

Drug Metabolism and Pharmacokinetics Interest Group
Report of the Interest Group Workshop
60th ASMS Conference, May 20th-24th, 2012, Vancouver, Canada

Bioanalysis in R&D and Regulatory Submission: Challenges and Opportunities

The Drug Metabolism and Pharmacokinetics (DMPK) Interest Group Workshop was held on

- Monday, May 21st, 2012 from 5:45 until 7:00 PM. The current DMPK-IG co-coordinators, Petia Shipkova and Chandra Prakash led the meeting. Approximately 250 scientists attended the workshop, demonstrating a high level of interest in drug metabolism and pharmacokinetics topics. The active discussion and strong attendance were a strong endorsement for continuing efforts by the DMPK IG. The workshop included an initial DMPK IG business meeting, followed by discussion of the topic: **“Is New Technology Answering the Question?: Regulatory Perspective”** and **“New Technology in Research and Development: Resistance is Futile?”** as well as a discussion of the results obtained by a DMPK Survey conducted two weeks prior to the meeting.

1. Review of the DMPK IG Goals

The IG goals were reviewed: to provide a discussion forum to MS practitioners in drug metabolism, pharmacokinetics, qualitative and quantitative, non-regulated bioanalysis on:

- 1.1. Recent advances in techniques and methodologies for metabolite identification and pharmacokinetic bioanalysis
- 1.2. Interpretation of and application of related guidance documents (i.e. MIST, ICH M3)
- 1.3. Sharing of best practices across industry and academia
- 1.4. Provide input on ASMS conference program of interest to scientists working in DMPK
- 1.5. Reach out and coordinate with related groups to complement scope and broaden outreach to scientific community

2. Solicitation for nominations for 2013 and 2014 DMPK IG Coordinators

2012: Petia Shipkova, Chandra Prakash and Joanna Pols

List of proposed DMPK-IG coordinators for 2013/2014:

Outgoing 2013: Chandra Prakash

New coming 2013: Don McKenzie, Mustafa Viroglu, Kevin Bateman,

New coming 2014: Natasha Penner, Don McKenzie, Mustafa Viroglu, Kevin Bateman

3. Update on the DMPK Interest Group’s Impact on the 2012 ASMS Program

- | | |
|---------------|--|
| Monday AM: | 1. Quantitative Analysis by MS in Drug Discovery and Development: Novel Approaches |
| | 2. Biotherapeutics and Their Impurities and Degradants: Structural Characterization and QC |
| Monday PM: | 3. Integrated Qualitative and Quantitative LC-MS for Small Molecule Analysis |
| | 4. Biotherapeutics and Biomarkers: New Developments in Quantitative Analysis |
| Tuesday AM: | 5. Imaging MS: Biological Applications |
| | 6. Biomarkers in Drug Discovery and Development |
| Tuesday PM: | 7. Imaging MS: Pharmaceutical Applications |
| | 8. Biomarkers of Drug Toxicity, Response & Efficacy Biomarkers: Innovative MS Approaches |
| Wednesday AM: | 9. Imaging MS: Instrumentation and Ionization Sources |

Wednesday PM:	10. Accurate Mass Applications: Pharmaceutical, Bioanalytical, and Clinical 11. Regulated Bioanalysis and Diagnostics using High Resolution LC/MS: Headache or Opportunity? 12. Overcoming Challenges in MS Analysis through Improvements in Sample Preparation
Thursday AM:	13. Drugs, Metabolites, Proteins and Biomarkers: Novel Approaches for Analysis of Dried Biological Samples
Thursday PM:	14. Antibodies and Antibody-Drug Conjugates

4. Suggestions on ASMS 2012 Oral Session Topics From DMPK-IG Attendees

The attendees agreed that the current topics were still of high interest and supported keeping them on the 2012 program. Additionally, attendees expressed additional interest in:

- 1) Imaging MS: Pharmaceutical Applications
- 2) Microflow Systems: Discovery Applications
- 3) Microdosing (AMS vs LC-MS/MS)
- 4) Unusual and uncommon metabolites

5. Discussion Topics: “Is New Technology Answering the Question?: Regulatory Perspective” and “New Technology in Research and Development: Resistance is Futile?”

Dr. Chongwoo Yu represented the regulatory perspective on new technologies and encouraged open dialogue and collaboration between scientist and the FDA to address current and future questions and issues brought by newly emerging technologies.

Dr. Lucinda Cohen discussed current obstacles to implementation of new technologies in drug discovery and development and introduced the findings of a very recent survey that was sent to the large DMPK IG base. Both talks provided a great introduction and raised important questions that were addressed in the active discussions that followed.

Presentations from the workshop will be uploaded to the DMPK-IG page on the ASMS web-site together with a summary from the survey conducted on current obstacles for innovation.

Current Officers for the ASMS DMPK Interest Group:

Petia Shipkova, Ph.D. (outgoing coordinator for 2012)
Bristol-Myers Squibb
Princeton, NJ 08534
Phone: 609-818-3202
e-mail: petia.shipkova@bms.com

Chandra Prakash, Ph.D. (proposed coordinator for 2013)
Biogen Idec
14 Cambridge Center
Cambridge, MA 02142
Phone: 617-679-3725
e-mail: chandra.prakash@biogenidec.com