



Annual Scientific Meeting

Standards without Borders: Protecting the Public Health in the Modern World

September 22–25, 2009

Sheraton Centre Toronto Hotel, Toronto, Ontario Canada
(As of September 24, 2009)

On-site Agenda

See Pocket Schedule for Room Names

Tuesday, September 22, 2009

10:00 a.m.–6:00 p.m.

Registration and Information

1:00 p.m. – 4:30 p.m.

Adulteration and Contamination: Technologies of the Future

Resolution 3 Advisory Panel General Session (open to all ASM attendees)

Moderator: Roger L. Williams, M.D., Chair of the Council of Experts, USP

- *Overview of Instrumentation, David Bugay, Ph.D.*
- *Spectral Identification, Steve Choquette, NIST*
- *Excipient Technologies, Dale Carter, M.S., JM Huber*
- *Advanced Imaging/High Resolution Photography, David Hale, NIH/National Library of Medicine*
- *Surveillance, Anthony Zook, Ph.D., Merck & Co.*

6:00 p.m. – 7:00 p.m.

General Session(s) Speaker Rehearsal

7:00 p.m.

Speaker Dinner

Wednesday, September 23, 2009

7:00 a.m.–5:00 p.m.

Registration and Information

7:00 a.m.–8:00 a.m.

Continental Breakfast

8:00 a.m.–10:00 a.m.

Opening General Session

8:00 a.m.–8:30 a.m.

**Board of Trustees Update, Duane M. Kirking, Pharm.D., Ph.D.,
USP Board of Trustees**

USP Update, Roger L. Williams, M.D., Chief Executive Officer, USP

8:30 a.m. –9:45 a.m.

Canadian Food and Drug Regulation

Health Canada, Health Products and Foods Branch

Moderator: Susan S. de Mars, J.D., Chief Documentary Standards Officer and General Counsel

- *Health Products and Foods Branch, Siddika Mithani, Associate Assistant Deputy Minister*
- *Health Products and Food Inspectorate, Diana Dowthwaite, Director General*
- *Therapeutic Products Directorate, Andrew Adams, Director, Pharmaceutical Sciences*
- *Biologics and Genetic Therapies Directorate, Peter Ganz, Ph.D., Director, Centre for Biologics Evaluation*
- *Food Directorate, Samuel Godefroy, Ph.D., Director General*
- *Natural Health Products Directorate, Michele Boudreau, Director General*

9:45 a.m. –10:00 a.m.

-Annual Scientific Meeting Overview

-Housekeeping Announcements

10:00 a.m.–10:30 a.m.

Break

10:30 a.m.–12:30 p.m.

Session I

Track I:

**Quality of Manufactured Medicines – Supply Chain Management
Regulatory Perspective**

Moderator: Michael Eakins, Ph.D., Vice Chair, Packaging Storage Expert Committee

- *Impact of Globalization on Pharmaceutical Supply Chain Management, Marv Shepherd, Ph.D., University of Texas–Austin*
- *Role of Product Development in the Efficient Management of Supply Chain, Krishnan Tirunellai, Ph.D., Health Canada*

Wednesday, September 23, 2009 (continued...)

10:30 a.m.–12:30 p.m.

Session I

Track II:

**Quality of Manufactured Medicines – Measurement Science
Advanced Analytical Technologies**

Moderator: Kevin Hool, Ph.D., Vice President, Applied Compendial Research, USP

- *Nuclear Magnetic Resonance, Joseph Ray, Baxter*
- *Quantitative Proteomics for Endometrial Cancer Biomarkers via Multiple Reaction Monitoring, K.W. Michael Siu, Ph.D., Centre for Research in Mass Spectrometry*
- *Surface Plasmon Resonance, Ralph Abraham, Ph.D., Bristol-Myers Squibb*

Track III:

**Quality of Manufactured Medicines – Biologics & Biotechnology
Process and Ancillary Materials**

Moderator: Anthony Ridgway, Ph.D., Member, USP B&B-Cell, Gene and Tissue Therapy Expert Committee

