

HPLC Analytical Method Development and Validation

15 & 16 October 2019, London UK

Good HPLC methods must satisfy both technical requirements (sensitivity, specificity, linearity, accuracy and precision) as well as business needs (reliability in routine use and a run time appropriate to the number of samples to be tested). These requirements are equally important in both a development and routine QC context: decisions during drug development must be based on reliable data, and routine QC testing, including stability studies, must control risks to product quality and patient safety.

This course presents a logical, step-wise approach to the development of HPLC methods (Day 1) and then explains how to validate chromatographic methods in line with regulatory expectations and best practice (Day 2).

The course is intended for analytical scientists who have experience of operating HPLC instrumentation.

Speaker:

Dr Mark Powell

Mark is a Fellow of the Royal Society of Chemistry with over twenty years' experience as an analytical chemist. His PhD project involved the characterisation of bitumen by chromatographic, spectroscopic and thermal methods, providing a good grounding in a wide range of analytical techniques.

He then worked for five years in the environmental industry, with responsibility for the development of analytical methods capable of quantifying very low levels of pollutants in drinking water and a variety of other sample types.

Having joined Liverpool John Moores University's School of Pharmacy and Chemistry in 1997 as a Senior Lecturer, Mark was responsible for the University's MSc programme in analytical chemistry, and was also active in research and consultancy.

In 2003, he joined the newly-formed Quay Pharmaceuticals, a contract research and manufacturing organisation specialising in early-stage drug development, where he was responsible for analytical development. Since 2010, as Scientific Manager, Mark was involved more generally with drug development programmes and also established collaborations with a number of UK universities and instrument manufacturers. His work at Quay has resulted in a number of published papers and presentations at scientific conferences.

The 2 day course '**HPLC Analytical Method Development and Validation**' is designed to follow the 1 day course '**Development Stability-Indicating HPLC Methods**'. On 14 October 2019

Reduced rates are available for booking both courses.



HPLC Analytical Method Development and Validation

Course Programme

Day One

Revision of chromatographic theory

- Separation modes
- Factors affecting resolution
- Peak symmetry
- Band broadening
- The effect of particle size and extra-column volume on efficiency

Important chemical concepts

- Factors affecting analyte/stationary phase interactions (polarity, hydrogen bonding and pKa)
- Stationary phase endcapping

Analyte properties affecting pKa, solubility and detectability

Workshop: reading solute structures

Matrix properties

- Effect on extraction
- Chemical interference
- Selectivity and detector wavelength
- Injection solvent strength

Method performance requirements

- Defining method performance requirements
- Measurement uncertainty vs. specification limits

Sample preparation

- Selective sample preparation
- Choice of filter membrane
- Chemical and physical stability of samples

Developing the separation

- Starting conditions for different separation types
 - * Neutral/ionisable organic molecules
 - * Special cases
- Separation modes: isocratic, gradient, ion pairing/suppression, HILIC, aqueous normal phase, normal phase, ion exchange and size exclusion
- Retention mechanisms
- Choice of stationary phase (including silanol activity considerations)
- Mobile phase pH and solute pKa
- Choice of pH buffer
- Temperature effects
- Core-shell and UHPLC columns
- Detector selection

Gradient elution

- When to use gradient elution
- Significance of gradient delay volume
- Retention and resolution models in gradient separations
- Gradient profile optimisation
- The effect of column dimensions and temperature
- Step-wise gradient method development strategy

Case studies

Workshop: selecting starting conditions for method development

Day 2 – HPLC Method Validation

Regulatory guidance (ICH, US, EU, WHO)

Validation terminology

Setting meaningful acceptance criteria

- Acceptance criteria based on specification limits
- Measurement uncertainty and sources of error
- Typical acceptance criteria
- Lifecycle approach to method validation: Analytical Target Profile (ATP) and analytical control strategy

Experimental approaches to method validation

- Specificity: with and without impurity standards
- Linearity: best practice
- Use of spiking experiments
- Options for evaluating sensitivity
- Recommended robustness experiments

Phase-appropriate method validation

Workshop – setting method validation acceptance criteria

Writing effective analytical methods, validation protocols and reports

- Pre-validation check-list
- Contents of method and validation documentation
- Mistake-proofing analytical methods

Dealing with validation failures

Setting system suitability criteria

- Regulatory guidance
- Statistically-based methods

Verifying compendial procedures

- Regulatory guidance
- Approaches for different method types

Workshop – planning a method validation exercise



Development of Stability-Indicating HPLC Methods

14 October 2019, London UK

Overview

Stability testing is an essential part of drug development which ensures the quality, safety and efficacy of the drug for the lifetime of the drug product.

Appropriate storage conditions can only be assessed once a stability study has been conducted and it is never too early to start gathering stability data. Stability studies are a pharmacopoeial requirement and guidance is provided by regulatory authorities, including ICH.

This course provides a comprehensive review of the considerations relevant to developing a stability-indicating analytical method, principally focussing on analysis by HPLC. This course starts by anticipating likely degradation based on chemical structure. Consideration is then given to forced degradation (stress study) to produce likely degradants, followed by the selection of an HPLC method which is capable of resolving any degradants that have been formed.

