PharmaTraining

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***PharmaTraining** and **PMcG Consulting** present -*

QbD and Lifecycle Management for Analytical Methods

13 & 14 October 2016, London UK

The pharmaceutical industry is starting to apply a Quality by Design (QbD) approach to the development of pharmaceutical products. It follows therefore, that the analytical procedures which are used to test these products throughout their lifecycle could also benefit from such an approach. This approach encompasses understanding variables and optimising a control strategy using tools such as risk assessment and Design of Experiments (DOE) in order to provide scientific rationale for the choices made during the process. Using the QbD and lifecycle management approach during analytical method development and qualification will result in more robust methods which produce consistent, reliable, quality data throughout the lifecycle. This, in turn, will lead to less method transfer failures, OOS results and method "incidents" when used in the routine environment.

This two day training course presents a brief overview of method validation according to ICHQ2 (R1) and discusses the limitations of this approach in terms of its contribution to failure of methods with regards to method transfer and generation of OOS results later in the method lifecycle. It then illustrates that the lifecycle approach is a holistic process which embraces the philosophies of the traditional approach but results in more robust analytical procedures. Finally a comparison of the current approach (ICHQ2) and the QbD approach is presented.

The course focuses on HPLC methods; therefore experience in developing, validating and transferring analytical HPLC methods would be an advantage to participants.

Course objectives

This course is designed to provide training in how to apply Quality by Design and lifecycle management to the development and qualification of analytical methods. It aims to highlight the limitations of the current approach to method validation (ICHQ2) and the benefits to using the QbD approach. Although the QbD and Lifecycle management approach is not yet officially recognised for analytical methods, the course is based on the approach used for manufacturing processes and products as described in ICH Q8, Q9 and Q10.

The course emphasises practical issues such as:

- Comparison of the traditional approach and QbD/lifecycle approach to analytical methods
- Applying the QbD and lifecycle approach to development and qualification of analytical methods
- Exploring and controlling variables of analytical methods

This course will deliver the tools to enable you to:

- Consider a QbD and lifecycle management approach to analytical methods
- Define an Analytical Target Profile
- Recognise the importance of understanding method variables of individual methods
- Develop more robust analytical methods

Who Should Attend?

This 2 day course is valuable for Managers, Supervisors, Laboratory Analysts and Associates involved in the development, validation, transfer or review of analytical methods in the Pharmaceutical and related industries with daily responsibilities in the following areas:

- Quality Assurance
- Quality Control Laboratory
- Regulatory Affairs
- Contract Laboratory
- Analytical Development Laboratory
- Training

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Questions and answers will be taken throughout the duration of the course.

The material is presented by means of slides, handouts and participation of the attendees through discussion, case studies and hands on group exercises.

Day 1
8.45 am Registration and Coffee
9.15am
- Introduction
- Traditional approach to validation (ICHQ2)
- Exercise
- The limitations of this approach

10.45am Morning refreshments

11.00 am to 12.30pm
- Discussion of current approach (Groups share experiences of method problems)
- Definition of QbD
- Overview of ICH Q8, Q9 and Q10
- Applying QbD to analytical methods (The three stages)

12.30 pm Lunch

1.30 pm to 3.00 pm
Stage 1
- Gather Knowledge
- The Analytical Target Profile
- Exercise

3.00 pm Afternoon refreshments

3.15 pm to 4.30pm
Method design and Method Understanding
- Risk assessment (exercise)
- Understanding and controlling variables (Robustness and Ruggedness)

Day 2
9.00 am to 10.15 am
Practical Experiment

10.15 am Morning refreshments

10.30 am to 12.00 pm
- Robustness study
- Design of experiments

m Lunch

1.00pm - 2.30 pm
Ruggedness study
- Conclusion of Stage 1

2.30 pm Afternoon refreshments

2.45 pm to 4.30 pm
Stage 2 - Procedure Performance Qualification
Stage 3 - The lifecycle approach
- Continued method verification
- Quality systems - Change control and trending
- How can the QbD approach to translate to less method transfer failures"
- Overview Comparison of Traditional and QbD approach
- Advantages of QbD

4.30 pm End of course

Venue:

London: DoubleTree Hilton Hotel, 60 Pentonville Road, Islington London N1 9LA
Website: www.doubletree3.hilton.com

Nearby Hotels: Premier Inn Islington, Premier Inn Euston, Premier Inn Kings Cross, Premier Inn London St Pancras Travelodge Kings Cross

Numbers are limited to give participants the opportunity for thorough discussion of the issues to be covered by the programmes and one-to-one consultation with speaker(s)

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Contact **Judy Callanan Ph:** 0044 (0)20 7193 7703,
Email: judy@pharma-training-courses.com

Course Speaker
Dr Pauline McGregor

Twenty years in the pharmaceutical industry has included working for pharmaceutical companies and Contract Testing Laboratories in Canada and the UK.

Pauline completed her honours degree in Scotland on a part time basis while employed full time. She left the industry to pursue her PhD in photo organic chemistry where she also taught analytical techniques to undergraduate students. On completing her PhD in 1995, she travelled to UWO in London, Ontario, Canada to complete her post doctoral studies. She is an experienced trainer and has been delivering analytical R& D, method validation, GMP and related Quality Systems courses across Canada, in the US, the UK and China . She is a very highly rated presenter.

Throughout her career, Pauline has identified a lack of shared knowledge between Manufacturing, Quality Control, R & D and Quality Assurance sectors in the Healthcare Industries. She believes there is a need for cross education and training to allow the different disciplines to communicate with each other so that realistic objectives can be met by all in a timely manner with a harmonised understanding.

In today's pharmaceutical/Biotech industry there is a definite need to understand technical issues in regards to daily operations, development and regulatory requirements.

Maintain your competitive edge—keep up to date with the latest industry requirements

REGISTRATION DETAILS

QbD and Lifecycle Management for Analytical Methods:
13 & 14 October 2016
Full Fee: 2 day course £1200.00 (+ VAT if applicable, see VAT NOTES)
Early-bird rate 2 day course £1080.00 (+ VAT **if applicable, see VAT NOTES)**
for registering and paying by 31 August 2016

VAT NOTES:

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

Please register online at www.pharma-training-courses.com

Delegate fees
Fees for this programme are shown above. 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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