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Speaker

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Stability Testing Update: The New ICH Q1 Draft Guideline

Live Online Training on 17 October 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

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 and was released for public consultation. The document is currently under discussion.

The aim of this Live Online Training is to provide you with an overview of changes, new aspects and interpretations of the upcoming regu-latory expectations with respect to the stability strategy. Incon-sistencies, gaps, and opportunities for improvement will be discussed. The training might also support your assessment for potential implementation.

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 investiga-tions, 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

- Historical developments
- Extent of change
- Scope and applications
- Types of stability studies
- Critical Quality Attributes and stability-indicating analytical procedures
- Reference materials
- Stability of Advanced Therapy Medicinal Products (ATMPs)

Design of Formal Stability Studies

- Development studies (stress and forced conditions)
- Photostability
- Batch selection, climatic zones and storage conditions, testing frequency
- Intermediates
- Short-term and in-use stabilities
- Ongoing and lifecycle stability studies, new dosage forms
- Reduced protocol design (Bracketing and Matrixing)

Data Evaluation

- Statistical analysis (fixed & mixed effects models)
- Confidence intervals and batch pooling
- Prerequisites for extrapolation (decision tree)
- Extrapolation for biologicals
- Enhanced stability modelling

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 responsibili-ties included head of laboratory within the analytical drug development at Hoechst AG, Frankfurt, Germany, a global function as Director of Ana-lytical Processes and Technology at Aventis, head of Quality Control and head of QC Lifecycle Management Frankfurt Chemistry, Sanofi, Germa-ny, 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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Reservation Form (Please complete in full)

Stability Testing Update: The New ICH Q1 Draft Guideline, Live Online Training on 17 October 2025

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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Date of the Live Online Training

Friday, 17 October 2025, 09.00 - 12.30 h
All times mentioned are CEST.

Technical Requirements

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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 22482.

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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