



OOS/OOT Investigations for Analytical Laboratories Interactive Workshops!!

Registration Fee: £865

Date: June 21-22, 2010

Course Duration: Two Days 9am-5pm

Objective:

Deficiencies of OOS investigations continue to be the major cause of warning letters in the pharmaceutical industry. Regulatory Agencies including FDA require that all out-of-specification results must be investigated; therefore, an effective and compliant quality management system requires well-documented, thorough investigations for OOS. Key challenges for many companies are having a clear understanding of regulatory expectations on how to handle OOS and OOT. Lack of consistency around investigation and root-cause analysis processes will lead to error and expensive laboratory activities.

This workshop will discuss the Guidance for Industry on OOS/OOT investigation issued in October 2006 by the FDA. As testing become critical to determine the cause of OOS results, investigation process will be discussed and procedure that will minimize OOS and identify OOT. It will also discuss the documentation system as well as CAPA activities. (This session is not for micro testing)

Learning Benefits:

- Understand regulatory expectations for OOS investigation
- Define documentation system for reporting data
- Build ruggedness into the analytical procedures to prevent OOS occurrences
- Build compliance into the investigation process to minimize OOS
- Define and monitor Corrective and Preventive Actions.

Key Topics

Part I: Understanding Regulatory Expectations on OOS/OOT

- Determine regulatory impact of OOS
- Review of warning letters relating to OOS/OOT
- Definition of OOS and OOT
- Outline a general OOS procedure

Workshop: Develop a check list for OOS investigation

Part II: OOS Investigation Process

- Identifying and assessing OOS test results
- Phase I: Laboratory Investigation
- Phase II: Full Scale OOS Investigation



- Conclusions and Documentations

Workshop: Develop an investigation plan to determine the root cause.

Part III: Understanding OOT and Documentation

- Recognize different types of OOT results
- Determine course of actions to process
- Understand cross-functional investigation
- Establish documentation and performance metrics

Workshop: Discuss key factors to identify suspect data.

Part IV: Wrap Up an Investigation

- Determine corrective actions based on findings
- Monitor reoccurrence
- Systems to prevent OOS/OOT
- Follow up and Conclude an investigation

Faculty

Kim Huynh-Ba **Technical Director, Pharmalytik**

Kim Huynh-Ba is the Technical Director of Pharmalytik Consulting & Training Services (www.pharmalytik.com). With over twenty three years of experience in various analytical areas of pharmaceutical development and a primary focus in stability sciences, she specializes in analytical development, stability, outsourcing and technology transfer management. She has been involved with several projects harmonizing and optimizing analytical best practices in several companies, including those under Consent Decree.

Kim has authored numerous technical publications and book chapters. She is a frequent speaker at national and international conferences. Since 2001, she has conducted training activities on cGMP compliance and quality issues for national organizations such as ACS, PittCon, AAPS, IIR, SWE, IPA, IVT and CBI. She is an active member of AAPS, PSDG, ACS as well as serving on the Governing Board of Eastern Analytical Symposium (EAS). She is the founder and past-chair of the AAPS Stability Focus Group, and serves in the Steering Committee of the CMC Focus Group. She is Chair of the Distance Learning Committee of AAPS Analysis & Pharmaceutical Quality (APQ) and participates in the USP Stake Holder and also USP Reference Standard Project Team.

Kim received 2008 Leadership Award from APQ and 2008 Recognition Award from AAPS Regulatory Sciences (RS) section. She is the editor of "***Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies and Best Practices***", Springer, 2008 [ISBN: 978-0-387-85626-1].

Who Will Benefit:

This series will benefit analyst to group manager who are responsible for acquiring, evaluating or reporting analytical results. It is designed to provide key principles for OOS and OOT investigations.



CERTIFICATE OF ATTENDANCE AND COURSE MATERIAL

- All participants will receive a certificate of attendance upon completion of the course
- The participants will be receiving specially prepared course manual

Location

Park Inn– Central London

Just a stone's throw from the **British Museum** and within walking distance to **Covent Garden & Oxford Street**, the Park Inn (former Bonnington Hotel) is nestled between London's financial district and the West End.

Conveniently located within the heart of **historic Bloomsbury**, the Park Inn (former Bonnington Hotel) is situated between Russell Square and Holborn tube stations and is within easy reach of Kings Cross and Euston Train stations.

Address:

92 Southampton Row, London, England, WC1B 4BH

Telephone: +44 (0)20 7274 2828

Fax: +44 (0)20 7274 2828

www.parkinn.co.uk

Registration

Please refer to the **register** tab on the CATD website (www.catdglobal.com) or click on the title of the course on the conferences/meeting or home page to register on line.

If you have any problem registering please do not hesitate to contact us at info@catdglobal.com or call us at + 44 (0) 20 8485 1234 or fax us at + 44 (0) 20 8485 1234

***Registration Fee Includes:**

Presentation Materials, Luncheon, and Refreshment

***Please indicate any special Dietary requirements when registering for the course**

Contact for More Information

Centre for Applied Training and Development

27 Old Gloucester Street

London

WC1N 3XX

T: +44 (0) 20 8485 1234

F: +44 (0) 20 8485 1235

www.catdglobal.com

info@catdglobal.com