



U.S. PHARMACOPEIA
The Standard of QualitySM

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International Excipient Workshop

Excipient Quality Control, Testing, and International Harmonization

Monday, July 20, 2009 – Tuesday, July 21, 2009 • USP Headquarters, Rockville, Maryland

Goals and Anticipated Outcomes:

- Highlight Issues and Challenges Surrounding the Global Sourcing of Excipients from a Safety and Quality Control Perspective and the Current Status on Excipient Regulation
- Focus on Challenges for Developing Excipient Compendia Monographs in the 21st Century
- Highlight the Primary Issues for Excipients in a Quality by Design Framework as It Relates to Functionality and Performance and Updates on International Harmonization and Functionality Related Characteristics (FRCs)
- Seek Constructive Input from a Wide Range of Stakeholders including Industry, Regulatory, and Compendia; Possibly Seek Consensus on Key Excipient Issues from a Global Perspective.

Cost:

The registration fee for the Workshop is \$600 for regular registration and \$300 for association/academic and government attendees. Registration fee includes meals and all program materials. If you are a full-time student or need further information please contact conferences@usp.org or call 301-816-8130. To register please go to <http://www.usp.org/meetings/workshops/>. For available Table Top Networking Exhibition Opportunities, contact Christopher Rochette at cwr@usp.org (301-816-8169).

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Preliminary Agenda (subject to change)

Monday, July 20, 2009

7:30 a.m. **Registration and Information**

7:30 a.m. **Continental Breakfast**

8:00 a.m. **Welcome**

- Roger Williams, MD, Chief Executive Officer, United States Pharmacopeia (USP)
- Susan de Mars, Chief Legal Officer, USP
- James Griffiths, Ph.D., Vice President, Food, Dietary Supplement, and Excipient Standards

SESSION I: Excipient Supply Chain Integrity

Moderator: David R. Schoneker, M.S.

8:30 a.m. **Excipient Supply Chain Control: How It Impacts Safety and Quality Control**

- **Overview of Supply Chain Problems**
Richard C. Moreton, Ph.D., Vice-Chair, Excipient Monograph 2 Expert Committee (EM2)
- **Regulatory Perspective – Quality Systems for Management of Drug Component Supply Chain**
Steven Wolfgang, Ph.D., Office of Compliance, FDA

9:30 a.m. **Q & A**

9:40 a.m. **Break**

9:50 a.m. **Excipient GMPs**

- **Regulatory Aspects on Pharmaceutical Excipients in China**
Jiasheng Tu, Ph.D., China Pharmaceutical University, Member of the China Pharmacopoeia Commission
- **Update on European Commission Directive for Excipient GMPs**
Sabine Atzor, Ph.D., European Commission, Belgium
- **Japanese System on GMPs Applied to Excipients**
Hiroshi Tokunaga, Ph.D., Pharmaceuticals and Medical Devices Agency (PDMA)

11:30 a.m. **Q & A**

12:00 p.m. **Lunch**

1:00 p.m. **Self-Regulation: Third Party Audits**

- **Excipient Certification and Supply Chain Security**
Iain Moore, Ph.D., Croda Europe Ltd / Chair-IPEC Europe
- **Rx-360, How an Industry Consortium will Contribute to Assuring Quality Materials**
Eric Berg, Ph.D., Director of Supplier Quality, Amgen Inc.,
- **USP Verification Program for Excipients**
Srini Srinivasan, Ph.D., Vice President, Verification Program, USP

3:00 p.m. **Q & A**

3:20 p.m. **Break**

SESSION II: Challenges in Developing Excipient Compendia Monographs for the 21st Century

Moderator: Richard C. Moreton, Ph.D.

3:30 p.m. **Compendial, Regulatory, Industry, and Scientific Perspectives**

- **Excipient Challenges in the 21st Century: An FDA Perspective**
Mansoor A. Khan, R.Ph., Ph.D., Division of Product Quality Research, FDA
- **New Excipient Development from the USP Perspective**
Lawrence H. Block, Ph.D., Chair, EM2

4:30 p.m. **Q&A**

5:00 p.m. **Reception**

FOR MORE INFORMATION AND TO REGISTER:

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Tuesday, July 21, 2009

7:30 a.m. **Registration and Information**

7:30 a.m. **Continental Breakfast**

SESSION II: Challenges in Developing Excipient Compendia Monographs for the 21st Century (Cont'd)

Moderator: Richard C. Moreton, Ph.D.

8:00 a.m. **Compendial, Regulatory, Industry, and Scientific Perspectives**

- **European Pharmacopoeia Update**
Susanne Keitel, Ph.D., European Directorate for the Quality of Medicines and Healthcare (EDQM)
- **Japanese Pharmacopoeia Update**
Hiroshi Tokunaga, Ph.D., JP-Secretariat
- **Excipient Innovation, Classification, and Regulatory Acceptance**
Ranga Velagaleti, Ph.D., BASF

9:30 a.m. **Q & A**

9:50 a.m. **Break**

Session III: Excipient QbD as It Relates to Performance and Functionality

Moderator: Mansoor A. Khan, R.Ph., Ph.D.

10:00 a.m. **QbD, Excipient Performance, and Multi-Sourcing**

- **QbD, Excipient Performance, and Multi-Sourcing: The Role of Excipients in Quality by Design**
Jeffrey Medwid, Ph.D., Office of New Drug Quality Assessment, FDA
- **Excipients in QbD: Myths and Realities**
Richard C. Moreton, Ph.D., Vice Chair, EM2
- **Is There a Problem with Multi-Source Excipient Equivalency?**
Lawrence H. Block, Ph.D., Chair, EM2

12:00 p.m. **Q & A**

12:30 p.m. **Lunch**

1:30 p.m. **International Harmonization and Excipient Performance**

- **European Pharmacopoeia Perspective on Functionality-Related Characteristics**
Anne Gayot, Ph.D., University of Lille, France
- **International Harmonization: EDQM Perspective**
Susanne Keitel, Ph.D., EDQM
- **The Future of Excipient Performance Testing in USP: Excipient Performance Chapter <1059>**
Greg Amidon Ph.D., Chair, Excipient General Chapters (EGC), USP
- **International Harmonization: JP Perspective**
Hiroshi Tokunaga, Ph.D., JP-Secretariat

3:30 p.m. **Q & A**

3:50 p.m. **Break**

4:00 p.m. **Session IV: Closing Summary**

Moderator Session I – David R. Schoneker, M.S.

Moderator Session II – Richard C. Moreton, Ph.D.

Moderator Session III – Mansoor A. Khan, Ph.D.

Conclusion Moderator – Catherine Sheehan, M.S.

4:30 p.m. **Closing Remarks**

Roger Williams, M.D., CEO, USP

4:45 p.m. **Q&A**

5:00 p.m. **Adjourn**

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