q2(Revision 2), direct and indirect demonstration of specificity, parameters of separation, peak purity, stability indication

11:00 am

Calibration model (response function)

- Changes in ICH Q2(R2) (formerly "Linearity"), linear and non-linear models, requirements to calibration models, evaluation (residual plots, intercept)

11:45 am

Tea / Coffee Break

11:55 am

Workhshop: Selection of an appropriate validation design

- Specificity, precision, accuracy several alternative designs are provided to be assessed, selection of the appropriate design

12:45 pm

Wrap-up part 2

Agenda Day 3

09:00 am

Lower range limit (Detection and Quantitation Limit)

- Design of QL studies: general and intermediate QL, verification of the required QL (reporting threshold), linearity-based approaches (ICH Q2) and their prerequisites and pitfalls, from precision, from signal-to-noise ratio

09:45 am

Verification of compendial procedures

- GMP Requirements, compendial procedure or not? USP <1226> Verification of compendial procedures (Verification process & requirements, performance attributes), Ph.Eur. 5.26: Implementation o f pharmacopoeial procedures (critical analytical procedure performance characteristics), examples

10:30 am

Tea / Coffee Break

10:45 am

Workshop: Selection of an appropriate validation design

- Calibration model, detection and quantitation limit, several alternative designs are provided to be assessed, selection of the appropriate design

11:15 am

Utilisation of data from method development

- Revision of ICH Q2/Q14, avoiding repetitions, prerequisites for using development data, which experimental studies in which stage?

11:45 am

Summary: Validation Quiz

- Assessment of multiple-choice questions
- Wrap-up & final Discussion