IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Stability Testing of Pharmaceuticals and Biopharmaceuticals

19-21 May 27
+ 8-10 November 27

Design efficient stability studies that are suitable for global marketing. Be able to carry out appropriate stability studies and manage stability samples and facilities, learn how to save resources on stability testing and improve the likelihood of regulatory approval of stability protocols.

Format:
Live online

CPD:
18 hours for your records

Certificate of completion

Course overview

Master modern stability testing so that you can design, justify, and defend robust stability programmes fully aligned with the existing ICH Q1A–Q1F + ICH Q1E + ICH Q5C + EU/CPMP & WHO Guidelines and new ICH Q1(Draft).

As products become more complex and supply chains more global, it is crucial to stay up to date with the latest regulatory expectations, statistical approaches, and best practices for stability programme design.

Stability requirements continue to tighten, with the updated ICH Q1(Draft) bringing enhanced clarity around protocol justification, statistical modelling, pooling decisions, and data interpretation. Organisations that fail to modernise their stability programmes risk delays, failed submissions, and avoidable resource costs.

This course will keep you abreast of the latest developments, providing a complete, practical, and scientifically grounded approach for small molecules and biologics alike.

Benefits of attending

- **Understand** the modernised principles and lifecycle concepts introduced in the new draft ICH Q1
- **Learn** how to design scientifically justified stability protocols for global submissions
- **Gain** confidence applying updated statistical tools, pooling rules, and regression approaches
- **Strengthen** your ability to interpret stability trends and identify true instability
- **Master** practical approaches to forced degradation and photostability studies
- **Explore** key degradation pathways and CQAs for proteins and other biologics
- **Improve** your ability to design reduced stability studies (matrixing, bracketing) compliantly
- **Develop** strategies for cold chain, frozen, and transport stability
- **Enhance** your ability to optimise shelf-life assignments and defend decisions to regulators

Who should attend?

- Development scientists
- Analytical chemists
- Stability programme leaders
- QC/QA specialists
- Regulatory affairs professionals
- CMC and technical development teams
- Formulation scientists

Programme

Day 1

Regulatory foundations for stability programmes

- Role of stability in the global pharmaceutical quality system (ICH framework vs. regional requirements
- ICH Stability Framework: Q1A–Q1F, Q1E, and Q5C (How the Guidelines Work Together)
- EU/CPMP and EudraLex expectations for stability

Overview of new ICHQ1 draft

- New proposed structure of the guideline

Stability Study Types , Conditions and Protocols

- Long-term, accelerated, intermediate and in use studies
- Storage conditions and periods requirements
- Connection to ICH Q1B–Q1F

Photostability (ICH Q1B)

- Study design
- Light sources and required exposure
- Problems in light testing

Packaging Considerations

- Current guidelines and requirements for changes
- Demonstration of equivalence
- Permeation examination and interaction studies

Governance of stability samples and facilities

- Sample administration
- Validation of the storage facilities
- Excursions management and OOS

Day 2

Requirements for existing products, line extensions and variations

- Current guidelines (ICH, EU and USA)
- Obligations for Active ingredients and Finished products
- Prerequisites for variations of marketed products

Data treatment, shelf-life assignment and extrapolation

- Requirements for statistical treatment
- Limit of extrapolation and shelf life specifications
- Presentation of data for submission

Matrixing and bracketing stability studies

- ICHQD guidelines
- Bracketing design
- Matrixing design

Bulk stability

- Distinction between intermediates, bulk DS and bulk DP
- Study design and selection of CQAs
- Impact of changes to stability data

Environmental zones considerations

- Selection of study design based on distribution scale
- Regulatory expectations
- Governance of excursions

Day 3

Stability for biopharmaceuticals

- ICHQ 1 for Complex Products
- Application to proteins, peptides and other biologics
- Integrating ICHQ5C considerations

Degradation pathways

- Impact of aggregation and oxidation
- Clipping and deamidation effects on trend analysis and shelf life
- Conditions accelerating biological instability

Analytical and bio assay considerations

- Stability indicating methods
- Potency and bioassay variability
- Trending non -linear responses

Cold chain and frozen storage stability

- Frozen storage, thaw cycles
- Container closure and packaging
- Transport impact

Design of modern stability programme using updated ICHQ1

- Integrated approach for small molecules and biologics
- Shelf life assignment for complex modalities

Course dates

19-21 May 27	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 17199*	GBP **1,599** ~~1,899~~ EUR **2,239** ~~2,659~~ USD **2,571** ~~3,039~~ **Until 24 Mar**
8-10 November 27	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 17464*	GBP **1,599** ~~1,899~~ EUR **2,239** ~~2,659~~ USD **2,571** ~~3,039~~ **Until 13 Sep**

How to book

Online:
ipi.academy/1996

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

I was hoping to gain knowledge and be exposed to different interpretations of the guidelines. I accomplished this. It was a great opportunity to see the guidelines from a pharmaceutical perspective. I enjoyed seeing the tolerances the most, in terms of aspects that do not have specific guidelines but would be considered best practice. I have a positive opinion of the webinar, content and presentation. I also enjoyed the way it was clearly broken down into distinct parts, being able to see the exercises in advance [to help] pay particular attention on those parts, and apply what I have just been taught. The speakers were of high quality, and knowledgeable within the field delivering a highly engaging session.

Kallum Smith
Technical Scientist II - Laboratory Services
ConvaTec Ltd
Nov 10 2025

★★★★☆

The webinar was very informative and the speaker had very good knowledge of the topic covered.

Lucy Barden
QC Analyst
Pets Choice Ltd.
Nov 11 2024

★★★★★

The content of the webinar was good, thorough. Paul answered any questions which I asked. With clear and concise reasoning. He made it easy to follow and not boring for someone with 4 years stability testing experience and basic knowledge. This has given me the tools I need to go back and hopefully improve the stability studies for the future. I enjoyed, I feel like I'm better prepared to justify the requirements of a stability study to my company. With an understanding of how to reduce costs and apply it to the industry I am in.

Elinor Jarvis
Quality Control Team Supervisor
Purolite Ltd
Nov 13 2023

★★★★★

Good speaker and content was very well explained. It met absolutely all my expectations.

Carmen Lopez
SCIENTIST
IMMUNOCORE
Nov 13 2023

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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