



U.S. PHARMACOPEIA
The Standard of QualitySM

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International Excipient Workshop

Excipient Quality Control, Testing, and International Harmonization

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

You need to attend USP's International Excipient Workshop if you are a ...

- Excipient Manufacturer
- Pharmaceutical Manufacturer
- Excipient Distributor
- Excipient Supplier
- Excipient Repackager
- Regulatory Affairs Professional
- QA/QC Professional
- Formulations Scientist
- Materials Scientist
- Academic Researcher

Sadly, diethylene glycol (DEG) adulteration has struck yet again, causing over 80 deaths in Nigeria in 2008. To better protect public health, USP collaborated with the Food and Drug Administration (FDA) to update and strengthen the USP Glycerin monograph. Experts from USP and FDA will discuss the proactive approach taken to detect adulteration of glycerin and other at-risk excipients with DEG or ethylene glycol (EG).

Expert presenters will also discuss the challenges in developing Excipient Compendia Monographs for the 21st century from compendial, regulatory, and industry perspectives starting with glycerin and other at-risk excipients. The discussion will extend to new types of compendial monographs needed for excipients being used in approved dosage forms. The roles of science and technology in facilitating revision of current monographs and developing new ones will be considered.

The workshop will also focus on the challenges related to the global sourcing of excipients from safety and performance perspectives, and the impact of the global supply chain on multi-source excipient equivalence. Discussions will conclude with an overview of the effective use of harmonized monographs to reduce the testing burden for pharmaceutical excipients.

Registration:

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:

Visit www.usp.org/meetings/workshops

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Preliminary Program

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 (FRC's).
- ▶ Seek Constructive Input from a Wide Range of Stakeholders Including Industry, Regulatory and Compendia and Possibly Seek Consensus on Key Excipient Issues from a Global Perspective.

Day 1: Monday, July 20, 2009

7:30 a.m. Continental Breakfast

8:00 a.m. Welcome

- Roger Williams, M.D., Chief Executive Officer, USP
- Darrell Abernethy, M.D., Ph.D., Chief Science Officer, USP
- James Griffiths, Ph.D., Vice President, Food & Dietary Supplements, Standards, USP
- Excipient Collaborative Group Representative

8:30 a.m. Session I: Excipient Supply Chain Integrity

- Excipient Supply Chain Control: How It Impacts Safety and Quality Control
- Excipient GMP's
- Self-Regulation: Third Party Audits

9:30 a.m. Q & A

9:40 a.m. Break

9:50 a.m. Session I: Excipient Supply Chain Integrity (contd.)

- Excipient Supply Chain Control: How It Impacts Safety and Quality Control
- Excipient GMP's
- Self-Regulation: Third Party Audits

11:20 a.m. Q & A

12:00 p.m. Lunch

1:00 p.m. Session I: Excipient Supply Chain Integrity (contd.)

- Excipient Supply Chain Control: How It Impacts Quality Control
- Excipient GMP's
- Self-regulation: Third Party Audits

3:00 p.m. Q & A

3:20 p.m. Break

3:30 p.m. Session II: Challenges in developing Excipient Compendia Monographs for the 21st Century

- Compendia Perspective
- Regulatory Perspective
- Industry Perspective
- Scientific Perspective

4:30 p.m. Q & A

5:00 p.m. Adjourn

Day 2: Tuesday, July 21, 2009

7:30 a.m. Continental Breakfast

8:00 a.m. Session II: Challenges in developing Excipient Compendia Monographs for the 21st Century (contd.)

- Compendia Perspective
- Regulatory Perspective
- Industry Perspective
- Scientific Perspective

9:30 a.m. Q & A

9:50 a.m. Break

10:00 a.m. Session III: Excipient QBD as It Relates to Performance and Functionality

- QBD, Excipient Performance, and Multi-sourcing
- International Harmonization and FRC's

12:00 p.m. Q & A

12:30 p.m. Lunch

1:30 p.m. Session III: Excipient QBD as It Relates to Performance and Functionality (contd.)

- QBD, Excipient Performance, and Multi-sourcing
- International Harmonization and Excipient Performance

3:30 p.m. Q & A

3:50 p.m. Break

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

4:30 p.m. Closing Remarks

- Roger Williams, M.D., Chief Executive Officer, USP
- Darrell Abernethy, M.D., Ph.D., Chief Science Officer, USP

4:45 p.m. Q & A

5:00 p.m. Adjourn



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