Stability Testing in Pharmaceutical Development and Manufacturing
1 & 2 April 2009

Analytical Method Development and Validation
3 April 2009

This suite of courses is designed to give a comprehensive, integrated overview of pharmaceutical stability testing and method development and validation requirements that are essential to progress a pharmaceutical compound, at each stage of product development.

The Window Conference Venue
13 Winsor Street, Angel Islington London N1 8QG

The venue is situated 10 minutes from St Pancras Eurostar Terminal providing easy access from Europe

Speakers:

Dr Michael Gamlen
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. Dr Gamlen specialises in managing product development, formulation, tablet and process development studies. He has been teaching professional courses for many years.

Dr Roland Collicott is the senior consultant and founder of Chalpharm consultancy. Roland has a broad background in pharmaceutical R&D. He is widely experienced in analytical method development and validation and other CMC issues to regulatory requirements. Having worked in a range of pharmaceutical companies: Glaxo, British Biotech and OSI Pharmaceuticals, Roland has demonstrated an adaptability and flexibility and has achieved a number of successes in his career. Roland is also a very experienced conference speaker and trainer.

***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.*

PharmaTraining Services

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Stability Testing in Pharmaceutical Development and Manufacturing 1 & 2 April 2009

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
- New approaches to stability testing.
- Stability Testing and QbD

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

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

Speaker: Dr Michael Gamlen

Additional Resources

An extremely comprehensive memory stick will be provided containing guidelines as well as colour copies of all presentations and case studies

Analytical Method Development and Validation
3 April 2009

Analytical methods must be validated to provide reliable data for regulatory submissions. These methods are essential for a number of purposes, including testing for QC release, testing of stability samples, testing of reference materials and to provide data to support specifications.

This course provides a comprehensive coverage of the method development and validation requirements that are essential to progress a pharmaceutical compound, at each stage of product development.

Upon completion of this course, delegates will have learned what is necessary to develop and validate methods for drug substance and drug product to comply with international regulatory guidelines.

Course Programme

Requirements for a stability-indicating analytical method

- Anticipation of likely degradation products
  - From experience with compound
  - From forced degradation (stress testing) of drug substance, as per ICH guidance
  - What problems may be anticipated with likely degradation products?
  - Are degradation products likely to be enantiomers or diastereoisomers?

Analytical method development

- Specificity: peak purity determination (Diode array and MS detectors)
- Reminder of the importance of resolution, separation factor (selectivity), capacity factor and column efficiency).
- Selecting the column for analysis
- Selecting the mobile phase (optimise pH etc)
- Gradient/isocratic operation appropriate?
- Calculation of mass balance and its significance
- Avoiding false identification, particularly in drug product analysis
- Consideration of ICH Q3A/B (identification of deg prods > identification threshold)
- Other attributes to be monitored during the stability study?

Validation of stability-indicating analytical method

- To ICH Q2(R1)
- Intro/reminder of parameters to be validated
- Extent of validation
- Acceptance criteria
- Validation procedures and protocols
- Dealing with validation failures

Transfer of stability-indicating analytical method

- In-house or external transfer
- Which parameters should be compared between originator and second lab?
- Comparative testing or re-validation?
- Reference standards and samples
- The process and communication
- Transfer protocols and acceptance criteria
- Typical pitfalls in method transfer
- What if the acceptance criteria are not met?

Stability study documentation

- Designing the ideal stability study
- The stability protocol
- The stability report

Speaker: Dr Roland Collicott

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 Services 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.

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REGISTRATION FORM	
Please select the course you wish to book:	
Stability Testing in Pharmaceutical Development and Manufacturing: 1 & 2 April 2009—London 2 day course £1160 + VAT £174 Total £1334.00	
Analytical Method Development and Validation 3 April 2009—London 1 day course £600 + VAT £90 Total £690.00	
Stability Testing in Pharmaceutical Development and Manufacturing *and* **Analytical Method Development and Validation** 1, 2 & 3 April 2009—London 3 days at the reduced rate of £1584 + VAT £237.60 Total £1821.60	
I would like to claim a 10% discount for booking before Friday 30 January 2009	

Total payable £_____

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

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

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