- *Ancillary Materials in Cell Manufacturing, Fouad Atouf, Ph.D., Scientist, Biologics & Biotechnology, USP and Anthony Ridgway, Ph.D., Member, USP B&B-Cell, Gene and Tissue Therapy Expert Committee*
- *Reagents Used in Cell Manufacturing, Thomas Montague, BD Advanced Bioprocessing*
- *Qualification of Ancillary Materials (e.g. Fetal Bovine Serum) John Harrington, Life Technologies*
- *Raw Material Testing – Marina Kirkitadze, Ph.D., Sanofi Pasteur*

Track IV:

**Quality of Manufactured Medicines – New Compendial Initiatives
Performance Based Monographs**

Moderator: Todd L. Cecil, Ph.D., Vice President, Compendial Science, USP

- *Statistical Implications, Walter Hauck, Ph.D., Senior Scientific Fellow, USP*
- *Industry Perspective, Phil Nethercote, Ph.D., GlaxoSmithKline*
- *Council of Experts Perspective, Timothy J. Wozniak, Ph.D., Chair, USP MD-Cold, Cough and Analgesics Expert Committee*

Track V:

**Quality of Food Ingredients – One Day Offering
International Food Ingredient Safety Issues Workshop
Adulteration from International Perspectives**

Moderator: Kristie Bowman, M.S., Scientific Liaison, USP

- *Jonathan DeVries, Ph.D., Member, USP Food Ingredients Expert Committee*
- *Robin Marles, Ph.D., Health Canada*
- *Catherine Sheehan, M.S., Director, Excipients, USP*

12:30 p.m.–2:00 p.m.

Lunch

2:00 p.m.–4:30 p.m.

Session II

Track I:

**Quality of Manufactured Medicines – Supply Chain Management
International Supply Chain Management**

Moderator: Michael Eakins, Ph.D., Vice Chair, Packaging Storage Expert Committee

- *Pitfalls in Establishing an Ethical Supply Chain, Michael N. Eakins, Ph.D., Vice Chair, USP Packaging & Storage Expert Committee*
- *Drug Importation, Fazal Lockhat, Ph.D., Health Canada*
- *Authentication and Identification in Botanicals Paula Brown, M.Sc., British Columbia Institute of Technology*

Track II:

**Quality of Manufactured Medicines – Measurement Science
Combined Session with Biologics & Biotechnology**

Wednesday, September 23, 2009 (continued...)

2:00 p.m.–4:30 p.m.

Session II

Track III:

**Quality of Manufactured Medicines – *Biologics & Biotechnology and Measurement Science*
Residual DNA Testing**

Moderator: Michael Ambrose, Ph.D., Director, B&B Laboratory, USP

- *Assay Approaches-Overview, Wesley Workman, Ph.D., Member, USP B&B-Proteins and Polysaccharides Expert Committee*
- *National Control Laboratory Perspectives, Junzhi Wang, Ph.D., NICPBP*
- *Reference Material/ Metrology Lab Perspective– Marc Salit, Ph.D., NIST*
- *Industry Perspective 1- Seeven Vydellingum, Ph.D., Sanofi Pasteur*
- *Industry Perspective 2 - Audrey Chang, ThermoFisher*

Track IV:

**Quality of Manufactured Medicines – *New Compendial Initiatives*
General Chapters of the Future**

Moderator: Anthony DeStefano, Ph.D., Vice President, General Chapters, USP

- *Stimuli Article and Industry Perspective—General Chapters Project Team, Phyllis Walsh, MBA, Schering Plough Corporation*
- *Procedural Standards, Ancillary Materials, Tina Morris, Ph.D., Vice President, Biologics & Biotechnology, USP*
- *Route of Administration Chapters, Vinod Shah, Ph.D., USP Consultant*
 - *Default Monograph Chapters*
 - *Performance Verification Chapters*
 - *Informational Chapters*

Track V:

**Quality of Food Ingredients – *One Day Offering*
International Food Ingredient Safety Issues Workshop**

Moderator: Markus Lipp, Ph.D., Director, Food Standards, USP

- *Food Security (Bioterrorism), Frank Busta, Ph.D., University of Minnesota*
- *Food Import Safety, U.S. Perspective, Richard Chiang, FDA*
- *Food Import Safety, Canada Perspective, Matthew Bauder, M.S., Health Canada*

5:00–7:00 p.m.

