

HPLC Analytical Method Development and Validation

27 & 28 November 2012

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

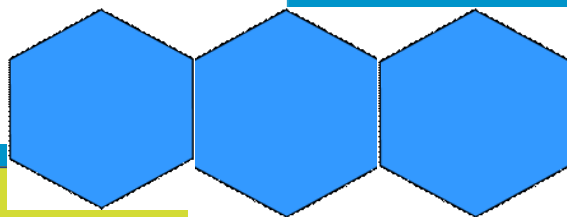
Scientists working with HPLC who need to further their understanding of the technique in order to develop better methods faster. Scientists who have to validate HPLC methods in accordance with current internationally-accepted guidance. HPLC technicians working in R&D laboratories, quality control laboratories 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 OSI's 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
- New column technologies
- 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
- A review of other companies' procedures

Workshop: Developing stability-indicating methods

- Overview of Chiral Separations
- Chiral separation by HPLC

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
 - System suitability testing

The course will include interactive workshops

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



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.

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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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Keep up to date with industry requirements

REGISTRATION FORM

HPLC Analytical Method Development and Validation :

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Early-bird fee: 2 day course £1062.00 (+ VAT £212.40 if applicable, see notes on VAT)
For registering and paying before **2 October 2012**

Full Fee: 2 day course £1180.00 (+ VAT £236.00 if applicable, see notes on VAT)

UK: Under UK law all UK-based applications are subject to VAT at the prevailing rate however most UK VAT registered companies/organisations can reclaim this tax.

EU: With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT **PROVIDED THAT** valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.

OTHER: With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT, ie no VAT is charged or payable.

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%

Methods of Payment available:

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Bank transfer

Credit/Debit Card (If paying by Credit Card please register online)

Online Registration is available on our website:

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