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bridging the gap with expert training, education and communcation

SEMINAR AND WORKSHOP SERIES
MARCH 29 & 30, 2010

BioCity, Pennyfoot Street
Nottingham, NG1 1GP

BOOK BOTH COURSES AND SAVE **£50.**

Course 1

Method Qualification - "Past, Present and Future"

Date: **Monday March 29th, 2010 (9:00am - 5:30pm)**
Cost: **£395** (VAT included)

FULL DAY

This one day workshop addresses current regulatory requirements for qualification of analytical methods. It also introduces a way forward for qualification of analytical methods as we enter the second decade of the 21st century.

(Basic knowledge of validation and analytical performance (validation) characteristics is assumed).

Regulatory authorities require documentation to show that a laboratory is qualified to run specific analytical test methods. Currently there are three main approaches to qualifying an analytical method: Validation, Verification or Transfer.

Method transfer (or technology transfer) is generally distinguished from verification as being applied to validated industry methods whereas verification applies to a compendial method (USP, EP, JP). Many terminologies with many interpretations exist and there is a need to standardise terms and approaches. They all share the same goal which is to qualify the analytical procedure for its intended use in the environment in which it will be routinely used.

Contract laboratories play a key role in supporting the industries needs in analytical testing and are faced with their own sets of challenges with regard to qualification of analytical procedures. A standardised approach would benefit all sectors of the industry including contract laboratories, R &D and generic and innovator pharmaceutical companies.

As the industry is moving towards applying Quality by Design (QbD) to process development, this course raises the question in the final session- Is this also the way forward to revolutionise, improve and standardise our approach to method qualification?

This workshop presents a brief review of method validation and analytical performance (validation) characteristics. It then extends this knowledge to the technical challenges of method transfer of industry methods and verification of compendial procedures. Common problems with verifying compendial procedures are addressed and the most common reasons why method transfers fail are identified. Examples and guidance are provided for successful method verification and transfer. In the final session the future needs and a suggested route for a harmonized approach to method qualification is presented.

Note: The final session leads into an evening discussion group on "QbD applied to analytical method qualification" to which all are welcome and encouraged to attend.

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Course Objectives

This course is designed to provide essential training for verification and transfer of analytical methods. It is presented in a dynamic environment created by a power point presentation, interactive exercises and group discussion. Participants are welcome to bring their own examples for group discussion sessions. The course material is based on ICH Q2B, USP chapters <1225> and <1226>, and current industry practices.

The workshop emphasizes practical issues such as:

- The importance of good quality support systems
- Determining acceptance criteria
- Selecting appropriate validation characteristics
- Writing a method transfer protocol
- Writing a protocol for verification of a compendial procedure
- Addressing failures and maximising success
- Future application of QbD to analytical method qualification

Note: The main focus is on HPLC and general chemistry test methods. Unfortunately micro methods could not be included within the timeframe.

This course will deliver the tools to enable you to:

- Review validation characteristics
- Understand the critical role GMP compliance has on method qualification
- Select appropriate validation characteristics and acceptance criteria on a case to case basis for verification and transfer.
- Write a method transfer protocol
- Write a verification protocol for a compendial procedure
- Become aware of future trends in analytical method qualification
- Apply your thought process to analytical qualification and QbD

Who Should Attend?

This one-day course is valuable for laboratory analysts, managers and Quality Assurance personnel who are involved with qualification of analytical methods for excipients, API and finished products in the Pharmaceutical industry and those involved with writing protocols and reports for method qualification. The course is applicable to personnel from the following areas:

The workshop emphasizes practical issues such as:

- Quality Control Laboratory
- Contract Testing Laboratory
- Manufacturing
- R& D laboratory
- Validation
- Quality
- Regulatory Affairs
- Training
- Consultants

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Course Speaker

Dr. Pauline McGregor, PMcG Consulting (bio on page 7)

Course Outline

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

8.45 am Registration and Coffee

Session 1

9:00 to 10:30am

- Introduction
  - Why do we validate?
- Review of Analytical Performance (validation) characteristics
- Review of related quality systems and GMP requirements

10.30am Morning refreshments

Session 2

10:45am to 12:30pm

- Preparing for Qualification
  - Determining the end use of the method
  - Determining appropriate validation characteristics
  - Selecting acceptance criteria

12.30pm Lunch

Session 3

1:30 to 3:15pm

- Method Transfer
  - Recommended approach
  - Maximising success
- Method verification (USP General chapter <1226>)

3:15pm Afternoon refreshments

Session 4

3:30 to 5:30pm

- Method verification
  - Recommended approach
  - Exercise - verification protocol for a USP monograph
- The future of method qualification
  - Applying QbD and the Lifecycle approach
  - Why Validate?

