

Calibration & Validation Group

The 2nd Canadian Workshop on Recent Issues in GLP Bioanalysis

“This is a must attend event for those involved in Bioanalysis: The participants will receive an exhaustive update on the hot topics from experts in the field (FDA, Health Canada TPD, Pharmas and CROs)”

April 17th – 18th, 2008 Montreal, Canada (Four Points by Sheraton Montreal Airport)
Short Course: April 16th, 2008

CONTRIBUTING SPEAKERS

Regulatory Bodies

Dr. Brian P. Booth
Deputy Director
FDA

Eric Ormsby
A. Manager
Health Canada TPD

Dr. Alan Viau
Associate Director
Health Canada TPD

Pharmas

Michael Lindsay
Director Bioanalytical Lab
Apotex

Dr. Rupinder Phull
Associate Director PK/BE
Barr Laboratories

Zhimeng Zhu
Director Biopharmaceutics
Pharmascience

CROs

Dr. Fabio Garofolo
VP Bioanalytical Services
Algorithme Pharma

Dr. Nicola C. Hughes
Director Bioanalytical Lab
Biovail Contract Research

Dr. Saleh Hussain
Director Bioanalytical Operation
Anapharm–PharmaNet Comp.

Dr. S. Peter King

VP Global DMPK

Quest Pharmaceutical Services (QPS)

HIGHLIGHTS

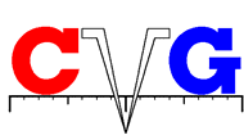
The upcoming workshop is a **one and half day** full immersion for all the CROs and Pharmaceutical Companies involved in providing **bioanalytical data for bioavailability, bioequivalence, pharmacokinetic, and comparability studies**. We anticipate more than 200 attendees. The invited speakers are a balanced blend of international experts from FDA, Health Canada TPD, CROs and Pharmaceutical Companies. The first full day is dedicated to presentations from the invited speakers and collection of questions from the audience ending with a mixer reception. The next half day will be mainly dedicated to panel discussion.

A half day **short course** on “**Issues in GLP Bioanalysis: Bioanalytical Method Validation and Sample Analysis from Crystal City I to Crystal City III**” has been specifically designed to prepare the attendees to fully benefit from this workshop.

GOALS

After the success of “The 1st Canadian Workshop on 2006 Crystal City White Paper” (workshop report is available at www.cvg.ca), Calibration & Validation Group (CVG) is organizing “The 2nd Canadian Workshop on Recent Issues in GLP Bioanalysis” as a follow up to the first event. The following topics were suggested for discussion during the 1st Canadian Workshop by the audience and CVG members both on-site and on-line:

- What is your approach for assuring incurred samples reproducibility? What has already been done to implement the recommendations of the Crystal City III paper on assay



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- reproducibility? (Practices and techniques that have been used since the publication of the White Paper)
- What criteria for PK repeats are you using? Forum for discussing how various companies are handling PK repeats.
 - Matrix Effects and Hemolysis Effect: How and why?
 - Ion suppression and matrix effect: Do we need full or partial validation for the same compound in different species?
 - Autosampler Stability and re-injection reproducibility: are you still using a fresh curve?
 - Are standards being set by 483s and not by consensus, i.e. regulating by 483? Overreaction to avoid future 483s.
 - Can storage at -70°C and -80°C be considered equivalent?
 - Changing type of anticoagulants: what validation parameters should be evaluated?
 - Contamination Criteria: What criteria are you using?
 - Acceptance of nonlinear calibration models? How much “quadratic” is acceptable?

However, due to time constraints, only the first topic on incurred sample reproducibility was thoroughly discussed during the 1st Canadian Workshop. During the 2nd Canadian Workshop, the above topics will be discussed together with any other recent issues in GLP Bioanalysis.

