

CATD Webinars

Laboratory Series

Troubleshooting Chromatographic Method Transfer of Pharmaceutical Products

Registration Fee: £185

Date: April 23, 2010

**Course Duration: 90 min. 2:00pm-3:30pm London, UK (GMT) Time
9:00am-10:30am EST Time**

Key Topics & Agenda

HPLC analytical methods are a major tool in the pharmaceutical development to control the quality and integrity of the active drug substance or drug product. Qualifying analysts to perform these methods is a critical activity that would significantly impact the launch of a product. This webinar will discuss issues that can come across while transferring HPLC method from one site to another.

Outline:

- Discuss cGMP requirements for analytical methods.
- Review of Warning Letter citations.
- Discuss FDA expectations during methods transfer.
- Discuss method issues that can affect transfer experiments
- Discuss instrument discrepancies that can affect transfer exercises.

Faculty

Kim Huynh-Ba
Technical Director, Pharmalytik Consulting

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].

Registration

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