

General Chapters Physical Analysis Expert Committee (GC-PA EC)**Wednesday, April 22, 2020****10:00 a.m. – 12:30 p.m.****Teleconference, Conference Room 211****Draft 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. Welcome, Opening Remarks, Introduction Dr. He
 - b. Roll Call, Establish Quorum Mr. Freebern
 - c. Conflicts of Interest, Confidentiality, Code of Ethics
and Recording Policy Mr. Freebern
 - d. Approval of Agenda Dr. He
 - e. Approval of Minutes of Previous Meeting Dr. He
- 10:15 a.m. **2. Expert Committee Ballots items**
(Informational)
- a. **General Chapters**
 - i. <1051> Cleaning Glass Apparatus
 - b. **Reference Standards**
 - i. TBD
- 10:20 a.m. **3. Subcommittee / Expert Panel / Chapter Updates**
(Discussion and Decision-making)
- a. **Solutions** Drs. Coffey, Templeton
 - i. <631> *Color and Achromicity*
 - ii. <831> *Refractive Index*
 - iii. <781> *Optical Rotation*

See Harmonization section: <1061>
 - b. **Crystal/Microscopy** Dr. Hubert
 - i. Topic

See Harmonization section: <776>, <891>, <941>

- c. Rheology** Dr. Block
- i. <784> *Dropping Point*
 - ii. <911> *Viscosity - Capillary Methods*
 - iii. <914> *Viscosity-Pressure Driven Methods*
 - iv. <915> *Measurement of Structural Strength of Semisolids by Penetrometry*
 - v. <1912> *Rheometry of Semisolids*
- d. Powders** Dr. Sun
- i. *Stimuli article on Powder Flow Techniques*
See Harmonization section: <281>, <616>, <699>, <1174>
- e. Particles** Dr. Meury
- i. *Topic*
See Harmonization section: <429>, <430>
- f. Image Analysis of Particles** Drs. Welfare, Biba
- i. <1776> *Image Analysis of Pharmaceutical Systems*

11:00 a.m.

- 4. Updates on Joint Subcommittees and Expert Panels**
- a. Physical Stability JSC (PA EC)** Dr. Hancock, Mr. Hernández-Cardoso
 - b. Water Activity JSC (PA EC)** Drs. Coffey, He, Mr. Hernández-Cardoso
 - c. Nanotechnology JSC (DF EC)** Drs. Block, Welfare, Scoggins, Zaidi
 - d. Quality Standards for Pharmaceutical Continuous Manufacturing EP (CA EC)** Drs. Ali, Biba
 - e. Analytical Methodologies based on Light Scattering Phenomena EP (CA EC)** Drs. Welfare, Meury, Sun, Biba

11:20 a.m.

- 5. Harmonization Topics**
- a. Ongoing Activities**
(Discussion and Decision-making)
 - i. Solutions** Mr. Hernández-Cardoso
 1. <1061> *Color-Instrumental Measurement (Q-07)*
 - ii. Crystal/Microscopy** Mr. Hernández-Cardoso, Dr. Biba
 1. <776> *Optical Microscopy (G-09)*
 2. <891> *Thermal Analysis (G-16)*
 3. <941> *Characterization of Crystalline and Partially Crystalline Solids by X-Ray Powder Diffraction (G-14)*

- iii. Powders** Mr. Hernández-Cardoso, Dr. Liu
1. <281> *Residue on Ignition* (Q-10)
 2. <616> *Bulk Density and Tapped Density of Powders* (G-02)
 3. <699> *Density of Solids* (G-19)
 4. <1174> *Powder Flow* (G-05)

- iv. Particles** Dr. Biba
1. <429> *Light Diffraction Measurements of Particle Size* (G-13)
 2. <430> *Particle Size Analysis by Dynamic Light Scattering*

- b. Additional Harmonization Chapters** Dr. Moore
(Informational)
- i. <786> *Particle Size Distribution Estimation by Analytical Sieving* (G-01)
 - ii. <811> *Powder Fineness* (G-10)
 - iii. <846> *Specific Surface Area* (G-11)
 - iv. <1241> *Water-Solid Interactions in Pharmaceutical Systems* (G-15)

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| 11:50 p.m. | 6. Council of Experts Topics (Informational) a. Call for Candidates for the 2020-2025 Cycle | Dr. He |
| 12:00 p.m. | 7. Updated Work Plan Review and Subcommittees Rosters (Decision-making) | Dr. He |
| 12:10 p.m. | 8. Legacy Document (Discussion) | Dr. He |
| 12:25 p.m. | 9. Meeting Summary | Dr. He |
| 12:30 p.m. | Adjourn | |