6:30pm Evening Discussion Group – The future of method qualification and QbD
- see details on page 7

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Course 2

Analytical Instrument and Personnel Qualification - "IQ/OQ /PQ and YOU – Q"

Date: **Tuesday March 30th, 2010 (9am - 12:45pm)**
Cost: **£185** (VAT included)

HALF DAY

Prior to conducting any type of method qualification laboratory quality systems need to be in place. These include compliance to GMP, training of personnel and instrument qualification.

This half day workshop addresses current regulatory requirements for qualification of analytical instruments, laboratory personnel and GMP compliance. It defines DQ/IQ/OQ and PQ and provides a hands on approach to the technical challenges of qualifying laboratory instrumentation. Instrument calibration and maintenance programs are also discussed.

Course Objectives

This course is designed to provide essential training on qualification of personnel and analytical instrumentation in the laboratory. It is presented in a dynamic environment created by a power point presentation, interactive exercises and group discussion. Participants are welcome to bring their own examples for a group discussion session. The course material is based on USP chapters <1058> and current industry practices.

The workshop emphasizes practical issues such as:

- The importance of good quality support systems
- Selecting IQ/OQ/PQ parameters
- Writing an IQ and OQ protocol

This course will deliver the tools to enable you to:

- Understand the relationship between good quality systems and laboratory activities
- Plan an appropriate training program for laboratory personnel
- Determine when IQ/OQ and PQ are necessary on a case to case basis for analytical instrumentation.
- Write an IQ/OQ protocol

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Who Should Attend?

This half day course is valuable for laboratory analysts, managers and Quality Assurance personnel who are involved with qualification of analytical instruments and those involved with writing protocols and reports for instrument qualification. The course is applicable to personnel from the following areas:

The workshop emphasizes practical issues such as:

- Quality Control Laboratory
- Contract Testing Laboratory
- Manufacturing
- R & D laboratory
- Validation
- Quality
- Training

Course Speaker

Dr. Pauline McGregor, PMCG Consulting (bio on page 7)

Course Outline

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

8.45 am Registration and Coffee

Session 1

9:00 to 10:30am

- Introduction
- GMPs related to the Laboratory control system
- Good documentation practices
- Calibration and Maintenance program

10.30am Morning refreshments

Session 2

10:45am to 12:30pm

- Qualification and training of personnel
- Qualification of instruments overview
- Which pieces of equipment require IQ/OQ and PQ?
- Exercise – Writing an IQ/OQ protocol

12:45pm End

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Discussion

The Future of Method Qualification –
"QbD and lifecycle approach"

Date: **Monday March 29th, 2010 (18:30-20:30)**
Cost: **FREE**

BONUS

Evening Discussion Group : It is free to attend this event but registration must be completed to gain access to BioCity. No unregistered attendees will be permitted as per BioCity security requirements.

Regulatory authorities require documentation to show that a laboratory is qualified to run specific analytical test methods. Currently there are three main approaches to qualifying an analytical method: Validation, Verification or Transfer.

Many terminologies with many interpretations exist and there is a need to standardise terms and approaches. They all share the same goal which is to qualify the analytical procedure for its intended use in the environment in which it will be routinely used.

Contract laboratories play a key role in supporting the industries needs in analytical testing and are faced with their own sets of challenges with regard to qualification of analytical procedures. A standardised approach would benefit all sectors of the industry including contract laboratories, R &D and generic and innovator pharmaceutical companies.

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?

This discussion group activity provides the opportunity to get up to speed with the future trends of analytical method qualification. Already aware of what's going? 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 15 to 20 minute PowerPoint presentation, please identify this on your registration form.

If you have any questions regarding this, please do not hesitate to contact **pauline@pmcgconsulting.com**

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What's included with each 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

Course Speaker

Dr. Pauline McGregor, PMcG Consulting

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.

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.

