PharmaTraining

# OOS investigations in a GMP environment
## 23 & 24 October 2012
## Window Conference Venue, London UK

### Course objectives

This course is designed to provide essential training for conducting Out of Specification (OOS) investigations in a GMP environment. A background discussion of the associated GMP documentation required to support the OOS investigation is included but the majority of time is spent detailing the who, what, when, how and why of the investigation, determining the extent of the investigation during Phase I and Phase II, documenting findings determining root causes and assigning corrective and preventative actions. An introduction to OOT (Out of Trend) results and an overview of the different types and how they are typically handled is also discussed using industry examples in the first session of this course.

This course is presented in a dynamic environment created by a power point presentation, interactive exercises, case studies and group discussion. Participants are welcome to bring their own examples for group discussion sessions.

The workshop emphasizes practical issues such as:

- What is an OOT?
- The importance of good quality support systems
- FDA audit observations and how they could have been avoided
- Case studies for OOS results
- A detailed guide to conducting Phase 1 and Phase II of the OOS investigation
- Reporting and evaluating passing and failing results

The course provides ample opportunities for group discussions, case studies and exercises. It enables participants to gain the skills and knowledge necessary to meet current regulatory expectations. The course material is based on the FDA guideline *"Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production", October 2006*

### Who should attend

This Two-day course is valuable for Directors, Managers, Supervisors, Laboratory Analysts and Associates working in a GMP environment in the Pharmaceutical and related industries with daily responsibilities in the following areas:

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

### 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 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.

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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 and definition of OOT/OOS Out of Trend Results
- Defining the main categories of OOS results
- Review of FDA's guidelines (Oct 2006)
- Examples and case studies of regulatory observations

10.30 Morning refreshments

Morning Session 2 - 10.45 am to 12.30pm

- Quality documentation required to support OOS investigations
- Responsibilities
- Investigating OOS results - Phase 1
  - ° Flow chart
  - ° Checklist

12.30 Lunch

Afternoon Session 1 - 13.30 to 15.15pm

- Investigating OOS result - Phase 1 (continued)
  - ° Determining the root cause
  - ° Common Laboratory errors
- Regulations and industry response to invalidating OOS results

15.15 Afternoon refreshments

Afternoon Session 2 - 15.30 to 17.30pm

Phase 1 Case studies

These are interactive group exercises where the participants utilise their experience and new learnings to figure out more appropriate action than that which was taken as described in the examples. Their answers are then compared to the actual FDA response.

Group discussions follow.

17.30pm End of day

**Day 2**

Morning Session 1 - 9.00 to 10.30am

- Investigating OOS results Phase 2
  - ° Flow chart
  - ° Checklist
  - ° Examples of root causes found during Phase 2 investigations

10.30 Morning refreshments

Morning Session 2 - 10.45 am to 12.30pm

- Case studies Phase 2

12.30 Lunch

Afternoon Session 1 - 13.30 to 15.15pm

- Additional Laboratory Testing (Retesting and Resampling)
- Reporting Test Results
- Concluding the Investigation and Evaluating the results

15.15 Afternoon refreshments

Afternoon Session 2 - 15.30 to 17.00pm

- Corrective and Preventative Actions
- The Audit Trail
- Minimising future OOS results

**17.00pm End of day**

## 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**

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)

***We offer**: Moderate prices, small classes, interactive workshops given by knowledgeable speakers with many years of industry experience.*

## Course Programme

***GMP Auditor Training** 14 & 15 May 2012*
***How to Audit API Manufacturers** 16 May 2012*
***Stability Testing in Pharmaceutical Development and Manufacture** 22 & 23 May 2012*
***Pre-formulation Studies for Tablet Development** 21 & 22 June 2012*
***Tablet Formulation Development** 25 & 26 June 2012*
***Hands-on Tablet Development including Pre-formulation, Formulation and Process Development** 27 to 29 June 2012*
***Technology Transfer** 2, 3 & 4 July 2012*
***Tablet Process Development, validation and the application of QbD** 9, 10 & 11 July 2012*
***Hands-on Tablet Development including Pre-formulation, Formulation and Process Development** 26 to 28 September 2012*
***Quantitative Bioanalysis using LC/MS for Pharma** 25 & 26 September*
***OOS Investigations in a GMP Environment** 23 & 24 October 2012*
***QbD and Lifecycle Management for Analytical Methods** 25 & 26 October*
***Stability Testing in Pharmaceutical Development and Manufacture** 21 & 22 November 2012*
***Introduction to Photostability** 23 November 2012*
***Pharmaceutical Packaging - an introductory course** 23 November 2012*
***Introduction to Sterile Product Manufacturing for Junior Staff and New Staff** 28 & 29 November 2012*
***Introduction to Sterile Product Manufacturing for those with a cGMP basic understanding** 3 & 4 December 2012*
***Pre-formulation Studies for Tablet Development** 29 & 30 November*
***Tablet Formulation Development** 3, 4 & 5 December 2012*
***Technology Transfer** 5, 6 & 7 December 2012*
***Tablet Process Development** 11, 12 & 13 December 2012*
***Development and Manufacture of Effervescent Tablets** 14 December*
***Oral Solid Dosage Manufacturing Technology** 14 December 2012*

Check out the benefits, content, details, dates and times of our range of training programmes:

**www.pharma-training-courses.com**

We deliver a range of expert programmes in pharmaceutical development, quality assurance and regulatory topics, plus a new range of industry awareness courses. We employ speakers/trainers with a high degree of expertise, completely up to date with industry trends.

We run our programmes in a variety of locations, throughout the year. All of our programmes can be run in-house.

Contact **Judy Callanan** Ph: 0044 (0)20 7193 7703, Fax: 0044 (0)20 7681 3582
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***Maintain your competitive edge—keep up to date with the latest industry requirements***

## REGISTRATION DETAILS

**OOS investigations in a GMP environment:**
23 & 24 October 2011, London UK
Full Fee: 2 day course £1180.00 (+ VAT if applicable, see VAT NOTES)

**OOS investigations in a GMP environment:**
23 & 24 October 2012, London UK
**Discounted** rate for registering and paying before **17 August 2011**
**-** 2 day course £1062.00 (+ VAT **if applicable, see VAT NOTES)**

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%***

**VAT NOTES:**

**UK:** Under UK law all UK-based applications are subject to VAT at the prevailing rate however most UK VAT registered companies/organisations can reclaim this tax.

**EU:** With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT ***PROVIDED THAT*** valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.

**OTHER:** With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT, ie no VAT is charged or payable.

**Methods of payment available:**

☐ Cheque - **Please make payable to "PharmaTraining Ltd"**

☐ Bank transfer

☐ Credit/Debit Card

**Please register online at www.pharma-training-courses.com**

**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.

**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.

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