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bridging the gap with expert training, education and communcation

Working in a GMP ENVIRONMENT SERIES

Monday April 4th & Tuesday April 5th, 2011

BioCity Nottingham, Pennyfoot Street
Nottingham, NG1 1GP

BOOK BOTH COURSES AND SAVE **£50.**

Course 1

Good Manufacturing Practice (GMP) for APIs

Date: **Monday April 4th, 2011 (9:00am - 5:30pm)**
Cost: **£325** (VAT included)

FULL DAY

This one day workshop provides an overview of the current EudraLex Volume 4, Part II GMP regulations as applied to Active Substances used as starting Materials in Medicinal Products for Human and Veterinary use. A practical exercise is included to discuss common deficiencies noted by EMA, MRHA and FDA during regulatory inspections.

Good manufacturing practice is critical to every day operations in pharmaceutical related industries. Although the details of GMP regulations may vary between global counterparts, the fundamental goals and principles are the same - to protect the consumer by ensuring the quality, safety, identity strength and purity of drug substances and products, used in the manufacture of pharmaceutical medicines.

In the current climate of drug shortages, leading to procurement of drug substances from countries with under developed quality standards and an increasing responsibility on companies to audit API suppliers, a fundamental grasp of GMP requirements is a critical asset.

GMP requirements must be built into the beginning of the supply chain, to avoid potentially serious repercussions when the finished product reaches the patient. Manufacturers thus have greater responsibility to quality when production is streamlined or component chemicals are outsourced. Ultimately, the marketing authorization holder (industry) is responsible for assuring that all parties in the supply chain fulfil their responsibilities for delivering safe and effective medicines.

This course provides a valuable refresher course of current European GMP regulations for those who are working towards a pre-approval inspection for GMP compliance and for auditors of third party suppliers. It is also suitable for personnel who are new to the GMP environment and internal GMP trainers. Those wishing for confirmation of their day to day GMP activities will also find it useful.

Hands on exercises enable participants to map their individual GMP responsibilities and gain the skills and knowledge necessary to understand and work in a GMP compliant environment and contribute to the ongoing quality of their company.

Note: Section 18 Specific Guidance for APIs Manufactured by Cell Culture/ Fermentation is not covered.

Sections 2: Quality Management, 12: Validation, 13: Change Control and 15: Complaints and Recalls are covered in the course "Supporting Quality Systems in a GMP Environment" on April 5th (see page 4)

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Course Objectives

This course is designed to provide essential training for those involved in GMP related activities for active substances used as a starting material in drug products. Most of the day is spent reviewing current GMP regulations, leading to a workshop in the final session which discusses GMP deficiencies observed by global regulatory authorities and how they could have been avoided. This course also builds a foundation for the course on April 5th.

It is presented in a dynamic environment created by a power point presentation, interactive exercises and group discussion.

The course emphasizes practical issues such as:

- GMP deficiencies noted by Global regulatory authorities and how they could have been avoided.
- Sharing and discussion of GMP experiences

This course will deliver the tools to enable you to:

- Understand the importance of GMP compliance
- Be conversant with and understand current regulations
- Be aware of "hot topics" with regards to GMP deficiencies during regulatory inspections

Who Should Attend?

This one-day course is valuable for personnel working towards a pre-approval inspection for GMP compliance and for auditors of third party suppliers. It is also suitable for personnel who are new to the GMP environment and internal GMP trainers. Those wishing for confirmation of their day to day GMP activities will also find it useful. The course is applicable to personnel from the following areas:

- Quality Control Laboratory
- Contract Testing Laboratory and Manufactures
- Manufacturing
- Quality Assurance
- Regulatory Affairs
- Training
- Consultants
- Agents, Brokers, Traders
- Packaging and Labelling
- Distributors and Wholesalers
- Manufactures of APIs for clinical trials

Course Speaker

Dr. Pauline McGregor, PMcG Consulting (bio on page 6)

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Course Outline (Day 1)

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

8.45 am Registration and Coffee

Session 1

9:00am to 10:30am

- Introduction
- Exercise – Mapping personal GMP responsibilities
- Definition , History of GMP and fundamental principles
- Personnel Qualifications and Hygiene
- Buildings and Facilities
- Process Equipment

