



General Chapters Packaging and Distribution Expert Committee (GCPD)
Thursday, April 1, 2021
9:00a.m.-11:00 a.m.
Teleconference

Agenda - Draft

Goals and Anticipated Outcomes

- To approve items for ballot and discuss the ongoing projects of subgroups.

Attendees

- Attendee list to be provided the day of the meeting

- 9:00 a.m. **1. Opening, Procedural, and Administrative Matters**
- a. Welcome, Opening Remarks, Introduction Dr. Janssen
 - b. Roll Call Ms. von Berg
 - c. Establish quorum All
 - d. Conflicts of Interest, Confidentiality, Code of Ethics and Recording Policy Ms. von Berg
 - e. Approval of Agenda Dr. Janssen
 - f. Approval of Minutes of Previous Meeting (January 6, 2021) Dr. Janssen
- 9:15 a.m. **2. Approval of Chapters and Reference Standards for Balloting**
- Decision Making*
- a. **Discussion of Chapters (*Ballot dates June 25-July 4*)** Drs. Jenke, Hunt
 - i. *<665> Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products*
 - ii. *<1665> Characterization of Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products*
 - b. Call for Recusal for Conflicted Members Dr. Janssen
 - c. Discussion for any items warranting EC decision-making Non-conflicted EC members
 - d. Motion – Moving Chapters and Reference Standard to Ballot Non-conflicted EC members
 - e. **Discussion of Reference Standard (*Ballot dates April 12-April 18*)** Dr. Casay
 - i. High-density Polyethylene: RSCEP 11200 High Density PET Lot R149K0



- f. Call for Recusal for Conflicted Members Dr. Janssen
 - g. Discussion for any items warranting EC decision-making Non-conflicted EC members
 - h. Motion – Moving Chapters and Reference Standard to Ballot Non-conflicted EC members
 - i. Balloting Process Mses. Hammann, Jobe
- 10:20 a.m. **3. Expert Committee Sub-group Activities**
- Informational/Discussion*
- a. Biological Reactivity Subcommittee Drs. Eakins, Hunt
 - b. <660> Containers-Glass Expert Panel Drs. Eakins, Boltres
 - i. Stim Article: Light Transmission
 - c. Supplier Qualification Joint Subcommittee Drs. Braga, Hunt
 - d. Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel
 - i. Conclusion of Panel
 - e. Extractables and Leachables Subcommittee Kick-Off Drs. Jenke, Hunt
 - f. Supply Chain and Distribution Subcommittee Drs. Braga, Anderson, Hunt
 - g. Medical Devices Joint Subcommittee Ms. Furr
- 10:50 a.m. **4. Meeting Wrap-up and Action Items**
- a. Action items
 - b. Reminder next meeting: June 24, 2021 from 9-11am ET