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bridging the gap with expert training, education and communcation

Training Course and Discussion Group

QbD and Lifecycle Management for Analytical Methods

Monday Oct. 3rd & Tuesday Oct. 4th, 2011

BioCity Nottingham, Pennyfoot Street
Nottingham, NG1 1GP

Course

QbD and Lifecycle Management for Analytical Methods

Date: **Monday October 3rd, 2011 (9:00am - 5:00pm) and Tuesday October 4th, 2011 (9:00am - 12:00 pm)**

Cost: **£595** (VAT included)

1.5 DAY

A QbD and lifecycle management approach to analytical method development and qualification will result in a better understanding and fewer failures of analytical methods due to 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. As the industry is moving towards applying Quality by Design (QbD) to process development - Is this also the way forward to improve and standardise our approach to method qualification?

This one and a half 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 introduces the concept of QbD in relation to analytical methods and focuses on the application of a three stage approach of QbD and lifecycle management. 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.
The material is presented by means of slides, handouts and participation of the attendees through discussion, case studies and hands on group exercises.

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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 1.5 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

What's included with the course

- All participants will receive a certificate of attendance upon completion of the course.
- The participants will each receive a course manual and related printed materials
- Lunch (Day 1 only) and light refreshments (Day 1 & 2)

Course Speaker

Dr. Pauline McGregor, PMcG Consulting (bio on page 5)

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Course Outline (Day 1)

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

9:00 am Registration and Coffee

Session 1

9:30am to 10:45am

- Introduction
- Traditional approach to validation (ICHQ2)
- Exercise
- The limitations of this approach

10.45am Morning refreshments

Session 2

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

Session 3

1:30 pm to 3:00 pm

- Stage 1
  - Gather Knowledge
  - The Analytical Target Profile
  - Exercise
  - Method design and Method Understanding
    - Robustness and Ruggedness

3:00 pm Afternoon refreshments

Session 4

3:15 pm to 5:00pm

- Method design and Method Understanding (continued)
  - Risk assessment
  - Understanding and controlling variables
- Case Study and group practical exercise

Evening Discussion Group

5:30 pm to 8:00pm

- The future of method qualification and QbD (see description below)

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Course Outline (Day 2)

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

Session 5 - Applying QbD - continued

9:00 am to 10:15 am

- Presentation of group findings from practical exercise
- Stage 2 -Method Qualification

10.15am Morning refreshments

Session 6

10:30 am to 12:15 pm

- 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

12.15 pm End of course and certificates

Discussion

Evening Discussion Group:
The future method qualification and QbD

Date: **Monday October 3rd, 2011 (5:30 pm - 8:00pm)**

FREE

It is free to attend this event and all newcomers are welcome, however registration must be completed to gain access to BioCity Nottingham. No unregistered attendees will be permitted as per BioCity Nottingham security requirements.

As the industry is moving towards applying Quality by Design (QbD) to process development - is this also the way forward to revolutionise, improve and standardise our approach to method qualification? Is ICH Q2 adequate to meet our current lifecycle needs? These questions and more will be discussed.

This discussion group activity provides the opportunity to get up to speed with the future trends of analytical method qualification. Already aware of what is going on ? We would love to have you attend and share your thoughts. Be prepared to brainstorm and voice your opinions (all welcome). The session will start with a short presentation followed by refreshments and then an open discussion.

If you are interested in presenting your thoughts in a 10 to 15 minute PowerPoint presentation, please identify this at the time of registration. Since there is no fee required please register for this event directly by email

If you have any questions regarding this event or wish to register, please contact me at pauline@pmcgconsulting.com.

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Course Speaker

Dr. Pauline McGregor, PMcG Consulting

More than 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.

Pauline is also a member of The Royal Society of Chemistry, UK and listed on the RSC Directory of Consultants.

PMcG Consulting

Bridging the gap with expert training, education and communication

At PMCG Consulting, our mission is to bridge the gap between different stages in pharmaceutical development, global practices, academia and industry, contract laboratories and pharmaceutical companies, through education, training and communication. We contribute to the pharmaceutical/biotech industry by means of training, problem solving and technical support, creating internal, external and global partnerships whilst assuring the highest level of quality.

Training

PMCG provides training you'll enjoy. Our courses are presented in a unique manner which includes group interaction and discussion, hands on exercises and case studies.

Documentation

We can help prevent your documentation being the bottle neck of your operations and a cause of missed deadlines. Consistency, documentation and traceability are key factors in GMP compliance which protect the consumer and the company

Analytical Method and Technical Support

Analytical method support is offered to laboratories and manufacturing sites to aid in problem solving of analytical methods relating to stability studies, formulation development and cleaning validation. Before a product can be tested, documentation that the laboratory is qualified to run the test must be available to the Regulatory authorities.

