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TRAINING COURSE & EVENING DISCUSSION GROUP

Wednesday October 13, 2010

BioCity Nottingham, Pennyfoot Street
Nottingham, NG1 1GP

Standard Operating Procedures - (SOPs)

Date: **Wednesday October 13th, 2010 (9:00am - 4:30pm)**
Cost: **£395** (VAT included)

This one day training session provides helpful information on how to achieve effective SOPs by presenting topics relevant to the writing, formatting, execution and management of SOPs. An approach to global harmonisation of SOPs is also discussed.

Regulatory Authorities require written procedures for all systems and operations which impact the quality and safety of pharmaceutical products. Standard Operating Procedures (SOPs) provide the main forum for the documentation of a Company's systems and operations. These are key documents used in the day to day operations of a company and are favourite audit items.

Effective SOPs lead a company not only to consistency, quality and compliance but also to executing efficient business operations. Often SOPs are written without consultation with the end user or by someone who has good writing skills but little experience of the topic. They can include too much information, making them difficult to follow or too little detail causing them to be ambiguous. Such SOPs can lead to audit observations that the SOP had not been followed or did not reflect current practices.

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Course Objectives

This course is designed to provide essential training towards achieving effective SOPs.

The course emphasises practical issues such as:

- The role of SOPs with respect to GMP operations, Quality Documentation Systems and Global Harmonisation
- Improving and maintaining the existing documentation system.
- Designing an SOP template to optimize efficiency of organization and formatting of SOPs
- The team approach to SOP writing, defining responsibilities and knowing the audience.
- The importance of capturing the flow of an operation within the document
- Writing tips on how to keep the document concise, unambiguous and accurate.
- Training of SOP documents
- Managing revisions

Interactive exercises include:

- The benefits of SOPs
- The logical approach to defining the SOP procedure
- Approaching SOPs as part of a team

This course will deliver the tools to enable you to:

- Understand the critical role SOPs play in daily operations
- Strengthen and maintain your current SOP system
- Write an effective SOP by
  - * Using the correct language
  - * Capturing the flow of the procedure
  - * Consulting with the appropriate people
- Organise effective training for SOPs

Who Should Attend?

This one day course is targeted at Personnel from Quality Assurance, Production, Quality Control, Regulatory Affairs and other departments who are involved in the organization; writing or management of SOPs required for GMP purposes

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Course Speaker

Dr. Pauline McGregor, PMCG Consulting (bio on page 4)

Course Outline

Questions are welcome throughout the duration of the course.

8.45 am Registration and Coffee

Session 1

9:00 to 10:30 am

- Introduction - Exercise
- Benefits of SOPs
- The role of SOPs with respect to GMP operations, Quality Documentation Systems
- Global Harmonisation

10.30 am Morning refreshments

Session 2

10:45 am to 12:30 pm

- Reviewing current SOP's to determine gaps and overlaps to strengthen the existing documentation system and Maintenance of SOPs
- Designing an SOP template to optimize efficiency of organization and formatting of SOP's
- Exercise
- The team approach to SOP writing, defining responsibilities and knowing the audience.

12.30 pm Lunch

Session 3

1:30 to 3:00 pm

- The importance of capturing the flow of an operation within the document
- Exercise
- Writing tips on how to keep the document concise, unambiguous and accurate.

3:00 pm Afternoon refreshments

Session 4

3:15 to 4:30 pm

- Training of SOP documents
- Managing revisions
- Final exercise

4:30 pm Close

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What's included

- 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 and light refreshments

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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Discussion

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

Date: **Wednesday October 13th, 2010 (17:30-19:30)**
Cost: **FREE (please register by email)**

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.

This is a follow up to our March meeting. Thank you to all who attended. I hope you can join us again and bring your friends.

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 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, please do not hesitate to contact **pauline@pmcgconsulting.com**

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?