10.30am Morning refreshments

Session 2

10:45am to 12:15pm

- Documentation and Records
- Material Management
- Production and In-Process Controls
- Packaging and Identification Labelling

12.15pm Lunch

Session 3

1:15am to 3:15pm

- Storage and Distribution
- Laboratory Controls
- Rejection and Re-Use of Materials
- Contract Manufacturers and Laboratories
- API's for Use in Clinical Trials

3:15pm Afternoon refreshments

Session 4

3:30pm to 5:30pm

- Practical Exercise – GMP regulatory observations and how they could have been avoided
- Overview/Summary
- GMP Trivia Challenge

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Course 2

Supporting Quality Systems in a GMP Environment

Date: **Date: Tuesday April 5th, 2011 (9:00am - 5:30pm)**
Cost: **£420** (VAT included)

FULL DAY

This one day workshop provides guidance on how to transfer GMP regulations to day to day operations through essential quality systems. This course can be applied to GMP for drug substance and drug products.

When working in a GMP environment, it is critical that all operations remain in a state of control. A fundamental principle of GMP is traceability of all drug substance/drug product activities. This is achieved through good documentation, well written procedures and following quality systems which ensure all processes are validated, equipment is qualified and personnel are adequately trained. Also any deviations, changes and customer complaints are documented, investigated, evaluated, justified and effective corrective and preventative actions are applied. Self inspection, product quality review and audits of external suppliers are also an essential part of the overall Quality Program in a GMP environment.

Quality Systems covered are: Quality Management, Standard Operating Procedures, Validation, Deviations, Change Control, Self Inspection, Product Quality Review, External audits of third party suppliers, Complaints and Recalls.

A general knowledge of GMP in the attendees' respective environment is assumed.

Course Objectives

This workshop is designed to provide a practical approach to understanding and applying key quality systems in a GMP environment as part of an overall quality program. It bridges the gap between the hard copy regulations and day to day operations. Hands on exercises and examples enable participants to gain the skills and the knowledge necessary to understand the importance of good quality systems and apply them in the workplace.

The workshop emphasizes practical issues such as:

- Examples and exercises demonstrating key quality systems.

This course will deliver the tools to enable you to:

- Understand the critical role of robust quality systems in a GMP environment
- Become familiar with key quality systems and their function
- Apply key quality systems in an effective manner
- Recognise the quality systems which play a key role in self inspection, and external audits
- Understand how the overall Quality Program is critical to GMP compliance

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Who Should Attend?

This one-day course is valuable for personnel working in a GMP environment who is involved in the set up or execution of quality driven systems. The course is applicable to personnel from the following areas:

- Quality Control Laboratory
- Contract Testing Laboratory and Manufactures
- Manufacturing
- Quality Assurance
- Regulatory Affairs
- Training
- Consultants
- Packaging and Labelling
- Distributors and Wholesalers

Course Speaker

Dr. Pauline McGregor, PMCG Consulting (bio on page 6)

Course Outline (Day 2)

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

8.45 am Registration and Coffee

Session 1

9:00am to 10:30am

- Introduction
- Quality Management
- Standard Operating Procedures (SOPs)

10.30am Morning refreshments

Session 2

10:45am to 12:15pm

- Validation
- Deviations/Non Conformance
- Change Control

12.15pm Lunch

Session 3

1:15am to 3:15pm

- External audits of third party suppliers
- Internal Audits (Self Inspection)

3:15pm Afternoon refreshments

Session 4

3:30pm to 5:30pm

- Product Quality Review
- Complaints and Recalls
- Summary

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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
- 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.