Networking Reception/Fellowship Posters

Thursday, September 24, 2009

7:00 a.m.–5:00 p.m.

Registration and Information

7:00 a.m.–8:00 a.m.

Continental Breakfast

8:00 a.m. – 10:00 a.m.

Interactive General Session—*Biomeasurement*

Moderator: William F. Koch, Ph.D., Chief Standards Acquisition and Metrology Officer, USP

- *Canada: National Research Council, James McLaren, Ph.D.*
- *China: National Institute of the Control of Pharmaceuticals and Biologics, Junzhi Wang, Ph.D.*
- *United Kingdom: National Institute for Biological Standards and Control, Adrian Bristow, Ph.D.*
- *United States: National Institute of Standards and Technology, Marc Salit, Ph.D.*

Interactive Panel Discussion

10:00 a.m.–10:30 a.m.

Break

Thursday, September 24, 2009 (continued...)

10:30 a.m.–12:30 p.m.

Session III

Track I:

**Quality of Manufactured Medicines – Supply Chain Management
Anti-counterfeiting/Adulteration**

Moderator: Michael Eakins, Ph.D., Vice Chair, Packaging Storage Expert Committee

- *Health Canada and WHO Anti-counterfeiting Initiatives, Jean Saint-Pierre, Health Canada*
- *Progress Towards Establishing E-pedigree for Drugs
Michael N. Eakins, Ph.D., Vice Chair, USP Packaging & Storage
Expert Committee*
- *Online Medicine – Cost-effective Healthcare/Fundraiser for Global
Cyber Crime, James Thomson, Center for Mental Health*

Track II:

**Quality of Manufactured Medicines – Measurement Science
Combined Session with Biologics & Biotechnology**

Track III:

**Quality of Manufactured Medicines – Biologics & Biotechnology and
Measurement Science
Monographs and Reference Standard Modernization**

Moderator: Harold N. Rode, Ph.D., Member, USP B&B-Proteins and Polysaccharides Expert Committee

- *Heparin, Wesley Workman, Ph.D., Member, USP
B&B-Proteins and Polysaccharides Expert Committee*
- *Glucagon, Anne Munk Jespersen, Member, USP
B&B-Proteins and Polysaccharides Expert Committee*
- *Pancrelipase, Harold N. Rode, Ph.D., Member, USP
B&B-Proteins and Polysaccharides Expert Committee*
- *Biosynthetic Human Insulin, Matthew Borer, Ph.D., Eli Lilly and Company*

Track IV:

**Quality of Manufactured Medicines – New Compendial Initiatives
General Notices—Revision 2009**

Moderator: Matthew Van Hook, J.D., Assistant General Counsel, USP

- *USP Proposed Update: Matthew Van Hook, J.D., Assistant
General Counsel, USP*
- *Stakeholder Perspective: Neil Schwarzwald, M.S., Eli Lilly and
Company*

Track V:

**Quality of Food Ingredients
GMPs**

Moderator: Catherine Sheehan, M.S., Director, Excipient Standards, USP

- *Compare/Contrast Food, Dietary Supplement and Drug (Excipient)
GMPs, Dale Carter, Ph.D., JM Huber*
- *Supply Chain Integrity, Edward Fletcher, Ph.D.*
- *Reference Materials, Tony Windust, Ph.D., National Research
Council*

12:30 p.m.–2:00 p.m.

Lunch

2:00 p.m.–4:30 p.m.

Session IV

Track I:

**Quality of Manufactured Medicines – Supply Chain Management
Transportation**

Moderator: Michael Eakins, Ph.D., Vice Chair, Packaging Storage Expert Committee

- *Revision to Health Canada's Guidelines for Temperature Control of
Drug Products During Storage and Transportation, Sarah Skuce,
Health Canada*
- *Revision to USP <1079> Good Storage and Shipping Practices,
Mary G. Foster, Pharm.D., Member, USP Packaging & Storage
Expert Committee*
- *Air Transport Logistics for Time and Temperature Sensitive
Healthcare Products: Meeting the Requirements of the New
International Air Transport Association Regulations,
Kevin O'Donnell, Tegrant Corporation*

Thursday, September 24, 2009 (continued...)

