

The USP Excipients Stakeholder Forum
Meeting #1 for 2010-2015
Friday, June 7, 2013
Spalding Auditorium
USP Headquarters, Rockville, Maryland and via Webex
Priscilla Zawislak, IPEC-Americas, Chair

Agenda

Goals and Expected Outcomes

1. Provide overview of USP and its standards for excipients for new participants
2. Provide updates on excipients topics of interest
3. Receive stakeholder feedback on excipient and related standards

7:30 a.m. **Registration and Information, Continental Breakfast**

8:00 a.m. **1. Opening and Introductory Remarks**

- a. Opening and Introduction
- b. Call to Order
- c. Welcome

Mario Sindaco
 Priscilla Zawislak
 Roger Williams

8:15 a.m. **2. Elemental Impurities**

- a. USP Elemental Impurities Update
- b. Discussion

Roger Williams

8:45 a.m. **3. USP and FDA Excipient Activities**

- a. USP's Global Science and Standards Division
- b. USP Excipients Standards-setting Process
- c. FDA Perspective on Excipient Quality
- d. USP Spectral Library Updates
- e. Discussion

Srinu Srinivasan
 Catherine Sheehan
 Steve Wolfgang
 Bei Ma/Michael Dotlich

10:00 a.m. **Break**

10:15 a.m. **4. Excipient Stakeholder Roundtable**

Each stakeholder group will provide a five-minute overview of their organizations and interests in USP standards followed by general discussion

Stakeholders

11:00 a.m. **5. Excipient Monograph Modernization**

Lawrence H. Block

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

1:00 p.m. **6. Excipient Monographs in the *Medicines Compendium***

- a. *Medicines Compendium* Overview
- b. Excipients in the *Medicines Compendium*
- c. Discussion

Todd Cecil
 Jiasheng Tu

1:45 p.m. **7. Excipient Related General Chapters**

Catherine Sheehan

2:45 p.m. **8. Pharmacopeial Education**

Peihong Liang

3:00 p.m. **9. Next Steps, Closing Remarks**

Priscilla Zawislak