

Calibration & Validation Group
2-3415 Dixie Rd., Suite 402
Mississauga, Ontario
Canada, L4Y 4J6

REGISTRATION FORM

Name _____
Address _____
Phone _____
e-mail _____
Fax _____
Method of Payment: Cheques only _____
Signature _____

Price \$600.00
\$30.00

Sign up as:
 CVG Member
 CVG Membership

Total: _____

CVG Discussion Group Meeting will be held at the following sites:

Registration: 8:15am-9:00am
Meeting: 9:00am-4:00pm

- **April 13, 2007, Purdue Pharma**, 575 Granite Court, Pickering, Ontario
- **June 22, 2007, PharmEng Innovations**, Bldg:190 Albany, Suite 216, York University, 4700 Keele Street, Toronto, Ontario
- **October 5, 2007, CVG Convention and Discussion Group Meeting**, DoubleTree Airport, 655 Dixon Road, Toronto

Register early!

One time Registration fee includes:

All three meetings

Continental breakfast, lunch and refreshments

Registration is limited to increase interaction between participants.

CVG Member \$600.00
CVG Membership \$30.00

Mail registration form and fee payable to:

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Mississauga, Ontario
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To register personally or on-line, contact us at:

Phone: 416-650-8116 (Melissa Chan)
Website: www.cvg.ca
e-mail: melissa.c@pharmeng.com

Program

CVG is pleased to announce that it had consolidated the Discussion Group Activities and bring them together to provide focused forums for scientific exchange among pharmaceutical scientists in different companies and regulators.

If you have any questions about the individual CVG discussion group, please feel free to contact:

1. **General Discussion Group Question**
– YC Lee, Ph.D. (416-650-8116)
2. **Pharmacopoeial**
– Chung Chow Chan, Ph.D. (954-433-7480)
3. **Pharmaceutical Analysis and Dissolution**
– Malcolm Angod (416-699-7528)
4. **PAT**
– David Mayers (905-420-6400)
5. **Equipment Qualification**
– Herman Lam, Ph.D. (905-819-7131)
6. **Process Validation**
– Jerry Holatko (905-415-3922)



Pharmacopoeial

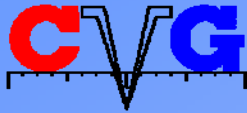
Pharmaceutical Analysis
(HPLC and Dissolution)

PAT

Equipment
Qualification/Verification

Process Validation

April 13, 2007 (Purdue Pharma)
June 22, 2007 (PharmEng Innovations)
October 5, 2007 (DoubleTree Airport)



Objectives of the CVG discussion groups

- Provide a forum for free exchange of scientific information
- Solicit feedback on best practices
- Discuss and provide feedback on proposed guidelines from different regulatory agencies

Who Should Attend

The Discussion Groups are training/learning resource to share learnings and exchange of information.

These discussion group meetings are designed for technical and regulatory scientists at all levels who want to share learnings and experiences.

Topics for discussion will span the CM&C section of the pharmaceutical industry and will include new analytical, instrumental technology and new guidances that will affect the pharmaceutical industries.

DRAFT AGENDA - April 13, 2007

Morning

1. Introduction
- *YC Lee, Ph.D.*
2. Updates from USP stakeholders meeting (Pharmacopoeial)
- *Elaine Vandenberg, Ph.D. GSK*
3. Tool kit approach for Capillary Electrophoresis method development (Pharm. Analysis)
- *Nicole Baryla, Ph.D., Eli Lilly*
4. Dissolution method development for intramuscular injection drug product by USP 4 -flow through apparatus (Pharm. Analysis)
- *Hitoshi Masui, Ph.D., PharmEng Innovations*
5. Process validation for parenteral drug product

DRAFT AGENDA - April 13, 2007

Afternoon

5. PAT Playground Initiatives
- *David Mayers, Purdue Pharma*
6. PAT Applications for Raman Spectroscopy (PAT)
- *Mark Kemper, Kaiser Optical Instrument*
7. PAT Applications for NIR
8. Interface between analytical and manufacturing equipment

PRELIMINARY AGENDA - June 22, 2007

1. Updates from USP Stakeholders meeting (Pharmacopoeial)
- *Elaine Vandenberg, Ph.D.*
2. PAT framework (PAT)
- *Herman Lam, Ph.D.*
3. Formulation challenges for special formulation (Formulation)
- *speaker to be confirmed.*
4. Development challenges of dissolution method for special formulation e.g. delayed release (Dissolution)
5. Process validation challenges for special formulation (Process Formulation)
6. Submission Requirements for Natural Health Products in Canada (Pharmacopoeial)
7. UPLC method development
8. Laboratory Automation
9. Implementation strategy and validation of LIMS