

Stability Testing in Pharmaceutical Development and Manufacturing

22 & 23 May 2012

The Window Conference Venue, London UK

Course objectives

New and important techniques in stability testing are facilitating product development using the Quality by Design approach. Using these it is possible to develop products more quickly and reliably, through improved methods of shelf life prediction and excipient testing. New stability testing protocols using the published ASAP method from Pfizer can generate information quickly and reliably. The purpose of this course is to give a comprehensive, integrated overview of pharmaceutical stability testing in a highly interactive, relaxed environment:

- Why is stability testing required for product registration and GMP purposes?
- What are the requirements for Clinical Trials, new, and existing products?
- How can stability testing be applied during product development to shorten development times as well as improve product quality
- Stability testing outsourcing - successful management and execution

It will include:

- A comprehensive review of ICH stability testing guidance ICH Q1A
- Pitfalls in stability testing. Outsourcing—costs and benefits
- New approaches to stability testing including ASAP and the role of peroxides in product stability
- Stability Testing and QbD
- Workshops for attendees to present and discuss their own stability testing issues with the group

Speaker:

Dr Michael Gamlen is Managing Director of Pharmaceutical Development Services Ltd, a pharmaceutical consultancy based in Nottingham (UK). Dr Gamlen has over 30 years experience of tablet development. Awarded a First Class Honours degree in Pharmacy, specialising in Pharmaceutical Engineering, he studied for a PhD at Nottingham University. He was Head of Tablet Development at the The Wellcome Foundation for 15 years, and worked as an outsourcing manager before starting his consultancy business in 2000.

Dr Gamlen specialises in managing product development, formulation, tablet and process development studies. He has been teaching professional tableting courses for many years and his courses are highly rated, exceeding the expectation of the participants in many cases.

Michael continually updates the content of his courses with the latest guidance and extracts of up-to-the minute scientific papers.

He provides a substantial body of relevant literature to all course participants as well as copies of all notes and guidance used and a workbook. He is a popular and highly respected presenter.

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Who will benefit:

The course is designed for people working in:

- Analytical and Product Development
- Analytical Chemistry
- Stability Testing
- Formulation Development
- Regulatory Affairs
- Pharmaceutical & Biopharmaceutical Production
- Quality Control and Quality Assurance
- Technical Operations

Course Programme

Day 1

Introductions

- The life cycle approach to product development and Quality by Design
- Stability testing in product development
- ICH Q6 – specifications, and how to set them. Role of specifications in stability testing. Alternative approaches to deriving specifications

Lunch

- ICH Guidance Q1A (R2) – a comprehensive review
- Case study
“Effect of Processing and Formulation Variables on the stability of a salt of a weakly basic drug candidate (tablet)” – Badawy et al, BMS
- EU GMP guidance on stability testing

DAY 2

- Evaluation of stability data – ICH guidance Q1E. Identifying out of trend data. Alternative approaches.
- Data interpretation case studies including attendee problems

Lunch

- Bracketing and matrixing designs for stability testing of new drug substances and products - ISC Q1E
- Photostability testing—Q1B
- Action Planning and Final Q&A

Workshop and examples based on delegate’s interests

Group discussion, problem solving and consultancy

Additional Resources

Online access to comprehensive publications including all relevant guidance will be provided as well as colour copies of all presentations and case studies .



COMMENTS FROM PREVIOUS ATTENDEES

“Very good course, would recommend PharmaTraining”

“Very interesting and interactive”

“Good content and delivery”

Venue

Window Conference Venue 13 Windsor Street, Islington London, N1 8QG
convenient for central London, in a pleasant informal setting. *Our preferred venue*

Course fee includes all course materials, refreshments and lunch, accommodation is not included.

Accommodation and travel directions are available on our website

www.pharma-training-courses.com

For 5 or more staff requiring training it may be beneficial to run a course in-house.

The benefits of running a course in-house:

- Up to 70% savings on delegate fees
- Save on travel or accommodation costs
- Customised content to meet your requirements
- Big print savings on course material - especially with larger groups
- Courses arranged for large groups up to 24 staff
- Tutorials available for small groups of 2 or 3 staff
- Meet course speakers in advance to discuss design and content

Contact **Judy Callanan** at any time to discuss

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We deliver a range of expert programmes in pharmaceutical development, quality assurance and regulatory topics, plus a range of industry awareness courses. We employ speakers/trainers with a high degree of expertise, completely up to date with industry trends. *Please check our website for other courses added throughout the year.*

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Keep up to date with industry requirements

REGISTRATION DETAILS

Stability Testing in Pharmaceutical Development and Manufacturing:

22 & 23 May 2012 - London

November 2012 - London (date to be confirmed)

2 day course £1180.00 (+ VAT £236.00 if applicable, see VAT NOTES)

2 day course £1062.00 (+ VAT £212.40 if applicable, see VAT NOTES)

if booked and paid eight weeks prior to course commencement

A reduced rate is available if also booking Pharmaceutical Packaging an introductory course or Introduction to Photostability November 2012 (date to be confirmed)

Discount of 10% applies for booking 8 weeks in advance

Discount of 10% applies for booking more than 1 delegate

Discount of 10% applies for booking more than 1 course

Maximum discount received is 15%

VAT NOTES:

UK: Under UK law all UK-based applications are subject to VAT at the prevailing rate however most UK VAT registered companies/organisations can reclaim this tax.

EU: With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT PROVIDED THAT valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.

OTHER: With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT, ie no VAT is charged or payable.

Methods of Payment available:

Cheque (Please make payable to PharmaTraining Ltd)

Bank transfer

Credit/Debit Card (Paying by Credit Card please register online)

Registration is available online:

http://www.pharma-training-courses.com/stability-testing-in-pharmaceutical-development-and-manufacture_10.htm

www.pharma-training-courses.com

Data Protection

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Terms and Conditions

Delegate fees: Fees for this programme or suite of programmes are shown overleaf. Delegate fees are inclusive of course documentation, refreshments and lunch. Payment of the registration fee must be paid within 14 days of commencement of the course. Upon receipt of payment, a proof of payment will be sent to you.

Cancellation Policy: Full refunds less a handling fee of £100 will be made for cancellations received in writing within 28 days of the commencement of the course. Refunds of 50% will be made for cancellations received in writing between 28 and 7 days prior to the commencement of the course. Regrettably no refunds will be made after 7 days prior to commencement. Substitutions can be made at any time.

Liability: PharmaTraining Ltd reserves the right to change the programme, speakers, date or venue without notice or cancel the event. If cancellation occurs delegates will be notified as soon as possible and will receive full refund of fees paid.

PharmaTraining Ltd will not be responsible for any airfare, accommodation or other travel costs incurred.

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