US

Online Masterclass

METAMORPH

LIVE

CERTIFIED

CASE STUDY

Stability Testing for Substances & Drug Products

01st - 03rd April 2025

9.00am – 1.00pm EDT (UTC- 5)

Dr. Joachim Ermer

Course outline

Demonstrating the stability of drugs and establishing a reliable shelf life and suitable storage conditions is of vital importance to ensure appropriate quality, efficacy, and safety. Consequently, stability testing was the first topic of international harmonization (ICH-Guidelines Q1), to define and harmonize regulatory requirements. Stability testing aims to provide evidence of how the quality of a drug substance or drug product changes with time, under the influence of factors such as temperature, humidity, and light, and to establish a retest period for the drug substances or a shelf life for the drug products as well as long-term storage conditions, and label requirements for drug products. Due to the extensive effort to obtain the respective data, a thorough understanding and efficient management of the stability investigations throughout the product lifecycle has also a large economic impact on pharmaceutical companies.

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www.metamorphedu.com booking@metamorphedu.com +1 657 452 8174

This masterclass will provide the participants with a basic overview of factors and mechanisms of changes/degradation, and on regulatory guidelines and expectations regarding the stability of pharmaceuticals across the lifecycle, from forced degradation studies in development, over stability data required for submission, to stability confirmation in the marked phase using on-going stability studies and after changes. Possibilities to improve the efficiency of stability testing by reduced test designs (bracketing and matrixing) and by extrapolation of the shelf-life beyond the storage time covered by actual stability data are discussed, along with the risks to be considered.

Participants will

- gain an understanding on the fundamentals of stability investigations
- get an overview of regulatory guidelines and expectations concerning the design of studies
- learn about the various types of stability studies
- understand the purpose of stress stability studies
- learn how the effort can be reduced by bracketing and matrixing (ICH Q1D)
- receive information on how to extrapolate the shelf-life beyond the real-time coverage by stability data and the required prerequisites
- understand the requirements to confirm the stability by ongoing studies during routine manufacturing
- learn how to identify suspect trends in stability data and how to manage out-of-specification (OOS) results in an appropriate manner
- get information on the requirements for validation of stability-indicating analytical procedures (new ICH guideline Q2 (Revision 2))

Participants can "experience" the impact of factors such as analytical and batch variability, matrixing, and extrapolation on the statistical evaluation of stability data using statistical simulations. Excel™ worksheets are provided to illustrate stability fundamentals and calculations. Participants can use these worksheets later for their own examples and increase their understanding.

Target Audience

This course is designed for analysts and managers in Quality Control and Quality Assurance interested in obtaining an overview of pharmaceutical stability requirements or who are responsible for designing, executing, or evaluating stability investigations throughout the product lifecycle. Manufacturing and regulatory affairs representatives can benefit from participation by improving their understanding of stability investigations for drug substances and drug products.

Trainer

Dr. Joachim Ermer

Following a 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 the 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, harmonization, troubleshooting, and training of all industrial sites of Aventis concerning 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 stability logistics group and 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 program for continuous performance verification of all API-methods.

Dr. Ermer is a member 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 the editor and author of the three editions of the book "Method Validation in Pharmaceutical Analysis. A Guide to Best Practice" (Wiley-VCH, 2005, 2014, and 2025).

Agenda Day 1

09:00 AM Introduction

09:10 AM Overview Stability Testing

- Rationale for stability testing, types of pharmaceutical stability studies, ICH stability studies, EU and FDA stability guidelines, ongoing stability studies for marketed products, stability protocol and report, submission dossier

09:50 AM Stability background

- Degradation (chemical reactions, physical changes), reaction kinetics, climatic zones, mean kinetic temperature

10:50 AM Tea / Coffee Break

11:10 AM Stress stability studies

- Stress conditions, ANVISA Guideline no. 4 (2015), bibliographic research & experimental studies, predictive stability modelling

12:10 PM Q1B: Photostability testing

- General, light sources, drug substance, decision flowchart drug product

12:45 PM Summary & discussion

Agenda Day 2

09:00 AM Review & questions Part 1

09:10 AM Q1A(R2): Stability testing of new drug substances and drug products

- General considerations, batch selection, container closure system, specifications, significant changes, storage conditions, minimum data package for submission, stability commitment, evaluation, statements / labelling, ICH Q1C

10:20 AM Tea / Coffee Break

10:30 AM Q1D: Bracketing and matrixing

- Reduced stability testing, bracketing (strength, container closure sizes and/or fills), matrixing (design factors, examples), potential for reduction

11:00 AM Q1E: Evaluation for stability data

- General principles and statistical approach, prerequisites for extrapolation (decision trees), testing for poolability, evaluation models: individual batch analysis, common slope & individual intercepts, common slope and intercept

11:40 AM Tea / Coffee Break

11:50 AM Workshop

- Simulation, impact of analytical and batch variability, extrapolation, and matrixing on statistical evaluation (shelf-life prediction)

12:45 PM Summary & discussion

Agenda Day 3

09:00 AM Review & questions Part 2

09:10 AM Q5C: Stability of biotechnological products

- Considerations for biotechnological products, differences to Q1A

09:40 AM Stability investigations in the market phase

- EU variations regulation, post-approval changes, on-going stability studies (EU GMP Guide Chapter 6), management of OOS and OOT results

10:25 AM Tea / Coffee Break

10:35 AM Trending in stability investigations

- Regulatory requirements, statistical tools: regression control chart, slope control chart, time-point approach

11:20 AM Validation of stability-indicating analytical procedures

- ICH guideline Q2(R2), performance characteristics & stability considerations, use of stress samples, efficient validation designs

12:05 PM Tea / Coffee Break

12:15 PM Precision from stability

- Analytical procedure lifecycle, calculation of reliable assay repeatability and intermediate precision / reproducibility from stability data, challenges for degradation products

12:45 PM Final discussion & wrap-up