



## Stability Testing in Pharmaceutical Development and Manufacturing

28 & 29 June 2010

The Window Conference Venue, London UK

### Course objectives

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 required?
- What are the requirements for Clinical Trials, new products, and existing products?
- How can you ensure that your programme meets worldwide requirements?

It will include:

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

### Who will benefit:

The course is designed for people working in:

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

### 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.

### COMMENTS FROM PREVIOUS ATTENDEES

“Very good course, would recommend PharmaTraining”

“Very interesting and interactive”

“Good content and delivery. Questions answered competently and found additional information on specific questions not covered directly in course notes”

### PharmaTraining

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## Course Programme

### DAY 1

Stability testing in the new world of QbD

- Stability testing and the Lifecycle approach to product development
- Formulation development
- Manufacturing

History of stability testing

- How we got to where we are
- Role of ICH

Overview of ICH guidance relevant to stability testing

- Stability testing
- Impurities
- Specifications

LUNCH

Detailed review of ICH stability testing documents ICH Q1A

Defining and setting specifications – ICH Guidance Q6A

- Preclinical
- Clinical trial
- Product registration

ASAP – a new approach to stability testing the drug product

Question and Answer session

### DAY 2

Matrixing and bracketing pitfalls and purpose – ICH guidance Q1D

Quality systems issues

- Safeguarding data quality

Shelf lives and expiration dating – interpreting and using data.

- Applying ICH Guidance Q1E

Out spec and out of trend data. Assessing outliers.

LUNCH

Photostability testing of new dosage forms ICH Q1B

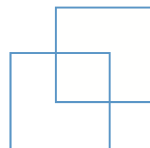
- History, purpose and implementation of guidance

Applications/case studies

- Case 1 syrup preformulation paper
- Case 2 tablet formulation selection
- Case 3 Definitive testing
- Case 4 Busulfan liquid

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.

## 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, lunch and course dinner or social activity, accommodation is not included.

Accommodation and travel directions are available on our website

[www.pharmatrainingsservices.com](http://www.pharmatrainingsservices.com)



## COURSE PROGRAMME 2010

GMP Auditor Training 19 & 20 May 2010  
How to Audit API Manufacturers 21 May 2010  
Technology Transfer 19 & 20 May 2010  
Integrated Tablet Formulation Development 10 & 11 June 2010  
Process Development, Validation and QbD 14 & 15 June 2010  
Development and manufacture of effervescent tablets 16 June 2010  
Pharmaceutical Documentation—a practical approach 17 & 18 June 2010  
Stability Testing in Pharmaceutical Development 28 & 29 June 2010  
Introduction to Photostability 30 June 2010  
An Integrated Approach to Pharmacokinetics in Drug Development 28 & 29 June  
GMP Auditor Training 10 & 11 November 2010  
How to Audit API Manufacturers 12 November 2010  
Technology Transfer 10 & 11 November 2010

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.*

**We offer:** *Moderate prices, small classes, knowledgeable speakers with many years of industry experience. We purposefully limit the number of speakers and attendees for each course to facilitate the building of a relationship between all parties in order to create a better learning environment.*

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  
Ph: 0044 20 7193 7703, Fax: 0044 20 7681 3582

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## REGISTRATION FEES

### Stability Testing in Pharmaceutical Development and Manufacturing:

28 & 29 June 2010—London

2 day course £1160.00 + VAT £203.00

Total £1363.00

### Stability Testing in Pharmaceutical Development and Manufacturing

28 & 29 June 2010—London

**Discounted** rate for registering and paying before **Friday 30 April 2010**

2 day course £1044.00 + VAT £182.70

Total £1226.70

If you are interested in this course you may also be interested in the one day course

**Introduction to photostability 30 June 2010**, the course will cover:

- Why do we do photostability tests?
- Concepts and background in photostability
- Identifying drug substances most likely to absorb light and display signs of poor photostability
- Understanding photostability terminology
- Where does photostability fit in the overall stability testing program?
- Why does photostability matter? (exercise)

Further details are available on our website



**Online Registration is available on our website:**

[www.pharmatrainingsservices.com](http://www.pharmatrainingsservices.com)

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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, lunch and course dinner. 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 of the course. Substitutions can be made at any time.

#### Liability

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

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