Writing effective SOPs in a GMP environment

13 & 14 October 2011

Window Conference Venue, London UK

Course objectives

Regulatory Agencies require written procedures for all systems and operations which impact the quality and safety of pharmaceutical products. Standard Operating Procedures (SOP's) provide the main forum for the documentation of a Company's systems and operations. SOP's are therefore the most popular documents audited by Regulatory Agencies during GMP inspections to ensure they reflect current practices and are followed as written.

This course provides helpful information by presenting topics associated with the writing, formatting, execution, management and global harmonization of SOP's. It also discusses good documentation practices required by companies to ensure GMP compliance and relates the role which SOP's play in achieving the required level of compliance and quality.

The course material is presented by means of slides, handouts and participation of the attendees through discussion and individual/group exercises.
Note: Participants may bring an SOP related to their work for the workshop exercise on day two.

The workshop emphasises practical issues such as:

- The benefits of SOP's
- The logical approach to defining and writing the procedure section of the SOP
- Writing SOP's as part of a team
- Critiquing an example of a badly written SOP

The course provides ample opportunities for group discussions and hands on exercises. It enables participants to gain the skills and knowledge necessary to meet the expectations of regulatory agencies.

This course will deliver the tools to enable you to

- Understand the purpose and benefit of effective SOPs
- Understand the critical role of SOPs in Quality Documentation systems
- Use various tools such as flowcharting to define a logical procedure
- Write a concise, unambiguous SOP for its intended purpose
- Ensure the document is written for the correct audience
- Link SOPs to good documentation practices
- Define clear responsibilities in order to promote action and closure within the document
- Manage revisions, non conformance and deviations from a current SOP

Who should attend?

This two-day course is valuable for all personnel who are involved in the organization; writing or management of SOP's required for GMP purposes.

- Quality Assurance
- Documentation and Technical Writing
- Quality Control Laboratory
- Regulatory Affairs
- Contract Laboratory
- Analytical Laboratory
- Project Management
- Training
- Validation
- Consultants

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

Day 1
8.30 Registration and Coffee

Morning Session 1
9.00 to 10.30am
- Introduction
- Individual Exercise
- Benefits of SOPs
- Global Harmonisation of SOP's

10.30 Morning refreshments

Morning Session 2
10.45 am to 12.30pm
- Overview of Regulatory Expectations
- The Role of SOP's in Quality Documentation Systems
- Good Documentation practices

12.30 Lunch

Afternoon Session 1
13.30 to 15.00pm
- SOP Maintenance
- Group discussion (Paper versus electronic maintenance)

15.00 Afternoon refreshments

Afternoon Session 2
15.15 to 17.15pm
- Designing an SOP template
- Exercise (groups of 2 or 3 people)

17.15pm End of day

Day 2

Morning Session 1
9.00 to 10.30am
- Review exercise for end of day 1
- The team approach to SOP writing
- Defining responsibilities and knowing the audience

10.30 Morning refreshments

Morning Session 2
10.45 am to 12.30pm
- Ensuring the flow of the document
- Group exercise
- Writing tips for a concise, unambiguous document

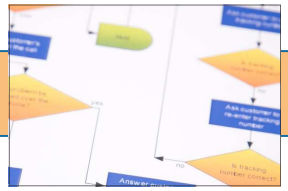
12.30 Lunch

Afternoon Session 1
13.30 to 15.15pm
- Writing tips for a concise, unambiguous document (continued)
- SOP's as a training tool
- Exercise – critique a badly written SOP
- SOPs and the Change Control System

15.15 Afternoon refreshments

Afternoon Session 2
15.15 to 17.00pm
- Managing revisions, Non-conformance and Deviations
- Final Advice and Summary
- Individual SOP work

17.00pm End of day



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 cGMP and validation training for the past 15 years. She is a very highly rated presenter.

Since then she has worked as a validation specialist at Pfizer, Manager of Research, Development and Validation at SGS Life Sciences, a consultant to the pharmaceutical industry and has taught analytical R& D, method validation, GMP and related Quality Systems courses across Canada, in the US and China.

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.

Venue

Window Conference Venue 13 Windsor Street, Islington London, N1 8QG convenient for central London, in a pleasant informal setting.

Travel directions and accommodation details are available on our website
www.pharma-training-courses.com

Liability

PharmaTraining 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.
PharmaTraining Ltd will not be responsible for any airfare, accommodation or other travel costs incurred.

Course Programme 2011

Planning for Commercial Launch: *29 & 30 March 2011*
GMP Auditor Training*: New Jersey USA - 11 & 12 April 2011*
London - 9 & 10 May, 7 & 8 November 2011
How to Audit API Manufacturers: *New Jersey USA - 13 April 2011*
London - 11 May, 9 November 2011
Supply Chain Management in Pharma/Biotech: *5 & 6 May 2011*
Technology Transfer: *London - 9 & 10 May, 7 & 8 November 2011*
Integrated Tablet Formulation Development: *New Jersey USA - 7 & 8 April*
London - 9 & 10 June, 24 & 25 November 2011
Tablet Process Development, Validation and the application of QbD:
New Jersey USA - 11 & 12 April, London - 13 & 14 June, 28 & 29 November
Pharmacokinetics in Drug Development - an Integrated Approach:
9 & 10 June 2011
An Introduction to LC/MS: *19 September 2011*
Quantitative Analysis: *20 & 21 September 2011*
Writing effective SOPs in a GMP Environment: *13 & 14 October 2011*
OOS investigations in a GMP Environment: *18 & 19 October 2011*
Stability Testing in Pharmaceutical Development: *16 & 17 May 2011,*
12 & 13 December 2011
HPLC Analytical Method Development and Validation: *22 & 23 November*
Oral Solid Dosage Manufacturing Technology: *28 November 2011*
Development and Manufacture of Effervescent Tablets: *30 November 2011*
Introduction to Photostability: *14 December 2011*
Pharmaceutical Packaging - an Introductory Course: *14 December 2011*

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REGISTRATION FORM	
Writing effective SOPs in a GMP environment: 13 & 14 October 2011, London UK 2 day course £1180.00 + VAT £236.00 **Total £1416.00**	
Writing effective SOPs in a GMP environment: 13 & 14 October 2011, London UK **Discounted** rate for registering and paying before **17 August 2011** 2 day course £1062.00 + VAT £232.40 **Total £1294.40**	
Discount of 10% applies for booking 8 weeks in advance Discount of 10% applies for booking more than 1 delegate Discount of 10% applies for booking more than 1 course ***Maximum discount received is 15%***	

Title _____First name _____

Surname: _____

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_____

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Delegate fees

Fees for this programme are shown overleaf. 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.

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