

**2015-2020 USP Green Tea Extract Hepatotoxicity Expert Panel
Meeting 04 (Face-to-face)
Thursday, August 31 – Friday, September 1, 2017
Bache and Wood Rooms
USP-U.S., Rockville, MD**

Meeting Agenda

Goals and Anticipated Outcomes

- Review and discuss available evidence on the potential role of CMC and PK/PD in the reported hepatotoxicity of GTE.
- Review the draft Health Risk Assessment report on Green Tea Extract.
- Review the outline of the Report and of the critical integrated review of GTE hepatotoxicity assessment slated for publication in a peer reviewed journal.

Attendees

Please see accompanying attendee list

Day 1, Thursday, August 31, 2017

7:30 a.m.	Breakfast at Cambria Social Circle	
8:00 a.m.	Shuttle Departs Cambria Hotel for USP	
8:30 a.m.	Shuttle Arrives at USP; Sign-in	
9:00 a.m.	1. Opening, Procedural, and Administrative Matters <ol style="list-style-type: none"> a. Welcome, Call to Order b. Conflict of Interest and Confidentiality c. Procedural and Administrative Matters d. Approval of Minutes of the Previous Meeting e. Approval of Meeting Agenda f. Review of Outstanding Action Items 	Dr. Ko/Dr. Roe Dr. Ko/Dr. Roe Ms. Ahing Dr. Ko/Dr. Roe Dr. Ko/Dr. Roe Dr. Ko/Dr. Roe
9:30 a.m.	2. CMC Subgroup Final Draft	CMC Subgroup
10:30 a.m.	Break	
11:00 a.m.	3. PKPD Subgroup Final Draft	CMC Subgroup
12:00 p.m.	Lunch	
1:00 p.m.	4. HRA Subgroup Progress (Clinical Studies)	HRA Subgroup
2:30 p.m.	Break	
3:00 p.m.	5. HRA Subgroup Progress (Animal Studies)	HRA Subgroup
5:00 p.m.	Adjourn for the Day	
5:45 p.m.	Shuttle Departs Cambria Hotel for Dinner	
6:30 p.m.	Arrive at (TBD)	

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9:00 p.m. Return to Cambria Hotel

Day 2, Friday, September 1, 2017

7:30 a.m. Breakfast at Cambria Social Circle

8:00 a.m. Shuttle Departs Cambria Hotel for USP

9:00 a.m. **6. HRA Subgroup Progress (Causality Assignment and Predictive Toxicology)** HRA Subgroup

10:30 a.m. Break

11:00 a.m. **6. Draft GTEH Report Outline** Dr. Ko/Dr. Roe

12:50 p.m. **7. Next Steps and Action Items** Ms. Ahing

1:00 p.m. **Adjourn and Lunch**

1:30 p.m. **Transportation to Port of Departure**