

General Chapters Physical Analysis Expert Committee (GC-PA EC)
Tuesday, January 23, 2018
Teleconference
Agenda

Goals and Anticipated Outcomes

The primary goal of this meeting is to go over action items generated during the previous meeting to monitor their status, update the Expert Committee on activities involving the different Subcommittees, and introduce new topics for discussion according to the work plan.

Attendees - list to be provided at the meeting

- 10:00 a.m. **1. Opening and Procedural Matters**
(Informational & Decision-making)
- a. Roll Call Mr. Freebern
 - b. Welcome, Call Meeting to Order Dr. He
 - c. Minutes of the Previous Meeting Dr. He
 - d. Approval of Agenda Dr. He
 - e. Administrative Items and Procedures Mr. Freebern
- 10:05 a.m. **2. Ballots** (Informational)
- a. Chapters on the February 12-26, 2018 Ballot for *Supplement 2 to USP 41-NF 36*
 - i. None
 - b. Reference Standards on the next Ballot
 - i. None
- 10:10 a.m. **3. Subcommittee / Expert Panel / Chapter Updates**
(Discussion and Decision-making)
- a. **Solutions** Drs. Templeton, Coffey
 - i. <631> *Color and Achromicity*
 - ii. <781> *Optical Rotation*
 - iii. <841> *Specific Gravity*
 - iv. <1236> *Determination of Thermodynamic Solubility Measurement (new)*
 - b. **Powders** Dr. Sun
 - i. <731> Loss on Drying
 - ii. <733> Loss on Ignition
 - c. **Crystal/Microscopy** Dr. Hubert
 - i. <741> *Melting Range or Temperature*

- d. Rheology** Drs. Block, Coffey
- i. <914> *Viscosity-Pressure Driven Methods*
 - ii. <915> *Measurement of Structural Strength of Semisolids by Penetrometry (new)*
 - iii. <1912> *Determination of Consistency in Semisolids (new)*
- e. Particles** Drs. Meury, Coffey
- i. <430> *Particle Size Analysis by Dynamic Light Scattering*
 - ii. <1xxx> *Image Analysis of Particles*
 - iii. <xxx> *Zeta Potential (with light-scattering Expert Panel)*
- f. Osmolality and Osmolarity-Expert Panel** Dr. Coffey
- i. <785> *Osmolality and Osmolarity*
- g. Updates on Joint Subcommittees and Expert Panels**
- i. Nanotechnology-JSC (DF EC) Drs. Block, Welfare, Scoggins
 - ii. Physical Stability-JSC (PA EC) Dr. Hancock
 - iii. Quality Standards for Pharmaceutical Continuous Manufacturing-EP (CA EC) Dr. Biba
 - iv. Analytical Methodologies based on Light Scattering Phenomena-EP (CA EC) Drs. Welfare, Meury
- 11:20 a.m. **4. Harmonization Topics**
- a. Ongoing Activities
(Discussion and Decision-making)
- i. <281> *Residue on Ignition (Q-10)* Mr. Hernández-Cardoso
 - ii. <776> *Optical Microscopy (G-09)* Mr. Hernández-Cardoso
 - iii. <891> *Thermal Analysis (G-16)* Mr. Hernández-Cardoso
 - iv. <429> *Light Diffraction Measurements of Particle Size (G-13)* Dr. Biba
 - v. <941> *Characterization of Crystalline and Partially Crystalline Solids by X-Ray Powder Diffraction (G-14)* Dr. Biba
 - vi. <616> *Bulk Density and Tapped Density of Powders (G-02)* Dr. Liu
 - vii. <699> *Density of Solids (G-19)* Dr. Liu
 - viii. <1061> *Color-Instrumental Measurement (Q-07)* Mr. Hernández-Cardoso
 - ix. <1174> *Powder Flow (G-05)* Dr. Liu

	b. Additional Harmonization Chapters (Informational)	Dr. Moore
	i. <267> <i>Porosimetry by Mercury Intrusion</i> (G-12)	
	ii. <651> <i>Congealing Temperature</i>	
	iii. <696> <i>Characterization of Crystalline Solids by Microcalorimetry and Solution Calorimetry</i> (G-18)	
	iv. <784> <i>Dropping Temperature</i>	
	v. <786> <i>Particle Size Distribution Estimation by Analytical Sieving</i> (G-01)	
	vi. <811> <i>Powder Fineness</i> (G-10)	
	vii. <846> <i>Specific Surface Area</i> (G-11)	
	viii. <1241> <i>Water-Solid Interactions in Pharmaceutical Systems</i> (G-15)	
11:30 a.m.	5. Council of Experts Topics (Informational)	Dr. He
	a. Call for Candidates for the Next Cycle	
	b. Collaborative Groups in the Next Cycle	
11:45 a.m.	6. Updated Work Plan Review and Subcommittees Rosters (Decision-making)	Dr. He
12:00 p.m.	7. Parking Lot Items (Discussion)	Dr. He
12:20 p.m.	8. Action Items	Ms. Temple
12:25 p.m.	9. Meeting Summary	Dr. He
12:30 p.m.	Adjourn	