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U.S. Pharmacopeial Convention

**The USP Excipients Stakeholder Forum**
**Meeting #2 for 2010-2015**
**Wednesday, June 18, 2014**
**9:00 a.m.-3:50 p.m.**
**Spalding Auditorium**
**USP Headquarters, Rockville, Maryland and via Webex**
**Steve Boudreau, Chair**

## Agenda

(As of June 16, 2014 subject to change)

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| 8:30 a.m. | Registration and Information, Continental Breakfast | |
| 9:00 a.m. | **1. Opening and Welcome** | Mario Sindaco/Steve Boudreau |
| 9:10 a.m. | **2. General USP Updates** | |
| | a. CEO Introduction | Ron Piervincenzi |
| | b. 2015 USP Convention | Joe Moerke |
| | c. Call for Candidates | Mario Sindaco |
| | d. Global Education and Training | Christine Lau |
| | e. Discussion | |
| 10:00 a.m. | **3. USP and FDA Excipient Activities** | |
| | a. USP Overview | Srini Srinivasan |
| | b. USP Excipients Standards-setting Process | Catherine Sheehan |
| | c. Planning Committee Introduction and Background | Planning Committee Members |
| | *Each stakeholder group on the Planning Committee will provide a five-minute overview of their organizations and interests in USP standards* | |
| | d. FDA/USP Spectral Library Updates | Steve Wolfgang/Bei Ma |
| | e. FDA/Inactive Ingredient Database Updates | Naiqui Ya |
| | f. Discussion | |
| 11:15 a.m. | **Break** | |
| 11:30 a.m. | **4. Excipient Monograph Modernization** | |
| | a. USP Priority Excipient Monograph Modernization updates | Catherine Sheehan |
| | b. EP Perspective: How to Develop/Update an Excipient Monograph | Lore Vignoli |
| | c. FDA Monograph Modernization initiative | Steve Wolfgang |
| | d. Gelatin NF Identification Test Update | |
| | i. GMIA Manufacturers Perspective | Dean Wood |
| | ii. Gelatin Capsules Manufacturers Perspective | Steven Leinbach |
| | iii. USP Update on Gelatin Capsules, New Monographs, and Dissolution Chapter | Margareth Marques |
| | iv. Discussion: Gelatin and Gelatin Capsule Quality Challenges | |
| 12:00 p.m. | **Lunch** | |
| 1:00 p.m. | **4. Excipient Monograph Modernization (cont.d)** | |
| 2:00 p.m. | **5. Standards Acquisition and Its Role in the Donor Recognition Program** | Donna Kaye Wilson |

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| 2:20 pm | **6. Stakeholder Roundtable Discussion**<br>*Challenges to modernization and harmonization of USP-NF monographs when FCC and CFR specifications exist (Speakers - five speakers representing industry makers, pharmaceutical users, distributors, and FDA, followed by open discussion)* | Mark Empie, Bob King, David Schoneker, Lore Vignoli, Bill Lamb |
| 3:20 p.m. | **7. USP Verification program** | John Atwater |
| 3:50 p.m. | **8. Next Steps, Closing Remarks** | Steve Boudreau |