Stability Testing in Pharmaceutical Development and Manufacturing

The Baltic Exchange
London UK
11 & 12 December 2007

Pharmaceutical Development Services

Course objectives

The purpose of this course is to give a comprehensive, integrated overview of pharmaceutical stability testing

- 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
- Interpreting data using statistics
- Pitfalls in stability testing
- Outsourcing—costs and benefits

Who should attend

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

Numbers in our courses are limited to ensure that participants have the opportunity for thorough discussion of the issues to be covered and individual attention from our top-ranked Speakers

Course Speakers

Dr Michael Gamlen is Managing Director of Pharmaceutical Development Services Ltd, a Guildford-based technical consultancy. 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 has since worked for Vanguard Medica Ltd and as a consultant. He specialises in managing product development, formulation, tablet and process development studies. He has been teaching professional courses for many years.

Philip Rabone is a Consultant and a well-qualified Chartered Chemist with over 20 years experience in the field of Analytical Development, Stability Testing, Quality Assurance, Regulatory Compliance and all aspects of documentation and procedures associated with the Pharmaceutical Industry.

Presented by:

PharmaTraining Services

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Course Programme

DAY 1

Stability testing in context – what we do and why
- Preclinical
- Clinical trial
- Formulation development
- Product registration
- Post approval

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
- Specification

Detailed review of ICH stability testing documents ICH Q1A

Analytical Method Selection and Development

LUNCH

Defining and setting specifications – ICH Guidance Q6A
- Preclinical
- Clinical trial
- Product registration

Analytical Method Validation
- Key techniques
- Method Selection
- Outsourcing of stability testing

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

Group discussion, problem solving and consultancy

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Venue

The Baltic Exchange, 38 St Mary Axe, London EC3A 8BH

The Baltic Exchange is situated within a five minute walk to Liverpool Street Station in the heart of the City of London with easy access to all the well known sights.

Hotel accommodation is not included in the course fee and should be booked and paid for separately.

A list of nearby hotels is available on request.

Terms and conditions

Delegate fees

Fees for this programme are shown overleaf. Delegate fees are inclusive of course documentation, refreshments and lunch as well as 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

PharmaTrainingServices 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.

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

Course Calendar Autumn 2007

- Molecules to Markets—London
- Integrated Tablet Formulation and Development—Copenhagen Denmark
- Tablet Process Development and Validation—Copenhagen Denmark
- GMP Auditor Training—London
- How to Audit API Manufacturers—London
- The Challenges and Formulation Strategies for Poorly Soluble Drug Substances—London
- Strategic Marketing—London
- Customer Focused Project Management—London
- Stability Testing in Pharmaceutical Development and Manufacturing—London

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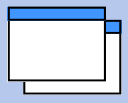

www.pharmatrainingservices.com

We deliver a range of expert programmes in pharmaceutical development, quality assurance and regulatory topics, plus a new range of industry awareness courses. We employ speakers/trainers with a high degree of expertise, completely up to date with industry trends.

We run our programmes in a variety of locations, throughout the year. All of our programmes can be run in-house.

Contact **Judy Callanan** by email or telephone at any time to discuss.

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REGISTRATION FORM

I wish to register for the following course	Please tick
Stability testing in pharmaceutical development and manufacturing: 2 day course £1160 + Vat £ 203 Total £1363.00	

Total payable £

Title (Mr/Mrs/Ms/Dr/Prof): _____ First name _____

Surname: _____

Position: _____

Company: _____

Address: _____

_____

Post Code: _____ Country: _____

Email address: _____

Tel: _____ Fax: _____

Signature: _____

Method of Payment

☐ Cheque **(Please make cheque payable to "JA Conference Management")**

☐ Bank transfer **Quoting Reference No. 719**
JA Conference Management
Barclays Bank, Muswell Hill & Crouch End Branch
Sort Code: 205851 **Account No:** 10245038

☐ Credit/Debit Card

Card Number: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Expiry Date: _ _ _/_ _ _/_ _ _

Cardholder: _____

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Signature: _____

For security purposes please supply Security Code separately (email)

Data Protection
PharmaTraining Services gathers personal data for the sole purpose of informing you about our products and services. We do not sell on or share this information with any other organisation.

Please send completed registration forms and payment to:
Judy Callanan at:

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