

General Chapters-Physical Analysis Expert Committee (GC-PA EC) Thursday, September 17, 2020 9:00 a.m. – 11:00 a.m. Teleconference

Agenda - Draft

Goals and Anticipated Outcomes

The primary goal of this meeting is to brief the newly-formed committee on upcoming ballot of chapters, the 2015-2020 Legacy Document, and Subcommittee approach to the Work Plan. Specific objectives include:

- 1) Review upcoming ballots for proposed revisions in *Pharmacopeial Forum (PF)*.
- 2) Go over the legacy of committee work accomplished and ongoing work. Allow USP Staff the opportunity to bring key chapters to the attention of the Expert Committee.
- 3) Review the existing Subcommittees and Expert Panels and provide strategic direction as needed.
- 4) Review Work Plan and new areas for possible consideration

Attendees

Attendee list provided on the day of the meeting

9:00 a.m.	1.	Opening, Procedural, and Administrative Matters (Informational, Decision Making)	
		a. Welcome and Opening Remarks	Dr. He
		 Roll Call and Establish Quorum 	Mr. Freebern
		c. Conflicts of Interest, Confidentiality, Code of Ethics and Recording Policy	Mr. Freebern
		d. Approval of Agenda	Dr. He
9:05 a.m.	2.	Introductions (Informational) a. Expert Committee Members (including Fun Facts) b. USP Staff (including Roles and Responsibilities)	All
9:40 a.m.	3.	COVID-19 Quorum Contingency Resolution (Decision Making)	Mr. Freebern
9:45 a.m.	4.	Voting Procedure (Informational)	Mr. Freebern
9:50 a.m.	5.	USP Science Framework and General Chapters (Informational)	Dr. Pappa
10:10 a.m.	6.	EC Vice-Chair and Subcommittee Chairs Selection (Decision Making)	Dr. He



- 10:20 a.m. **7. Legacy Document and Workplan Assignments** (*Informational*)
- 10:50 a.m. 8. Chapters for the USP-NF 2021 Issue 2 Ballot (Decision Making)
 - a. Guidelines for Assessing and Controlling the Physical Stability of Chemical and Biological Pharmaceutical Raw Materials, Intermediates, and Dosage Forms <1149>
 - b. Optical Rotation <781>

Dr. He, Ms. Gaitán

Mr. Hernández-Cardoso

11:00 a.m. Adjourn