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Venue Information

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

PARKING:

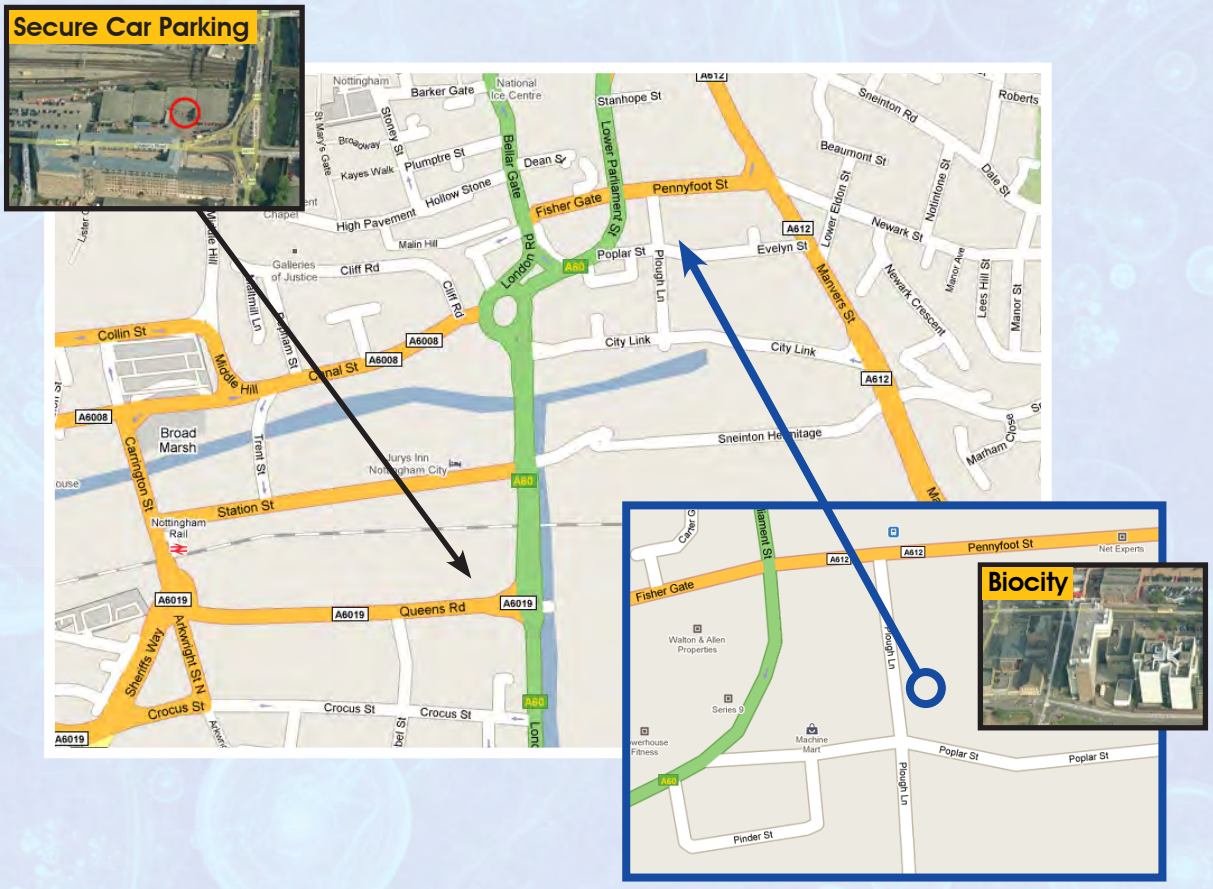
On-site parking for conferencing delegates and meeting attendees is not avaialble however there are suitable options noted below:

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

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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Print Form | Reset Form

REGISTRATION

Register by

mail: **PMᶜG Consulting, c/o BioCity, 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) ✓

☐ Method Qualification - Past, Present and Future **FULL DAY -** Monday March 29, 2010 (9am - 5:30pm)	**£395** (VAT included)	**FEES INCLUDE:** **Certificate** **Printed Manual** **Lunch** (Full Day course only) **Refreshments**
☐ Analytical Instrument and Personnel Qualification - "IQ/OQ /PQ and YOU – Q" **HALF DAY -** Tuesday March 30, 2010 (9am - 12:45pm)	**£185** (VAT included)	
☐ **REGISTER FOR BOTH COURSES AND SAVE £50**	**£530** (VAT included)	
☐ The Future of Method Qualification – "QbD and lifecycle approach" **EVENING -** Monday March 29, 2010 (6:30pm -8:30pm) Would you like to give a short presentation? **YES** ☐	**FREE**	**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. 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.

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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