



Designing an Effective Stability Program Includes 5 Workshops!!

Registration Fee: £865

Date: June 17-18, 2010

Course Duration: Two Days 9am-5pm

Key Topics

1. *Regulatory Requirements of Stability Testing*

- Overview of stability role in the drug development process
- Examine factors that may affect expiration dating of drug products
- Review cGMP and ICH stability requirements
- Review ICH process and Q1AR2

2. *Discuss Global Requirements of Stability Program*

- Discuss impact of global stability requirements (including WHO and ASEAN)
- Examine Packaging considerations
- Determine Special stability studies
- Design stability protocols by development phases

Workshop 1: Design a stability protocol to support new drug submission.

3. *Developing Stability Indicating Test Procedures*

- Impact of analytical testing in the drug development process.
- Review ICH Q2 A&B guidelines for method development/validation.
- Discuss Q3 for impurities monitoring
- Method specificity through forced degradation activities.
- How to develop stability-indicating test methods

Workshop 2: Discuss Warning Letters of Stability program.

4. *Understand Stability Operations*

- Stability Day-to-Day Operations
- Discuss best practices on these operations
- Discuss key factors of environmental chambers
- Define Bracketing and Matrixing from Q1A
- Benefits and drawbacks of bracketing and matrixing

Workshop 3: Discuss strategies of reducing stability testing to maximize resources.

5. *Out-of-Spec investigation for Stability Results*

- Perform data scrutiny based on types of samples
- Review FDA draft guidance on OOS and FDA Guides to inspection
- Determine root cause analysis
- Discuss the benefits and drawbacks of outlier test
- Determine quality markers for Out of Trend investigation



Workshop 4: Structure an OOS investigation.

6. Validation Data for Quality and Compliance

- Discuss GMPs requirements on records and reports
- Discuss CMC requirement highlights
- Establish information necessitate Stability Data tables
- Establish related SOPs on how to report stability data
- Review Q1E on evaluating stability data

Workshop 5: Discuss CMC strategies and experiences.

Interactive exercises or Discussions of warning letters are to be developed with every session.

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].

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.

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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

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