



**Workshop on Metals in Pharmaceuticals and Dietary Supplements
Tuesday-Wednesday, April 28-29, 2009
USP Headquarters, Rockville, Maryland
USP Meetings Center**

Agenda
Revised April 22, 2009

Goals and Anticipated Outcomes

1. Review and discuss metal impurities limits, methodology, risk assessment, harmonization, and implementation strategies
2. Encourage dialog among FDA, stakeholders, and USP experts and staff

Day One: *Interactive General Session and Breakout Sessions*

7:30 a.m. Registration, Continental Breakfast

8:30 a.m. **1. Opening Remarks** **Roger L. Williams, M.D.**
*Chair, Council of Experts
U.S. Pharmacopeia, Rockville, MD*

8:45 a.m. **2. Definition and Scope of Metal Impurities** **Moderator: Matthew Borer, Ph.D.**
*Research Advisor, Eli Lilly and Company, Indianapolis, IN
Presenter, Institute of Medicine Workshop on Heavy Metals
Member, USP Reference Standards Expert Committee*

During this session, a moderator will present initial perspectives, ideas, and opinions on the topic for general discussion by the audience.

- Definition - Problem Statement
 - Current State
 - Methodology
 - Limits
- Scope
 - Metals
 - Application

Interactive Discussion

10:15 a.m. Break

10:30 a.m. **3a. Perspectives on Metal Impurities Limits**

Introductory Presentation: Darrell R. Abernethy, M.D., Ph.D.
Chief Science Officer, USP

Moderator: Douglas M. Templeton, M.D., Ph.D.
Professor, University of Toronto, Toronto, ON, Canada

Moderator to facilitate Pharmacopeial, FDA, and Industry Perspectives on Limits

11:00 a.m. **3b. Breakouts on Metal Impurities Limits**

Attendees will break out into three groups to discuss the above topic. Discussions will be action-oriented and moderators will report back to the group on key outcomes.

12:30 p.m. Lunch

- 1:30 p.m. **3c. Metal Impurities Limits—Reports**
- a. Breakout Group 1
 - b. Breakout Group 2
 - c. Breakout Group 3
 - d. Interactive Discussion

2:30 p.m. **4a. Metal Impurities Methodology**

Introductory Presentation: William F. Koch, Ph.D.
Chief Metrology Officer, USP

Moderator: Michael Wierer, Ph.D.
Deputy Head, European Pharmacopoeia Department, EDQM-European Pharmacopoeia

Moderator to facilitate Pharmacopeial, FDA, and Industry Perspectives on:

- Current Methods – Heavy Metals, Lead, other Wet Chemistry
- Instrumental Tests for Specific Metals

3:00 p.m. Break

3:30 p.m. **4b. Breakouts on Metal Impurities Methodology**

Attendees will break out into three groups to discuss the above topic. Discussions will be action-oriented and moderators will report back to the group on key outcomes.

5:00 p.m. **4c. Metal Impurities Methodology—Reports**

- a. Breakout Group 1
- b. Breakout Group 2
- c. Breakout Group 3
- d. Interactive Discussion

6:00 p.m. Wine and Cheese Reception

7:30 p.m. Adjourn for the day

Day Two: *Interactive general session, breakouts and reporting, and a final summary session*

7:30 a.m. Continental Breakfast

8:30 a.m. **5a. Risk Assessment and Implementation Strategies**

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

Moderator: F. Scott Lyon
Director, Quality Control, Mylan Pharmaceuticals Inc.

Moderator to facilitate a discussion of pharmacopeial, FDA, and stakeholder perspectives on *Risk Assessment and Implementation Strategies*

- Material Sources
- Manufacturing Processes
- Supply Chains
- Additional Control for Articles of Risk
- Test Reduction
- Manufacturer Responsibilities
- Regulatory Considerations
- Phased Approach (if needed)
- Implementation time
- Harmonization

- 9:30 a.m. **Break**
- 10:00 a.m. **5b. Breakouts on Risk Assessment and Implementation Strategies**
Attendees will break out into three groups to discuss the above topic. Discussions will be action-oriented and moderators will report back to the group on key outcomes.
- 11:30 a.m. Lunch
- 12:30 p.m. **5c. Risk Assessment and Implementation Strategies—Reports**
a. Breakout Group 1
b. Breakout Group 2
c. Breakout Group 3
d. Interactive Discussion
- 1:30 p.m. **6. Final Summary Session** **Matthew Borer, Ph.D.**

During this session, the moderator will lead a discussion to summarize information gathered from the interactive general and breakout sessions with the goal of advancing revisions to the metal impurities standard that will help assure avoidance of or limited exposure to metals that may cause harm.
- 3:00 p.m. **Next Steps and Adjourn**