

Stability Testing in Pharmaceutical Development and Manufacturing

16 & 17 May, 12 & 13 December 2011
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.

PharmaTraining

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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

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

- ICH Q6 – specifications, and how to set them. Role of specifications in stability testing. Alternative approaches to deriving specifications
- 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.

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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Email: judy@pharma-training-courses.com

COURSE PROGRAMME 2011

Planning for Commercial Launch: 29 & 30 March 2011

GMP Auditor Training: New Jersey USA - 11 & 12 April 2011

London - 9 & 10 May, 7 & 8 November 2011

How to Audit API Manufacturers: New Jersey USA - 13 April 2011

London - 11 May, 9 November 2011

Supply Chain Management in Pharma/Biotech: 5 & 6 May 2011

Technology Transfer: London - 9 & 10 May, 7 & 8 November 2011

Integrated Tablet Formulation Development: New Jersey USA - 7 & 8 April

London - 9 & 10 June, 24 & 25 November 2011

Tablet Process Development, Validation and the application of QbD:

New Jersey USA - 11 & 12 April, London - 13 & 14 June, 28 & 29 November

Pharmacokinetics in Drug Development - an Integrated Approach:

9 & 10 June 2011

An Introduction to LC-MS: 19 September 2011

Quantitative Bioanalysis using LC-MS: 20 & 21 September 2011

Writing effective SOPs in a GMP Environment: 13 & 14 October 2011

OOS investigations in a GMP Environment: 18 & 19 October 2011

Stability Testing in Pharmaceutical Development: 16 & 17 May 2011,

12 & 13 December 2011

Introduction to Photostability: 14 December 2011

Pharmaceutical Packaging - an introductory course:

14 December 2011

HPLC Analytical Method Development and Validation:

22 & 23 November 2011

Oral Solid Dosage Manufacturing Technology: 28 November 2011

Development and Manufacture of Effervescent Tablets:

30 November

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Keep up to date with industry requirements

REGISTRATION FORM

Stability Testing in Pharmaceutical Development and Manufacturing:

16 & 17 May 2011 (*early-bird registration 18 March 2011*)

☐

12 & 13 December 2011 (*early-bird registration 14 October 2011*)

☐

2 day course £1180.00 + VAT £236.00

Total £1416.00

☐

2 day course £1062.00 + VAT £232.40

Total £1294.40

☐

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” 14 December 2011

☐

3 day course - ***at the reduced rate of*** £1611.00 + VAT £322.20 **Total £1933.20**

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%

Title (Mr/Mrs/Ms/Dr/Prof):

First Name:

Surname:

Company:

Job Title:

Address:

Post Code:

Country:

Tel:

Fax:

Email address:

Signature:

Method of Payment:

☐ Cheque (**Please make payable to “PharmaTraining Ltd”**)

☐ Bank transfer

☐ Credit/Debit Card (If paying by Credit Card please register online)

Online Registration is available on our website:

www.pharma-training-courses.com

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