2:00 p.m.–4:30 p.m.

Session IV

Track II:

**Track II: Quality of Manufactured Medicines – Measurement Science
Metrological Traceability and Equivalent or Better**

Moderator: William F. Koch, Ph.D., Chief Standards Acquisition and
Metrology Officer, USP

- *Traceability and Reference Standard Aspects, William Koch, Ph.D.*
- *Acceptable, Equivalent or Better Concepts, Walter Hauck, Ph.D., Senior Scientific Fellow, USP*
- *Acceptability Criteria, Todd Cecil, Ph.D., Vice President, Compendial Science, USP*
- *Performance Based Monographs-Practical and Analytical Considerations, William Weiser, Ph.D., Techlytic Consulting, Inc.*

Track III:

**Quality of Manufactured Medicines – Biologics & Biotechnology
Analytical Characterization**

Moderator: Tina S. Morris, Ph.D., Vice President, Biologics & Biotechnology, USP

- *Sub-visible Particulate Analysis or Aggregates, D. Scott Aldrich, Member, USP Parenteral Products: Industrial Expert Committee*
- *Sub-visible Particles, Linda Narhi, Ph.D., Amgen*
- *Proteomics Approaches, David Bunk, NIST*

Track IV:

**Quality of Manufactured Medicines – New Compendial Initiatives
Compendial Processes in the 2010-2015 Cycle**

Moderator: Angela G. Long, Vice President, Healthcare, Quality and Compendial
Affairs, USP

- *USP Bylaws and Rules and Procedures of the Council of Experts, Susan S. de Mars, J.D., Chief Documentary Standards Officer/General Counsel*
- *Process Improvements and Preparation for the 2010-2015 Cycle, Angela G. Long, Vice President, Healthcare, Quality and Compendial Affairs, USP*
- *Expert Committee Recruitment, Nelufar Mohajeri, Director, Volunteer Affairs and Compendial Initiatives, USP*
- *Stakeholder Perspective--Joseph Garber, Astra-Zeneca*

USP Compendia of the Future

- *Linda Guard, Vice President, Publications, USP*
- *Richard Wailes, MBA, Vice President, Sales and Marketing, USP*

Track V:

**Quality of Food Ingredients
Functionality**

Moderator: James Griffiths, Ph.D., Vice President, Food, Dietary Supplement &
Excipient Standards, USP

- *Botanicals, Brian Schaneberg, Ph.D., Mars Botanicals*
- *Probiotics and Prebiotics, Sarah Kraak-Ripple, Member, USP Food Ingredients Expert Committee*
- *Nanotechnology Derived Ingredients, Berna Magnuson, Ph.D., CanTox*
- *Designer Ingredients, David Land, Medisyn*

Free Evening for Attendees

Friday, September 25, 2009

7:00 a.m.–1:00 p.m. Registration and Information

7:00 a.m.–8:00 a.m. Continental Breakfast

8:00 a.m.–10:00 a.m. **General Session: Nanotherapeutics and Measurement**

Moderator: William F. Koch, Ph.D., Chief Standards Acquisition and Metrology Officer, USP

- *Overview: Todd L. Cecil, Ph.D., USP*
- *Therapeutics: Marianna Foldvari, D.Pharm.Sci., Ph.D., Canada Research Chair in Bionanotechnology and Nanomedicine*
- *Environment : Scott McNeil, Ph.D., Director, Nanotechnology Characterization Lab, SAIC*

10:00 a.m.—10:30 a.m. **Break**

10:30 a.m.—12 noon **Closing General Session**

Moderators: Susan S. de Mars, J.D., Chief Documentary Standards Officer and General Counsel

William F. Koch, Ph.D., Chief Standards Acquisition and Metrology Officer

- What was said? What was heard? What are our next steps?
 - Supply Chain Management
 - Measurement Science
 - Biologics and Biotechnology
 - New Compendial Initiatives
 - Quality of Food Ingredients
- Q&A and Discussion

12 noon **2009 Annual Scientific Meeting Adjourns***

**Following the Closing General Session, a USP memory stick will be available to all meeting attendees complete with the speaker abstracts, biographies, presentations, and background materials from the meeting. The memory stick will not be available before this time.*