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Venue Information

BioCity Nottingham
Pennyfoot Street
Nottingham
NG1 1GF
www.biocity.co.uk

PARKING:

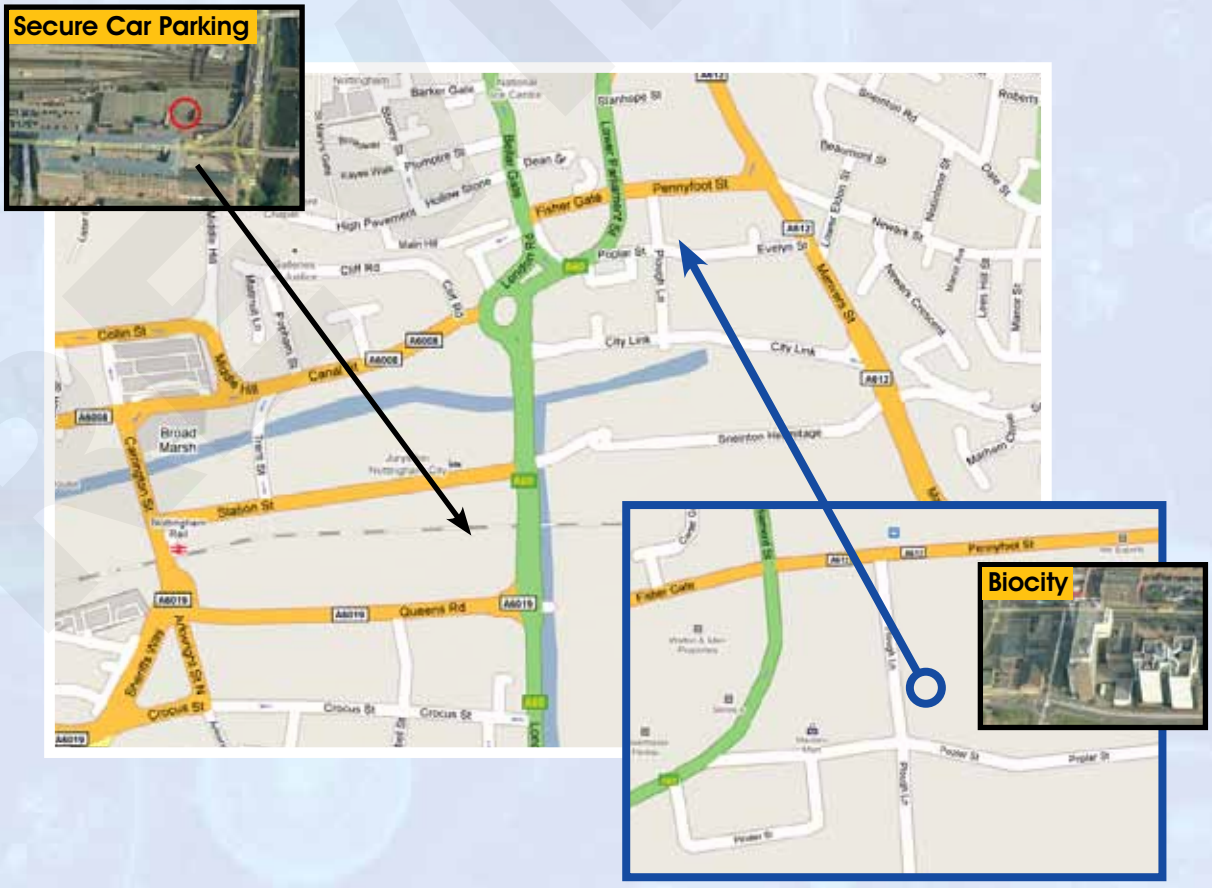
On-site parking for conferencing delegates and meeting attendees is not avaialble however there are suitable options noted below:

1. On street **metred parking** is available adjacent to BioCity - £1.20 per hour (up to 5 hrs). Free street parking after 6pm.

2. For **secured parking with a shuttle service** to and from the venue, please use the Park Centre, located on Queens Road. They are located near the *Nottingham Train Station*. Their fee is £5.00 per vehicle and arrangements regarding shuttle times and any other enquiries may be answered by contacting the car-park directly as follows:

MAGPIE SECURITY LTD & THE PARK CENTER
Head Office
Queens Road
Nottingham
NG2 3AS

Phone Office: 01159866000
Sam Mobile: 07792078315
Jason Mobile: 07967804715
Fax: 01159866003



ACCOMMODATIONS:

BioCity Nottingham has agreements with several hotels nearby.

Please visit **www.biocity.co.uk** (under "contacts and locations" menu) for further information

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REGISTRATION

Register by

mail: **PMᶜG Consulting, c/o BioCity Nottingham, Pennyfoot Street, Nottingham, NG1 1GF**
fax: **(00) -1-905-257-1145**
online: **www.pmcgconsulting.com**

Name: | Position:

Company:

Address:

City: | Postal Code:

Telephone: | Fax:

Email: | Alternate phone:

Signature:

Make your selection(s) ✓

☐ **QbD and Lifecycle Management for Analytical Methods**

1.5 DAY COURSE

Monday October 3rd, 2011 (9:00am - 5:00pm)
Tuesday October 4th, 2011 (9:00am - 12:15pm)

Please register for QbD Analytical Discussion group by email : **pauline @pmcgconsulting.com**

£595 (VAT included)

FEES INCLUDE:

Certificate
Printed Manual
Lunch (day 1)
Refreshments

Do you have any special dietary requirements? YES ☐ If yes, please describe:

Method of Payment:

☐ **Cheque -** Please make payable to PMᶜG Consulting

☐ **Credit Card -** Please visit our website for processing **(pmcgconsulting.com)**

NOTE: Course fees must be paid prior to the course date or registrant will be denied admittance to the course. Upon receipt of payment, a proof of payment will be sent to you.

PMᶜG Consulting reserves the right to modify the material or speakers, without notice or cancel the event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. PMᶜG Consulting cannot be responsible for discount airfare penalties, accommodation or other travel costs incurred due to a cancellation.

Full refunds less a handling fee of £ 35.00 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 can be made after 7 days prior to commencement of the course. Substitutions can be made at any time. If you fail to attend the course for which you're registered, full course fees will be charged.

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