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)

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  Srin 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
2:20 pm  6. **Stakeholder Roundtable Discussion**  
Mark Empie, Bob King, David Schoneker, Lore Vignoli, Bill Lamb  
*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)*

3:20 p.m.  7. **USP Verification program**  
John Atwater

3:50 p.m.  8. **Next Steps, Closing Remarks**  
Steve Boudreau