Introduction to Photostability

14 December 2011
The Window Conference Venue, London UK

Course objectives

All PharmaTraining courses focus on two key objectives. These are to provide attendees with knowledge - information, which will assist you in making better judgements - and skills, which will allow you to **apply** the knowledge you have received. We guarantee to engage your interest and commitment on the course, and we expect our training to improve your effectiveness.

About this course

The purpose of this course is to give an overview of photostability,and where it fits in the stability testing programme and the importance of photostability. The course is highly interactive and held in a relaxed environment.

It 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 phototstability fit in the overall stability testing program?
- Why does photostability matter? (exercise)

Who will benefit:

The course is designed for people working in:

- Analytical Development
- Analytical Chemistry
- Stability Testing
- Technical Operations
- Research and Development Chemistry
- QA/QC
- Formulation Development
- Pharmaceutical & Biopharmaceutical Manufacturing/Production
- Product Development
- Regulatory Affairs
- GLP/GMP Compliance

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 product stability testing. 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 tabletting 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
BioCity Nottingham
Pennyfoot Street
Nottingham NG1 1GF
United Kingdom

Tel: ++44 (0)1159 124249
Fax: ++44 (0)20 7681 3582

info@pharma-training-courses.com

Introduction to Photostability
14 December 2011
The Window Conference Venue, London UK

Course Programme

Coffee and registration will be available from 8.30am on Wednesday 14 December, course proper will commence at 9.00am. We anticipate the course will finish at 5.00pm..

Formulating and manufacturing unstable products

- Formulation development and evaluation for photolabile materials
- Protection during the manufacturing process
- Getting the product to the patient

ICH guidelines for photostability testing: Using ICH Q1B guidance in practice

- understanding the terms and procedures used in the guideline

Practicalities

- Light source selection - Options 1 and 2
- Sample presentation
- Humidity and temperature control
- Selecting sample containers

Forced degradation: Practical and regulatory aspects of photostability stress testing

- Selecting experimental conditions for stressing samples with respect to light

Meeting regulatory requirements

- Documentation – principles and practice
- Stability testing and the Quality System
- SOPs for stability testing
- Equipment validation and calibration – do the chambers work?
- Protocol development and approval

Reporting stability test data

Delegate Workshop

Problems and issues for discussion

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 and lunch, accommodation is not included.

Accommodation and travel directions are available on our website
www.pharma-training-courses.com

PharmaTraining Ltd is Registered in England and Wales No. 4235908

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
HPLC Analytical Method Development and Validation: *22 & 23 November*
Oral Solid Dosage Manufacturing Technology: *28 November 2011*
Development and Manufacture of Effervescent Tablets: *30 November 2011*
Introduction to Photostability: *14 December 2011*
Pharmaceutical Packaging - an Introductory Course: *14 December 2011*

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.*

Delegate fees

Fees for this programme 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 of the course. 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.

PharmaTraining
BioCity Nottingham
Pennyfoot Street
Nottingham NG1 1GF
United Kingdom

Tel: ++44 (0)159 124249

Fax: ++44 (0)20 7681 3582

info@pharma-training-courses.com

REGISTRATION FORM

Introduction to Photostability:
14 December 2011 - London
2 day course £610.00 + VAT £122.00 **Total £732.00** ☐

Introduction to Photostability:
14 December 2011 - London
Discounted rate for registering and paying before **18 October 2011**
1 day course £549.00 + VAT £109.80 **Total £658.80** ☐

Reduced rate of 10% if also booking ***Stability Testing in Pharmaceutical Development and Manufacture*** ☐

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 _____ First name _____

Surname: _____

Position: _____

Company: _____

Address: _____

_____

_____

Post Code: _____ Country: _____

Tel: _____ Fax: _____

Email address: _____

Signature: _____

Method of Payment

☐ Cheque - **Please make payable to "PharmaTraining Ltd"**

☐ Bank transfer

☐ Credit Card

Online Registration is available on our website:
www.pharma-training-courses.com

.

Please send completed registration forms and payment to Registrations at →

PharmaTraining
BioCity Nottingham
Pennyfoot Street
Nottingham NG1 1GF
United Kingdom
Tel: ++44 (0)1159 124249
Fax: ++44 (0)20 7681 3582
info@pharma-training-courses.com