LECTURES

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

PROGRAM

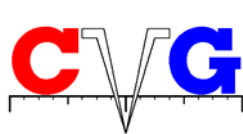
Wednesday, April 16th, 2008 – Short Course: “Issues in GLP Bioanalysis: Bioanalytical Method Validation and Sample Analysis from Crystal City I to Crystal City III”
(Instructor: Dr. Fabio Garofolo – Scientific Affairs Director, CVG)

12:30pm–01:00pm: *Short Course Registration*

01:00pm–02:00pm: Lesson 1 – Bioanalytical Method Validation: “History & Definitions”
(Definition of Bioanalytical Method Validation; History: Regulatory guidance on bioanalytical method validation: Crystal City I-III; FDA Guidance for the Industry, Bioanalytical Method Validation (May 2001); FDA Good Laboratory Practice for Nonclinical Laboratory Studies: Title 21, Code of Federal Regulations, Part 58; OECD Principles on Good Laboratory Practice (as revised in 1997); Drugs Directorate Guidelines, “Conduct and Analysis of Bioavailability and Bioequivalence Studies”; Health Protection Branch, Health and Welfare Canada, 1992; Statistics; Statistical Mean; Standard Deviation; Relative Standard Deviation; Deviation from Theoretical; Percent Difference; Correlation Coefficient; Rejection of Outliers with T-test; GLP Definitions; Key Terms & Concepts in Bioanalysis; GLP Documentation; GLP Analytical Method, GLP Data Review)

02:00pm–02:15pm: *Coffee Break*

02:15pm–03:15pm: Lesson 2 – Bioanalytical Method Validation: “Criteria & Concepts”,
(The Validation Process; Goals of Validation; Uncertainty in Quantitative Analysis; Validation Parameters: LOD, LLOQ, ULOQ, Accuracy, Precision, Analysis of Variance (ANOVA); Assessing Accuracy and Precision; Calibration; Limit of Quantification and other Key Terms; Stability Tests, Recovery; Method Validation; Defining Acceptance Criteria; Essential Documentation; System Suitability; Approaches to Quantification: Calibration Curve and Standard Addition Method; Quantitative Relationships in MS Instruments; Nature of Regression Errors; The Steps in a Typical MS Quantitative Analysis; Routine Sample Analysis)



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03:15pm–03:30pm: *Coffee & Refreshment Break*

03:30pm–04:30pm: Lesson 3 – Bioanalytical Method Validation and Sample Analysis: “Common Problems”

(Why LC-MS? Advantages & Disadvantages in Bioanalysis; Professor Fred McLafferty's Four S's of LC-MS Analysis; Internal Standard; Choice of the best Internal Standard; Sample Preparation Pros and Cons; Protein Precipitation (PPT); Liquid-Liquid Extraction (LLE); Solid Phase Extraction (SPE); Matrix Effect; Effects of Matrix Suppression of Ionization in Electrospray LC-MS/MS; Remedy for Ionization Suppression in SPE-LC-ESI; Matrix Induced Ionization Suppression in APCI; Differential Suppression; The 3 Different Scenarios of Matrix Effect; Instrument Optimization & Matrix Effect; Carry-over Definition; Carry-over Guidelines; Fighting Carry-over; Drug Metabolism; Metabolite Conversion During Sample Extraction; Metabolite Conversion During Instrumental Analysis; General Strategy for Method using UV or Fluorescence Detection; General Strategy for Method using MS or MS/MS; Study Cases)

04:30pm–05:15pm: Lesson 4 - Introduction & Review of the Main Topics Reported in the “2006 Crystal City White Paper.” What's new?

(The purpose of the 3rd AAPS/FDA Bioanalytical Workshop; Crystal City III: Conclusions; Quality Controls: Conventional and New Approaches; Evaluating Curve Models: Graphic & Mathematical Comparison; Factors contributing to Imprecision and/or Inaccuracy; Carryover and Contamination Evaluation; Evaluate Contamination in Validation; Incurred sample Re-Analysis; Reproducibility of QC vs. Incurred Samples; Determination of Metabolites During Drug Development; Documentation Issues; Repeat Analyses; Matrix Effects for MS-based assays; Run Acceptance Criteria; Stability Recommendations; Autosampler Re-injection Reproducibility; Blood Stability; Method Evolution & Stability Measurements; Internal Standard Stability; Validation Topics with No Consensus: -70C vs. -20C; Reference Standard Expiration Date vs. Stock Stability; Other Interesting Validation tests; What 's going on after the White Paper; The 1st Canadian Workshop Report)

