

**Biologics Stability Expert Panel**  
**of the General Chapters – Biological Analysis Expert Committee**  
**Monday, December 4, 2017**  
**USP – U.S., Rockville**

**Agenda**

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**Goals and Anticipated Outcomes**

- See goals under each agenda item

**Attendees**

*Attendee list provided on the day of the meeting*

**Monday, December 4, 2017**

		<b>[CLOSED to all Observers and Government Liaisons]</b>	
8:15 a.m.	<b>1. Procedural Matters and Standards of Conduct</b> a. Call Meeting to Order b. Establish Quorum c. Identification of Observers and Confidential Information d. Conflict of Interest, Confidentiality, Code of Ethics e. Review of the Agenda		Dr. Mire-Sluis Ms. Casino Dr. Mire-Sluis Ms. Casino Dr. Mire-Sluis
		<b>[END of CLOSED section]</b>	
8:30 a.m.	<b>2. Open Procedural Matters</b> a. Welcome b. Meeting Center Announcements c. Announce Changes to the Attendee List, Confirm Quorum d. Introductions of New Staff and Observers e. Approval of Agenda f. Open Action Items from Previous Meetings		Dr. Mire-Sluis Ms. Fletcher Dr. Mire-Sluis All Dr. Mire-Sluis Mr. Schmidt
8:45 a.m.	<b>3. Biologics Stability Chapter Updates</b> <i>Goal: To review the progress made and current draft chapter and discussion of new topics.</i> a. Updates and Overview of the draft chapter b. Discussion		Dr. Mire-Sluis All
10:30 a.m.	<b>Break</b>		
		<b>[CLOSED to all Observers and Government Liaisons]</b>	
10:45 a.m.	<b>4. New Discussion Topics</b> <i>Goal: To introduce new chapter discussion topics.</i> a. Nomenclature b. Time 0 Definition c. Transport vs, Time Out Of Temperature vs. Cycling Studies d. Packaged Lots and Secondary Packaging Requirements		All All All All

- e. Combination Products All
- f. Microbial Testing All
- g. Discussion All

**[END CLOSED Session]**

12:30 p.m. **Group Photo and Lunch**

**[CLOSED to all Observers and Government Liaisons]**

1:30 p.m. **5. Afternoon Chapter Section Discussions**

*Goal: Continue to review and discuss chapter sections.*

- a. Stability Study Development Cycle All
- b. Design of Additional Stability Studies All
- c. Stability Study Method Selection and Validation All
- d. Statistical Analysis of Stability Studies All
- e. Points to Consider in Stability Specification Setting All
- f. Life Cycle Management All

**[END CLOSED Session]**

3:15 p.m. **Break**

**[CLOSED to all Observers and Government Liaisons]**

3:30 p.m. **6. Afternoon Chapter Section Discussions (II)**

*Goal: Finalize discussions of chapter sections.*

- a. Stability Study Development Cycle All
- b. Design of Additional Stability Studies All
- c. Stability Study Method Selection and Validation All
- d. Statistical Analysis of Stability Studies All
- e. Points to Consider in Stability Specification Setting All
- f. Life Cycle Management All

**[END CLOSED Session]**

4:30 p.m. **7. Meeting Wrap-up**

- a. Reporting from Break-out Groups All
- b. Meeting Summary Dr. Mire-Sluis

5:15 p.m. Meeting adjourns, transportation to airport