

## Calibration & Validation Group

### **The Canadian Workshop on 2006 FDA/AAPS Crystal City White Paper “Quantitative Bioanalytical Methods Validation and Implementation: Best Practices for Chromatographic and Ligand Binding Assays”**

**Thursday, May 17<sup>th</sup>, 2007**

**Montreal, Canada** (Four Points by Sheraton Montreal Airport)

Calibration & Validation Group (CVG) is pleased to announce a unique **1-day full immersion workshop** for **ALL** the CROs and Pharmaceutical Companies involved in providing bioanalytical data for **Bioavailability, Bioequivalence, Pharmacokinetic, and Comparability Studies.**

#### **GOAL:**

This workshop will focus on discussing, reviewing, sharing perspectives, providing potential solutions, and perhaps agreeing upon a consistent approach on the main “hot topics” presented in the 2006 Crystal City White Paper just published on AAPS Journal, and it is available on line at: <http://www.aapsj.org/view.asp?art=aapsj0901004>

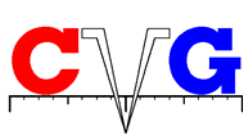
This white paper summarizes the conclusions of the 3<sup>rd</sup> FDA/AAPS Bioanalytical Workshop, held on May 1-3, 2006 in Arlington, VA, USA.

#### **LECTURES:**

The presentations, lectured by recognized experts from regulatory and industry, will be enriched by interactive discussion and audience participation.

#### **PROGRAM:**

- 08:30am–09:00am: Registration
- 09:00am–10:00am: Introduction & Review of the main topics reported in the “2006 Crystal City White Paper.” What’s new?
- 10:00am–10:30am: **KEYNOTE:** “Calibration Curve and QC Ranges” (**Dr. Eric Ormsby**, A. Manager, Office of Science, Health Canada-Therapeutic Product Directorate, HC-TPD, and 2006 Chrystal City AAPS/FDA White Paper Contributor)
- 10:30am–11:00am: Coffee Break
- 11:00am–11:30am: “Incurred Sample Re-analysis” (**Dr. Saleh Hussain**, Director Bioanalytical Operations, Anapharm, A PharmaNet Company)
- 11:30am–12:00pm: “Matrix Effect and Hemolysis Effect for MS Based Assays” (**Dr. Nicola C. Hughes**, Director Bioanalytical Laboratory Biovail Contract Research, A Division of Biovail Corporation)
- 12:00pm–01:00pm: Lunch
- 01:00pm–01:30pm: “Approaches to Assay Specificity in LC-MS/MS Methods” (**Xia Yin, B.Sc.**, Scientific Leader, Bioanalytical Method Development, Bioanalytical Development, BCD, Apotex Inc.)
- 01:30pm–02:00pm: “Confirmatory Re-analysis of Study Samples – An Interactive Session” (**Dr. Mario L. Rocci Jr**, CEO Prevalere Life Science Inc, AAPS Advisor, 2006 Chrystal City AAPS/FDA White Paper Editor)



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- 02:00pm–02:30pm: Coffee Break  
**02:30pm–03:00pm:** “Metabolite Issues” (**Dr. Fabio Garofolo**, VP Bioanalytical Services, Algorithme Pharma Inc., CVG Advisor)  
**03:00pm - 04:00pm:** Open Discussions (Moderators: Experts from regulatory and industry)  
**04:00pm – 04:30pm:** Meeting Wrap Up

### REGISTRATION:

Workshop Fee:.....**\$250.00 + GST + QST**

INTERESTED? You can register by sending email to CVG at [lcms\\_registration@cvg.ca](mailto:lcms_registration@cvg.ca) or calling (514)-236.4225 by **April 30<sup>th</sup>, 2007**

**This Workshop is sponsored by:**

