HPLC Analytical Method Development and Validation
22 & 23 November 2011

Window Conference Venue, London

Overview

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.

The course is designed for

Scientists working with HPLC who need to further their understanding of the technique in order to develop better methods faster. Scientists who have to validate methods HPLC methods in accordance with current internationally-accepted guidance. HPLC technicians working in R&D laboratories, quality control laboratories and stability testing laboratories. Managers with a responsibility for generating regulatory submissions.

Speaker:

Dr Roland Collicott, as an experienced consultant and trainer, provides assistance to the pharmaceutical industry in the areas of chiral analysis , polymorphic characterisation, stability studies, chemical analysis in a GMP environment, specifications and all aspects of international CMC documentation. He also runs training courses to cover many areas of analytical chemistry, particularly in chromatography, chiral and polymorphic analysis. He has served as an expert witness and consulted in trials in Canada, UK, South Africa and Germany.

Before becoming a consultant Roland was analytical section manager at OSI Pharmaceuticals responsible for delivering validated analytical chemistry methods and CMC documentation for OSIs regulatory submissions. In this role, he was responsible for collating and interpreting data from a wide range of analytical techniques, acquired in-house or at contract, for the characterisation of new compounds. There he also gained valuable international experience, working closely with regulatory and clinical groups as well as manufacturing and analytical contractors in Asia, Europe and the US.

Roland began his career in physical chemistry at Glaxo Group Research and originally specialised in chromatography, introducing the use of chiral HPLC columns to resolve enantiomers. He gained a PhD from his research into novel silicon-based chiral derivatisation reagents for HPLC, GC and NMR analysis. In 1998 he joined British Biotech, where he became involved in many other areas of analytical chemistry including polymorphism in pharmaceutical products. As Group Leader, he managed British Biotech's QC procedures, stability testing and the analytical development of its NCEs.

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Course Programme

DAY ONE

Analytical method development, part 1

- Theory and factors affecting resolution – a reminder of the importance of resolution, separation factor (selectivity), retention factor (capacity factor) and column efficiency).
- Selecting the HPLC separation mode (reversed-phase, normal-phase *etc.*)
- Overview of instrumentation
- Selecting the most appropriate detector
- Troubleshooting

Workshop: Selecting the separation mode

Analytical method development, part 2

- Gradient/isocratic operation appropriate?
- Selecting the column for analysis
- Selecting and optimising the mobile phase
- The effect of pH, considering pKa of the analyte

Workshop: Selecting the column and mobile phase

End of Day One: Group discussion

DAY TWO

Developing stability-indicating methods

- 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
  - Note findings of stress-testing industry comparison
  - Are degradation products likely to be enantiomers or diastereoisomers?
- Calculation of mass balance and its significance

Workshop: Developing stability-indicating methods

Validation of chromatographic methods, part 1

- Introduction to ICH guidelines: ICH Q2(R1)
- A detailed discussion on the parameters to be validated:
  - Specificity: peak purity determination (Diode array and MS detectors)
  - Linearity
  - Range
  - Accuracy
  - Precision
  - Detection Limit
  - Quantitation Limit
  - Robustness

Validation of chromatographic methods, part 2

- Extent of validation: how much work at each phase of development?
- Acceptance criteria
- Validation procedures and protocols
- Dealing with validation failures

Workshop: Validation of chromatographic methods

End of Day Two: Group discussion and close

The course will include interactive workshops

Venue

Window Conference Venue 13 Windsor Street, Islington London, N1 8QG convenient for central London, in a pleasant informal setting.

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

Terms and Conditions:

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.

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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 Analysis: 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
Oral Solid Dosage Manufacturing Technology: 28 November 2011
Development and Manufacture of Effervescent Tablets: 30 November 2011
Hands-on Tabletting: date to be advised

We deliver a range of expert programmes in pharmaceutical development, quality assurance and regulatory topics, plus a range of industry awareness courses.

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Keep up to date with industry requirements

REGISTRATION FORM

HPLC Analytical Method Development and Validation :
22 & 23 November 2011, London —2 day course
2 day course £1180.00 + VAT £236.00 **Total £1416.00** ☐

HPLC Analytical Method Development and Validation :
22 & 23 November 2011, London
Discounted rate for registering and paying before **26 September 2011**
2 day course £1062.00 + VAT £232.40 **Total £1294.40** ☐

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:
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