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Venue Information

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

PARKING:

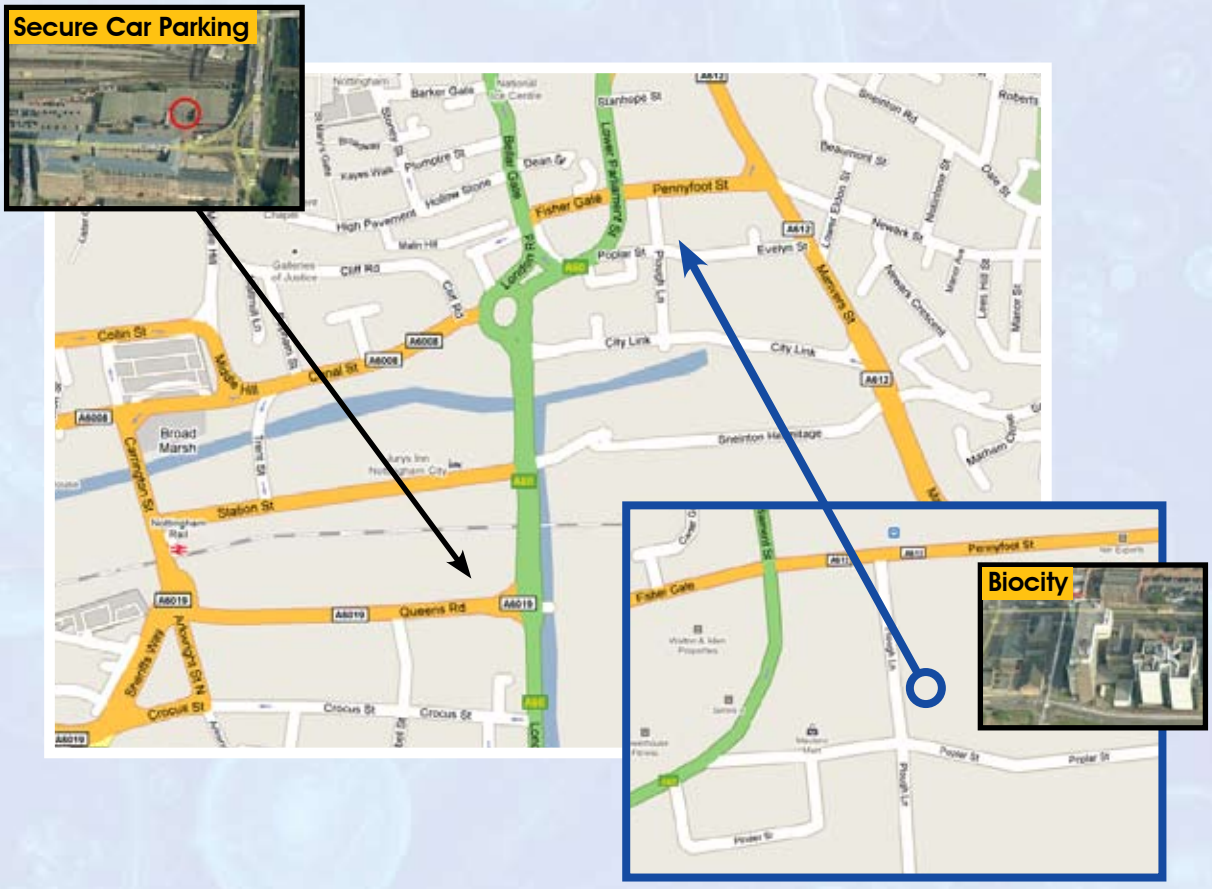
On-site parking for conferencing delegates and meeting attendees is not avaialble however there are suitable options noted below:

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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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:	

Standard Operating Procedures (SOPs)
Wednesday . October 13, 2010
9 am - 4:30 pm

£395 (VAT included)

FEES INCLUDE:

- **Certificate**
- **Printed Manual**
- **Lunch**
- **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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