



Coagulation Factors Expert Panel
August 21–22, 2019
USP – U.S., Rockville

Agenda - Draft

Goals and Anticipated Outcomes

Goals are provided under each agenda item.

Attendees

Attendee list provided on the day of the meeting

Day 1

Wednesday, August 21, 2019

8:15 a.m. Arrive at USP, register and check in

CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS

8:30 a.m. **1. Closed Procedural Matters and Standards of Conduct**

- a. Welcome, Opening Remarks, Introduction
- b. Conflicts of Interest, Confidentiality, Code of Ethics
- c. Review of Agenda for Specific Conflicts of Interest/Need for Recusal

Dr. Alai
Ms. Casino
Dr. Alai

END CLOSED SESSION

8:45 a.m. **2. Open Procedural Matters**

- a. Welcome
- b. Meeting Center Announcements
- c. Recording Policy and any other Procedural Announcements
- d. Roll Call and Introduction of Members, Government Liaisons, Staff, and Observers
- e. Establish Quorum
- f. Approval of Agenda
- g. Action Items from Previous Meeting

Dr. Alai
Ms. Fletcher
Ms. Casino

All

Dr. Alai
Dr. Alai
Ms. Casino

9:00 a.m. **3. Introduction of Bioassay Principles**

Goal: Introduce how statistical validity of bioassays is determined

- a. Bioassay Principles
- b. Discussion

Mr. Walfish
All



- 9:30 a.m. **4. Basis of Clotting and Chromogenic Assays**
Goal: Review basics of clotting and chromogenic methods
- a. Review Basics of Clotting and Chromogenic Methods Dr. Rosén
 - b. Discussion All
- 10:00 a.m. **Break**
- 10:30 a.m. **5. Potency Labeling of FVIII and FIX Products**
Goal: Give background on potency assignment, including history of assay discrepancies and regulatory perspectives
- a. Overview of Potency Labeling Dr. Gray
 - b. Discussion All
- 11:00 a.m. **6. Assays for FVIII**
Goal: Review current assays for FVIII
- a. Overview of Clotting Test Methods Dr. Gray
 - b. Chromogenic Method Details and Differences Dr. Rosén
 - c. Discussion All
- 11:30 a.m. **7. Assays for FIX**
Goal: Review current assays for FIX
- a. Overview of Clotting Test Methods Dr. Gray
 - b. Chromogenic Method Details and Differences Dr. Rosén
 - c. Discussion All
- 12:00 p.m. **Lunch & Group Photo**
- 1:00 p.m. **8. Case Study: Analytical Chapter Development**
Goal: Review a case study on development of a complex USP General Chapter
- a. USP General Chapter <129> Development Dr. Carrick
 - b. Reference Standard Development Dr. Carrick
 - c. Discussion All
- 1:45 p.m. **9. Assay Discrepancies for FVIII and FIX**
Goal: Understand the issue of assay discrepancies for modified products
- a. rFVIII Potency Assignment Dr. Gray
 - b. rFIX Potency Assignment Dr. Rosén
 - c. Discussion All
- 3:15 p.m. **Break**



3:45 p.m. **10. Landscape of Current and Upcoming Products**

Goal: Understand the current and future landscape of products

- a. Landscape of Products
- b. Discussion

Dr. Jing
All

4:00 p.m. **11. Use of Assays in the Clinic**

Goal: Understand the assays used in the clinic

- a. Use of Assays in the Clinic
- b. Discussion

Dr. Gray
All

4:45 p.m. **12. Wrap-up of Day 1**

Dr. Alai

5:00 p.m. **Adjourn – Day 1, