

HPLC Analytical Method Development and Validation

22 & 23 June 2020, London UK

9 & 10 November 2020, 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.



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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



Venue:

DoubleTree Hilton Hotel Islington, 60 Pentonville Road, London, N1 9LA
Website: [www.http://doubletree3.hilton.com/](http://doubletree3.hilton.com/) Close to Kings Cross/St Pancras 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
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- 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

Course Programme 2020

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
1, 2 & 3 April *and* 2, 3 & 4 December 2020, **Croydon Greater London**

Pharmaceutical Dissolution Testing – a Hands-on Course
12, 13, 14 & 15 October 2020, **London**

QbD and Lifecycle Management of Analytical Methods
21 & 22 May 2020, **London**

Stability Testing in Pharmaceutical Development and Manufacture
8 & 9 June 2020 **London**

HPLC Analytical Method Development and Validation
22 & 23 June 2020 **London**

HPLC Troubleshooting 24 June 2020 **London**

Pharmaceutical Packaging – an introductory course
25 & 26 June *and* 30 November & 1 December 2020 **London**

Introduction to the Formulation and Stabilisation of Protein and Peptide Drugs
14 & 15 September 2020 **London**

Latest Advances in the Formulation & Stabilisation of Protein and Peptide Drugs
16 & 17 September 2020 **London**

Powder Technology for Pharmaceutical Development and Manufacturing
23, 24 & 25 September 2020 **London**

Pharmaceutical Dissolution Testing – a Hands-on Course
13, 14, 15 & 16 October 2020 **London**

Parenteral Products
tba 2020 **London**

Pharmaceutical Granulation and Compression
tba 2020 **London**

GMP Auditor Training for Quality Systems
tba November 2020 **London**

HPLC Analytical Method Development and Validation
9 & 10 November 2020 **London**

Development of Stability-Indicating HPLC Methods
11 November 2020 **London**

Pharmaceutical Aerosols, Dry Powder Inhalation Systems and Nasal Delivery Devices
tba 2020 **London**

Pharmacokinetics in Drug Development - an integrated approach
23 & 24 November 2020 **London**

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Keep up to date with industry requirements

REGISTRATION DETAILS:

HPLC Analytical Method Development and Validation, 22 & 23 June 2020 London

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

For registering and paying by 11 May 2020

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

HPLC Analytical Method Development and Validation, 9 & 10 November 2020 London

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

For registering and paying by 30 September 2020

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

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- 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:
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