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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:

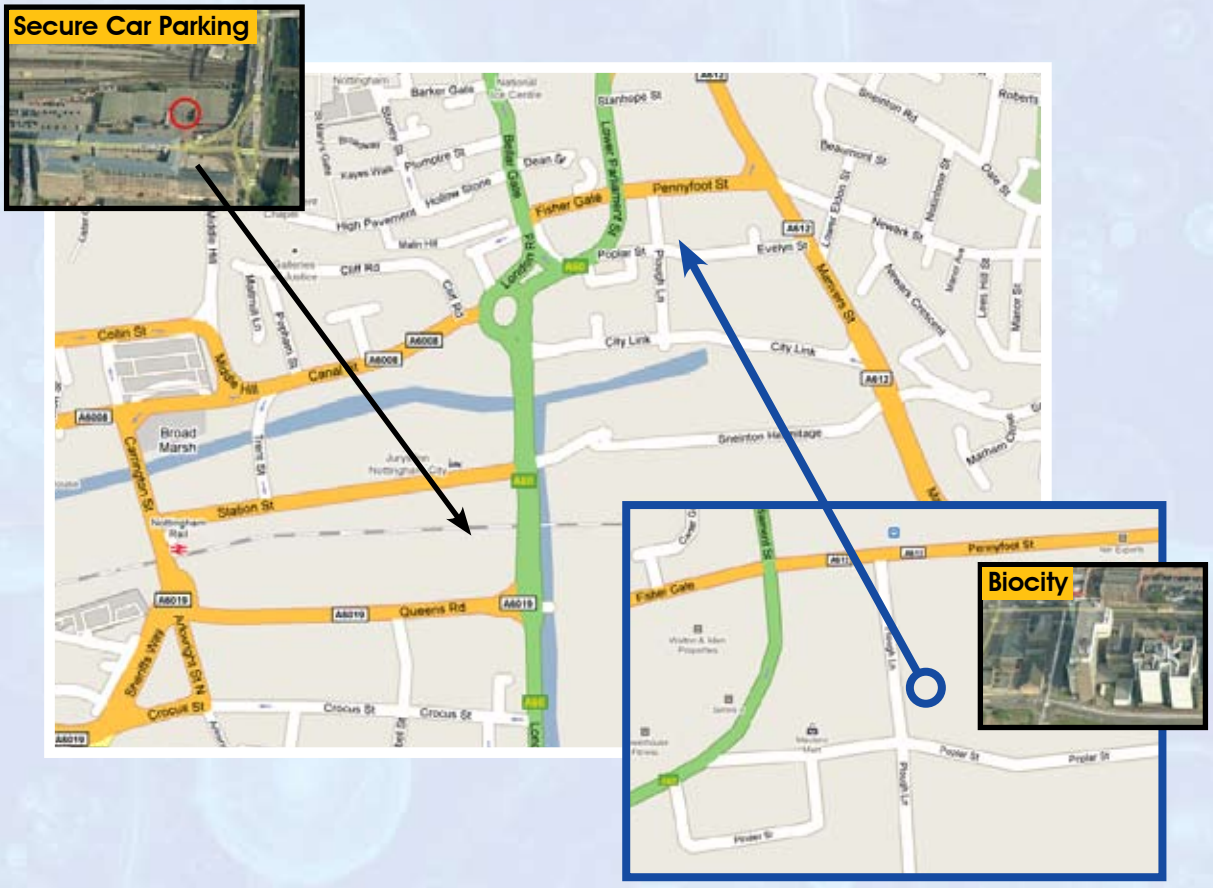
On-site parking for conferencing delegates and meeting attendees is not avaialble however there are suitable options noted below:

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) ✓

☐ Good Manufacturing Practice (GMP) for APIs **FULL DAY -** Monday April 4th, 2011 (9:00am - 5:30pm)	**£325** (VAT included)	**FEES INCLUDE:** **Certificate** **Printed Manual** **Lunch** (Full Day course only) **Refreshments**
☐ Supporting Quality Systems in a GMP Environment **FULL DAY -** Tuesday April 5th, 2011 (9:00am - 5:30pm)	**£420**(VAT included)	
☐ **REGISTER FOR BOTH COURSES AND SAVE £50**	**£695** (VAT included)	

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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Good manufacturing practices

GMPs are a set of regulations describing minimum standards and controls to be applied to manufacturing practices for the preparation of drug products.They are not arbitrary rules created simply to aggravate manufacturers, but rather they are responses to consumer concerns and documented tragedies in our history.

Training

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