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## Speaker

Dr Joachim Ermer
Ermer Quality Consulting, Germany

# Stability Testing Update: The New ICH Q1 Draft Guideline

## Live Online Training on 18 June 2025


*What's changing – and how to prepare for it*

## Highlights

- Stability Data Expectations for Drug Substances and Drug Products
- Application to Synthetic and Biological Drug Substances and Drug Products, including Vaccines and Advanced Therapy Medicinal Products (ATMPs), and Intermediates
- Development, Formal (primary, commitment, ongoing and product lifecycle) and Supportive (photostability, in-use, short-term) Stability Studies
- Establishment of Re-Test Period or Shelf Life, including Statistical Data Analysis and Extrapolation
- Enhanced Stability Modelling

Learn about new aspects and requirements in the Draft Stability Guideline and prepare for upcoming regulatory expectations

# Programme

## Objective

On 11 April 2025, the new draft of ICH Q1 "Stability Testing of Drug Substances and Drug Products" reached Step 2b of the ICH process. Shortly thereafter, at the end of April, the European Medicines Agency (EMA) also made the draft guideline available for public comment. The comment period ends on 30 July 2025.

The aim of this Live Online Training is to provide you with an overview of changes, new aspects and interpretations of the upcoming regulatory expectations with respect to the stability strategy. Inconsistencies, gaps, and opportunities for improvement will be discussed. The training might also support your assessment for potential implementation challenges and issues and encourage you to participate in the public consultation.

## Background

Stability testing is a fundamental part of pharmaceutical development and quality assurance. It provides evidence on how the quality of a drug substance or drug product varies over time under the influence of environmental factors such as temperature, humidity, and light. Well-designed stability programs are important to support regulatory submissions, product lifecycle management, and risk-based decision-making in the pharmaceutical industry, with a huge economic impact.

The new ICH Q1 Guideline represents a comprehensive revision and consolidation of the former ICH Q1A–F and Q5C Guidelines. The scope was extended to cover both synthetic and biological drug substances and drug products, including vaccines, gene therapies, and combination products. The concepts can also be applied to clinical stability investigations, proportionate to the increasing level of understanding during pharmaceutical development, and to reference standards.
An important extension is the coverage of post-approval changes and the stability life-cycle management, in alignment with the ICH Q12 Guideline. The new Q1 Draft includes all climatic zones and thus can achieve a real worldwide harmonization.
The general principles outlined and discussed in ICH Q1A–F are greatly expanded to biological products to provide much more comprehensive orientation than given in ICH Q5C. Stability considerations for gene therapy products (e.g. Advanced Therapy Medicinal Products (ATMPs) are newly added.
The principles of Quality by Design and risk-based approaches described within ICH Q8 to Q11, and their impact on the overall stability strategy are an important complementation, as for all recent ICH Guideline revisions. This is in particular important for alternative and scientifically justified approaches that encompass the variety of different situations that may be encountered.

## Target Audience

This Live Online Training is aimed at professionals from:

- Quality Assurance and Quality Control
- Regulatory Affairs
- Product and Pharmaceutical Development
- Analytical Development
- Stability Testing Management

who are involved in the design, execution, evaluation, and regulatory submission of stability studies for drug substances and drug products.

## Moderator

Dr Markus Funk
CONCEPT HEIDELBERG, on behalf of ECA

## Programme

### Introduction and General Principles

- Scope and applications
- Types of stability studies
- Intermediates, in-use, and reference standard stability
- Commitments and lifecycle management
- Ongoing stability studies
- Stability of Advanced Therapy Medicinal Products (ATMPs)

### Design of Formal Stability Studies

- Development studies (stress and forced conditions)
- Photostability
- Stability-indicating Critical Quality Attributes
- Batch selection
- Testing frequency
- Climatic zones and storage conditions

### Data Evaluation

- Start of shelf life
- Statistical analysis and extrapolation (fixed effects and mixed effects models)
- Enhanced stability modelling
- Reduced protocol design (Bracketing and Matrixing, commitment studies)

### Summary

- New aspects and requirements
- Challenges, gaps and issues
- Potential for improvements

## Speaker

### Dr Joachim Ermer
Ermer Quality Consulting, Bensheim
Germany

Following study of biochemistry and PhD thesis, 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.

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
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## Stability Testing Update: The New ICH Q1 Draft Guideline, Live Online Training on 18 June 2025

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## Date of the Live Online Training

Wednesday, 18 June 2025, 09.30 – 12.30 h
*All times mentioned are CEST.*

## Technical Requirements

We use WebEx for our live online training courses and webinars. At 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 EUR 590.-
APIC Members EUR 640.-
Non-ECA Members EUR 690.-
EU GMP Inspectorates EUR 590.-
The conference fee is payable in advance after receipt of invoice.

## Registration

Via the attached reservation form, by e-mail or by fax or search and register directly at www.gmp-compliance.org under the number 22412.

## 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.

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21 / 84 44-0
Fax +49(0)62 21 / 84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Markus Funk (Operations Director) at
+49(0)62 21/84 44 40, or at
funk@concept-heidelberg.de

For questions regarding organisation please contact:
Ms Manuela Luckhaupt (Organisation Manager) at
+49(0)62 21 / 84 44 66, or at
luckhaupt@concept-heidelberg.de