Development of Stability-Indicating HPLC Methods

21 June 2017, 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.

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

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

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
- Are degradation products likely to be isomers, enantiomers or diastereoisomers?

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?
- Note findings of stress-testing industry comparison

HPLC Methods

- Brief overview of HPLC theory
- Common modes of HPLC: Reversed and normal phase 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

The 2 day course '**HPLC Analytical Method Development and Validation**' is designed to follow this 1 day course.

Reduced rates are available for booking both courses.

The course will include interactive workshops

HPLC Analytical Method Development and Validation
22 & 23 June 2017, London UK

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

- Selecting the column for analysis
- Scouting runs as a guide to optimum conditions
- Using chromatographic parameters to decide quality of chromatography
- Gradient/isocratic operation appropriate?
- 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 Two: Group discussion

Day Two

Validation of chromatographic methods, part 1

- Introduction to ICH guidelines: ICH Q2(R1)
- Types of analytical procedure to be validated:
  - Identification test *Quantitative test (impurities content)
  - Limit tests (control of impurities)
  - Quantitative test of active moiety (assay vs. external standard)
- 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

Workshop: Validating a typical HPLC method

Validation of chromatographic methods, part 2

- Comparison of the traditional and Quality by Design (QbD) approach to validation
- Extent of validation: how much work at each phase of development?
- Acceptance criteria
- Validation procedures and protocols
- Dealing with validation failures
- Verification of compendial procedures

Workshop: Dealing with validation failures and how failures

End of Day Two: Group discussion and close

The course will include interactive workshops

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Venue:
Hilton London Euston
17 - 18 UPPER WOBURN PLACE, LONDON, WC1H 0HT, UK

Close to Kings Cross/St Pancras and Euston Stations

Website: www.doubletree3.hilton.com

Please note accommodation is not included in course fee.

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

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 7193 7703, **Email:** judy@pharma-training-courses.com

Course Programme 2017

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
22, 23 & 24 March 2017 Croydon Greater London

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Stability Testing in Pharmaceutical Development and Manufacture
- an update for the 21st Century
18 & 19 May London

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Pharmaceutical Dissolution Testing - a 2 day course
22 & 23 May London

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21 June London

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HPLC Analytical Method Development and Validation
22 & 23 June London, 20 & 21 November London

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Pharmaceutical Packaging – an introductory course
26 June London

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Pharmacokinetics in Drug Development - an integrated approach
November London

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GMP Auditor Training for Quality Systems
November London

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152 City Road
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UK

Tel: ++44 (0)20 71937703

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REGISTRATION DETAILS:

Development of Stability-Indicating HPLC Methods, 21 June 2017

Early-bird fee: 2 day course £540.00 (+ VAT £108.00 if applicable, see notes on VAT)
For registering and paying by 26 April 2017
Full Fee: 2 day course £600.00 (+ VAT £120.00 if applicable, see notes on VAT)

HPLC Analytical Method Development and Validation, 22 & 23 June 2017

Early-bird fee: 2 day course £1080.00 (+ VAT £216.00 if applicable, see notes on VAT)
For registering and paying by 26 April 2017
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, 21, 22 & 23 June 2017

Early-bird fee: 3 day course £1440.00 (+ VAT £288.00 if applicable, see notes on VAT)
For registering and paying by 26 April 2017
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

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.

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Methods of Payment available:

- Cheque (**Please make payable to "PharmaCourses Ltd")**
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Online Registration is available on our website:
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