

- 9:40 a.m. **5. Review USP-NF Standard Setting Process** Dr. Reddy/Ms. Macarthy
- a. Review Reference Standards and RS Candidate Evaluation Package (RSCEP)
 - b. Review Balloting Responsibilities
- 10:20 a.m. **Break**
- 10:35 a.m. **6. Monograph Updates**
- a. Newly added PDG Monographs SC K Members/Dr. Liu
 - i. Myristyl Myristate Dr. Maus
Expected Outcome: Review updated draft proposal
 - ii. Polysorbate 65 Dr. Sun
Expected Outcome: Review updated draft proposal
And discuss DEG/EG testing results in polysorbates
 - iii. Sodium Cetyl Sulfate Dr. Houck
Expected Outcome: Discuss JP's comments and discuss path forward
 - iv. Isostearyl Alcohol Dr. Serr
Expected Outcome: Review JP's first draft proposal and discuss path forward
 - v. Calcium Silicate Mr. Bluj
Expected Outcome: Review updated draft proposal
- 12:00 p.m. **Lunch (Group Photo)**
- 1:00 p.m. **7. Discuss PDG Reforms** Dr. Moore
- a. Update and Workstream Implementation
 - b. Impact on EM2 Workplan and USP
- 2:15 p.m. **Break**
- 2:30 p.m. **8. Monograph Updates (continued)**
- a. E-08 Carmellose Sodium (SC D) Dr. Cabelka
 - i. Assay and Viscosity
Expected Outcome: Prepare Stage 1 draft to PDG
 - b. E-23/24/63 Lactose, Anhydrous/Monohydrate/ for Inhalation (SC I) Dr. Tu
 - i. Assay & Impurity
Expected Outcome: Prepare Stage 1 draft to PDG
 - c. E-33/34/35 Saccharin/Sodium/Calcium (SC I) Dr. Osterberg/Dr. Liu
 - i. Assay/Impurity
Expected Outcome: Status update and discussion on impurity specs
 - d. E-28/29 Petrolatum/White (SC K) Mr. Yasika
 - i. Polycyclic aromatic hydrocarbons (PAHs)
Expected Outcome: Prepare Stage 2 draft to PDG

- e. E-17/18 Ethylcellulose/Hydroxyethylcellulose (SC D) Dr. Wu
 - Assay

Expected Outcome: Discuss data with and without catalyst
- 4:00 p.m. **9. Excipient Impurities Joint Subcommittee (EM1 & EM2)** All
 - a. Stimuli article
- 5:00 p.m. **Adjourn for the Day**
- 5:15 p.m. **Transportation Departs for Hotel**
- 6:00 p.m. **Dinner at:**
Trapezaria
11 N. Washington St.
Rockville, MD 20850

Day 2**Thursday, December 7, 2017**

- 8:30 a.m. **10. Expert Panel Updates**
 - a. Glycerin Dr. Cabelka/Ms. Rucker/Dr. Liu
 - b. Talc Methods Ms. Pier/Dr. Liu
 - 9:30 a.m. **11. Monograph Updates (continued)**
 - a. E-30 Polyethylene Glycol (SC K) Dr. Serr
 - i. ID by IR

Expected Outcome: Review final proposal to PDG

 - ii. Aldehydes
 - Expected Outcome: Discuss path forward on validation and specifications
 - b. E-36 Silicon Dioxide (SC E) Dr. Liu/Dr. Moore
 - i. Round Robin Study
 - ii. USP Lab Reports
 - Expected Outcome: Provide update on Round Robin and review lab reports
- 10:15 a.m. **Break**
- 10:30 a.m. **12. Monograph Updates (continued)**
 - a. E-16/32/54 – Crospovidone/ Povidone/ Copovidone (SC G) Dr. Wu/Ms. Tordik/Dr. Tu
 - i. GPC method for Assay & Impurity
 - ii. Expected Outcome: Prepare Stage 1 draft

- iii. Potential revision for lead and formic acid test
Expected Outcome: Discuss revision proposal from Sponsor
 - b. E-44 Stearic Acid Dr. Maus
Expected Outcome: Discuss JP fatty acid composition test results

- 11:15 a.m. **13. Element Specific Chapter Update** USP Staff
 - a. Elemental Specific Chapters

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

- 1:00 p.m. **14. General Chapters Revision Update** Dr. Liu
 - a. G-02 Bulk Density and Tapped Density
 - b. G-05 Powder Flow
 - c. G-19 Density of Solids

- 1:45 p.m. **15. Bilateral Progress and Updates** Dr. Moore/Dr. Kameyama/Dr. Liu
 - a. Japanese Pharmacopeia
 - b. Chinese Pharmacopeia
 - c. International Meeting of the World Pharmacopeias
 - d. ICH

- 2:45 p.m. **16. Meeting Wrap-Up and Action Items** Mr. Lew

- 3:00 p.m. **Adjourn**

- 3:15 p.m. **Transportation Departs for Hotel/Airport**