Upon completion of this course, delegates will have learned what is necessary to develop a stability-indicating method for drug substance and drug product to comply with international regulatory guidelines.

Course Programme

Overview of developing a stability-indicating method

- Regulatory framework
- What can go wrong on storage?
- Real-time, accelerated and forced degradation
- Chemical and photochemical decomposition
- Requirements for a stability-indicating analytical method
- Stress testing objectives
- Anticipation of likely degradation products
- Common degradation pathways
- Chiral degradation products

Workshop: Anticipation of likely degradation products

- Forced degradation (stress testing) of drug substance, as per ICH guidance
- How much degradation is enough? When do we stop?
- Typical stress testing approaches, including Accelerated Stability Assessment Program (ASAP)

HPLC Methods

- Brief overview of HPLC theory
- Common modes of HPLC
- Different approaches to stability analysis using HPLC
 - * Determination of degradants and HPLC assay calculation
- Mass balance

Essentials of the stability-indicating HPLC method

- Is the method doing everything I need?

Workshop: Selecting the Separation Mode for a Stability Indicating HPLC Method and Consideration of Detection Issues

End of Day: Group discussion

Who Should Attend?

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

Venue:

London: HILTON LONDON EUSTON

17-18 Upper Woburn Pl, Bloomsbury, London WC1H 0HT United Kingdom

Website: <https://www3.hilton.com/>

Hotel is within walking distance of Euston, St Pancras and Kings Cross Stations.

Please note accommodation is not included in course fee.

Accommodation and travel directions are available on our website

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:

- 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

Ph: 0044 (0)20 8133 2605, Email: judy@pharma-training-courses.com

Autumn/Winter Courses 2019

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development

10, 11 & 12 April 2019, **Croydon Greater London**

Pharmaceutical Dissolution Testing – a Hands-on course

21, 22, 23 & 24 May 2019 **London**

Stability Testing in Pharmaceutical Development and Manufacture

6 & 7 June 2019 **London**

Pharmaceutical Packaging – an introductory course

17 & 18 June, 2 & 3 December 2019 **London**

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development

26, 27 & 28 June, 4, 5 & 6 December 2019 **Croydon Greater London**

Powder Technology for Pharmaceutical Development and Manufacturing

25, 26 & 27 September 2019 **London**

Introduction to the Formulation and Stabilisation of Protein and Peptide Drugs

16 & 17 September 2019 **London**

Latest Advances in the Formulation & Stabilisation of Protein and Peptide Drugs

18 & 19 September 2019 **London**

Pharmaceutical Dissolution Testing – a Hands-on Course

8, 9, 10 & 11 October 2019 **London**

Parenteral Products

21, 22 & 23 October 2019 **London**

Pharmaceutical Granulation and Compression

11, 12 & 13 November 2019 **London**

GMP Auditor Training for Quality Systems

29, 30 & 31 October 2019 **London**

Development of Stability-Indicating HPLC Methods

14 October 2019 **London**

HPLC Analytical Method Development and Validation

15 & 16 October 2019 **London**

Pharmaceutical Aerosols, Dry Powder Inhalation Systems and Nasal Delivery Devices

25, 26 & 27 November 2019 **London**

Pharmacokinetics in Drug Development - an integrated approach

PharmaCourses Ltd
Suite 1327 Kemp House
152 City Road
London
UK

Tel: ++44 (0)20 71937703

Email: info@pharma-training-courses.com

REGISTRATION DETAILS:

Development of Stability-Indicating HPLC Methods, 14 October 2019 *London*

Early-bird fee: 2 day course £540.00 (+ VAT £108.00 if applicable, see notes on VAT)

For registering and paying by 30 August 2019

Full Fee: 2 day course £600.00 (+ VAT £120.00 if applicable, see notes on VAT)

HPLC Analytical Method Development and Validation, 15 & 16 October 2019

London

Early-bird fee: 2 day course £1080.00 (+ VAT £216.00 if applicable, see notes on VAT)

For registering and paying by 30 August 2019

Full Fee: 2 day course £1200.00 (+ VAT £240.00 if applicable, see notes on VAT)

Development of Stability-Indicating HPLC Methods *and* HPLC Analytical Method Development and Validation, 14, 15 & 16 October 2019

Early-bird fee: 3 day course £1440.00 (+ VAT £288.00 if applicable, see notes on VAT)

For registering and paying by 30 August 2019

Full Fee: 3 day course £1620.00 (+ VAT £324.00 if applicable, see notes on VAT)

To attend both courses please complete registration form attached or register online

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.

Methods of Payment available:

- Cheque (**Please make payable to "PharmaCourses Ltd"**)
- Bank transfer
- Credit/Debit Card (If paying by Credit Card please register online)

Online Registration is available on our website:

www.pharma-training-courses.com

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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: PharmaCourses 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. PharmaCourses Ltd will not be responsible for any airfare, accommodation or other travel costs incurred.

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Delegate 1:

Title **First Name**
Surname

Job Title

Delegate 2:

Title **First Name**
Surname

Job Title

Company

Address

PostCode **Country**

Telephone:

Email address

Signature

Methods of Payment available:

- Cheque (Please make payable to "PharmaCourses Ltd")
- Bank transfer
- Credit/Debit Card (If paying by Credit Card please register online)

Tick

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