



Presented by
Management Forum

Stability Testing of Pharmaceuticals and Biopharmaceuticals

10-11 November 2025

+ 20-21 May 2026, 9-10 November 2026

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

Presenters



Paul Palmer

10-11 Nov 2025
09-24 May 2026
9-10 Nov 2026

Paul R Palmer is a Director / Pharmaceutical Consultant and a practicing EU / UK Qualified Person. He has over 25 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, computerized 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.



Farah Nadeem

10-11 Nov 2025

Farah Nadeem is an Operations Manager at Paul R. Palmer Limited/ Pharmaceutical Consultant and a Trainee Qualified Person. Farah is a Pharmacist and recognised QA expert and has over 20 years of experience in the Pharmaceutical industry in the development, manufacture and supply of medicinal products.

Throughout her career, she has held various quality assurance roles and actively pursued new opportunities to expand her knowledge and expertise. As a result, she has gained a comprehensive understanding of manufacturing, storage, and distribution processes, as well as the facilities and services that support them.

Involved in documentation management: writes, reviews, and audits SOPs and QMS implementations. Assists companies in meeting regulatory requirements.

In her current role as a QA Operations Manager for a Pharmaceutical Consultant Company, Farah Nadeem provides various solutions, including assistance in obtaining the first MIA(IMP) and MIA licenses, as well as preparation and hosting for regulatory inspections.

Her work involves collaborating with Paul Palmer to offer services such as QP declarations for API manufacturers, regulatory inspection hosting, commercial and clinical batch release, compliance audits, and coaching and training in GxP.

Course dates

10-11 November 2025	Live online 09:30-17:15 UK (London) (UTC+00) <i>Course code 15056</i>	GBP 1,499 EUR 2,099 USD 2,399
20-21 May 2026	Live online 09:30-17:15 UK (London) (UTC+01) <i>Course code 16280</i>	GBP 1,299 1,499 EUR 1,819 2,099 USD 2,087 2,399 Until 15 Apr
9-10 November 2026	Live online 09:30-17:15 UK (London) (UTC+00) <i>Course code 16501</i>	GBP 1,299 1,499 EUR 1,819 2,099 USD 2,087 2,399 Until 05 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](tel:+442077494749)

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 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



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
Purilite 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



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

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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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