IPI Academy

MANAGEMENT forum


*Presented by*
**Management Forum**

# Stability Testing of Pharmaceuticals and Biopharmaceuticals

**21-22 July 2025**
+ 10-11 November 2025

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:**
12 hours for your records

Certificate of completion

# Course overview

## By attending this intensive two-day seminar, delegates will learn how to:

- Carry out appropriate stability studies and manage stability samples and facilities
- Design stability studies that are suitable for global marketing
- Increase the likelihood of studies receiving regulatory approval
- Save resources on stability testing with potential large financial savings

A series of practical exercises will take place throughout the programme to give participants the opportunity to apply their knowledge under the guidance of our experienced trainers.

**Please note that we are delighted to confirm that this course will now also include particulars of the stability of biopharmaceuticals.**

### Benefits of attending

- **Comply** with stability requirements for new and existing drug substances, products and line extensions
- **Gain** knowledge on storage tests, conditions and protocols
- **Learn** how to design highly efficient protocols for global marketing with potentially large financial savings
- **Discover** how to manage stability samples and facilities
- **Understand** what stability testing is required following changes to a product
- **Discuss** data treatment, shelf-life assignment and extrapolation

### Who should attend?

**Personnel involved in:**

- Stability testing of pharmaceuticals and biopharmaceuticals
- The design of stability protocols
- The management of stability samples and facilities
- The development of pharmaceuticals which require stability testing
- The production of regulatory documents which include stability data
- Quality assurance

# Programme

## Day 1

**Background to stability testing and guidelines**

- The rationale for stability testing
- Relevant guidelines

**Storage tests, conditions and protocols**

- Tests for drug substance and product types
- Storage conditions and periods required
- Typical protocols
- Developing global stability protocols
- In-use testing

**Exercise 1: designing a simple stability protocol**

**Management of stability samples and facilities**

- Sample management
- Validation of storage facilities
- How to treat excursions from condition

**Requirements for existing products, line extensions and variations**

- Guidelines available (ICH, EU and USA)
- Requirements for active ingredient
- Requirements for product
- Requirements for variations to marketed products

**Exercise 2: designing a more complex stability protocol**

**Data treatment, shelf-life assignment and extrapolation**

- When is statistical treatment required?
- How much extrapolation beyond real-time data is allowable?
- Presentation of data in submissions
- Setting shelf-life specifications

**Exercise 3: data treatment**

## Day 2

**Light stability testing**

- ICH Q1B guidelines
- Light sources
- Required exposure
- Problems in light testing

**Packaging considerations**

- Guidelines
- Requirements when changing packaging
- Demonstrating equivalence
- Permeation considerations
- Interaction studies

**Exercise 4: packaging**

**Biopharmaceutical stability**

- ICH Q5C and regulatory guidance
- Complexity associated with biopharmaceuticals
- Stability-indicating assays for biopharmaceuticals
- Stability considerations for new modalities

**Sundry considerations**

- Bulk stability
- Manufacture in zones III/IV to be sold in zone I
- Out-of-specification in stability

**Matrixing and bracketing stability studies**

- Bracketing designs
- Matrixing designs
- ICH Q1D guidelines
- What is acceptable for bracketing and matrixing?

**Exercise 5: designing efficient stability protocols**

# Presenter

**Paul Palmer**

Paul R Palmer is a Director / Pharmaceutical Consultant and a practicing EU / UK Qualified Person. He has over 35 years experience in the pharmaceutical industry in the development, manufacture and supply of medicinal products and medical devices.

Throughout his career, Paul has intentionally taken on all opportunities as they arose in order to develop a broad range of knowledge with an in-depth detailed understanding of manufacturing, storage, distribution, research, computerised systems, as well as the facilities and services to support each.

People and systems have always been a core focus, how to ensure best use, optimise and enhance efficiency. He has a level of curiosity rarely displayed in people taking on the qualified person role in pharmaceutical manufacturing. Culture, behaviour and psychology are all significant influences on the systems and processes we implement, but are often ignored.

Paul studied psychology as part of his MSc in 1993 and has always enjoyed observing the world around him with a curiosity that is rarely satisfied.

# Course dates

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|---|---|---|
| **21-22 July 2025** | **Live online**<br>09:30-17:15 **UK (London)** (UTC+01)<br>*Course code 14828* | GBP **1,299** ~~1,499~~<br>EUR **1,819** ~~2,099~~<br>USD **2,087** ~~2,399~~<br>**Until 16 Jun** |
| **10-11 November 2025** | **Live online**<br>09:30-17:15 **UK (London)** (UTC+00)<br>*Course code 15056* | GBP **1,299** ~~1,499~~<br>EUR **1,819** ~~2,099~~<br>USD **2,087** ~~2,399~~<br>**Until 06 Oct** |

## 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 **15% 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

★★★★☆

**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

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★★★★★

**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

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★★★★★

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

**Carmen Lopez**
SCIENTIST
IMMUNOCORE
Nov 13 2023

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★★★★☆

**I not only learned about these topics, but I now have an idea on how to build on this outside of the course. There was a lot of information that was new to me, so at times it was difficult to digest. I will definitely take advantage of the slides provided to go back and review.**

**Tya Keys**
Quality Control Technician
Hyaltech Ltd
Nov 14 2022

## 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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