05:15pm–05:30pm: Q&A and CVG Course Certificate

Thursday, April 17th, 2008 – Workshop Presentations

08:30am–09:00am: *Registration & Breakfast*

09:00am–09:30am: Introduction & Review of the Main Topics discussed during the previous Canadian Workshop and in other similar recent international meetings & conferences.

09:30am-10:00am: **Dr. Alan Viau** – Associate Director, Health Canada-Therapeutic Product Directorate

10:00am-10:30am: **Dr. Brian P. Booth** – Deputy Director, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, US Food and Drug Administration

10:30am-11:00am: *Coffee & Refreshment Break*

11:00am–11:30am: **Michael Lindsay** - Director, Bioanalytical Laboratory, Bioanalytical Development, BCD, Apotex Inc

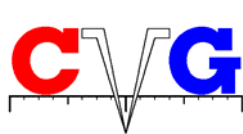
11:30am–12:00pm: **Dr. Rupinder Phull** – Associate Director, Pharmacokinetics & Bioequivalence (PK/BE), Barr Laboratories, Inc.

12:00pm-01:00pm: *Lunch at Ristorante Volare, Four Points by Sheraton Montreal Airport*

01:00pm–01:30pm: **Dr. Saleh Hussain** - Director Bioanalytical Operations, Anapharm, A PharmaNet Company

01:30pm–02:00pm: **Dr. S. Peter King** - VP, Global DMPK, Quest Pharmaceutical Services (QPS), L.L.C.

02:00pm–02:30pm: **Dr. Nicola C. Hughes**, Director Bioanalytical Laboratory Biovail Contract Research, A Division of Biovail Corporation



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02:30pm–03:00pm: *Coffee & Refreshment Break*

03:00pm–03:30pm: **Zhimeng Zhu** – Director, Biopharmaceutics & Clinical Research Department, Pharmascience Inc.

03:30pm–04:00pm: **Eric Ormsby**, A. Manager, Office of Science, Health Canada-Therapeutic Product Directorate

04:00pm - 04:30pm: **Dr. Fabio Garofolo**, VP Bioanalytical Services, Algorithm Pharma Inc.

04:30pm – 05:00pm: Audience Questions Gathering and Preparation for Panel Discussion

05:00pm – 07:30pm: *MIXER RECEPTION & Exhibition*

Friday, April 18th, 2008 – Panel Discussion

07:30am–08:30am: *Invited Speakers Working Breakfast & Panel Discussion Preparation*

08:00am–08:30am: *Attendees Breakfast*

08:30am–09:00am: Answer to Audience Questions (Invited Speakers)

09:00am–11:30am: Panel Discussion

11:30am–12:00pm: Closing Remarks and Adjournment

REGISTRATION:

Short Course Fee:..... **\$290.00 + GST + QST**

Workshop Fee:.....**\$450.00 + GST + QST**

Short course & Workshop Fee:.....**\$690.00 + GST + QST**

(Fees are in Canadian Dollars)

INTERESTED? You can register by sending email to CVG at registration@cvg.ca or calling (514)-236.4225 by **March 16th, 2008**

CANCELLATION POLICY

Cancellations must be sent by e-mail to registration@cvg.ca before March 31st, 2008. Refunds will be issued minus an administrative fee of \$100. All refunds will be issued after the meeting.

SPONSORSHIP/EXHIBITION OPPORTUNITIES

Please contact directly registration@cvg.ca for having more information on the numerous sponsorship/exhibition opportunities

ACCOMODATIONS

Hotel rooms have been blocked at discounted rate of \$104 (Canadian Dollars) plus tax per night April 15 through April 19.

Four Points by Sheraton Montreal Airport

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