

**General Chapters Packaging and Distribution Expert Committee (GCPD EC)
Tuesday-Wednesday, March 12-13, 2019
USP-U.S., Rockville
Draft Agenda**

Goals and Anticipated Outcomes

The primary goal of this meeting is to provide the members of the 2015-2020 GCPD Expert Committee with an introduction and overview of the chapters for which the GCPD EC has responsibility, and to chart the course of work for the coming cycle. Specific objectives include:

- 1) Review each chapter, including subcommittees and Expert Panels and provide strategic direction as needed.
- 2) Review chapters that will appear on the next ballot and address any issues raised by the Expert Committee.
- 3) Develop work plans and action items to be accomplished before the next meeting of the Expert Committee.
- 4) Educate the Expert Committee on emerging topics and issues.

DAY 1**CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS**

- 9:00 a.m. **Procedural Matters and Standard of Conduct** Dr. Foster
(Informational)
- a. Call Meeting to Order
 - b. Establish Quorum
 - c. Identification of Observers and Confidential Information
 - d. Conflicts of Interest

END OF CLOSED SESSION

- 9:15 a.m. **Opening, Procedural, and Administrative Matters**
- (Informational & Decision-making)
- a. Meetings Center Announcements Ms. Hawkins
 - b. Welcome, Call Meeting to Order Dr. Foster
 - c. Introductions All
 - d. Review of Minutes of the Previous Meeting Dr. Foster
 - e. Approval of the Agenda Dr. Foster
 - f. Procedural and Administrative Matters Ms. von Berg

PACKAGING

- 9:45 a.m. **<87> and <88> Biological Reactivity Tests, In Vitro and In Vivo; and <1031> The Biocompatibility of Materials Used in Drug Containers, Medical Devices and Implants** Dr. Norwood, Dr. Stults

10:15 a.m.	BREAK	
10:45 a.m.	Elastomeric Closures Expert Panel Review of Chapters <381> and <1381>	Dr. Janssen, Ms. Paskiet
11:15 a.m.	Elastomeric Closures Expert Panel Review of Chapters <382> and <1382>	Dr. Guazzo
12:15 p.m.	LUNCH	
1:15 p.m.	<665> Plastic Components and Systems Used in the Manufacturing of Pharmaceutical Drug Products and <1665> Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products	Dr. Jenke
1:55 p.m.	<660> Containers-Glass	Dr. Eakins, Dr. Boltres
2:25 p.m.	<671> Containers—Performance Testing	Dr. Xiong
2:40 p.m.	BREAK	

STORAGE AND DISTRIBUTION

3:10 p.m.	<659>, <1079> Good Storage and Distribution Practices	Mr. Anderson, Dr. Braga
3:40 p.m.	<1178> Repackaging	Dr. Carrico
4:10 p.m.	Call for Candidates 2020-2025	Dr. Braga
4:40 p.m.	Adjourn for the Day	
6:30 p.m.	Dinner at Botenaro	

DAY 2

9:00 a.m.	Expert Committee Strategy Discussion	All
10:30 a.m.	BREAK	
11:00 a.m.	Expert Committee Strategy Discussion cont'd	All
11:30 a.m.	TBA title: URAC Dr. Rafik Bishara, Dr. Heather Bonome, Dr. Mark Maurice	
12:30 p.m.	Meeting Summary and Action Items	Dr. Foster
1:00 p.m.	Adjourn/Lunch(one on one discussion with Guest speakers)	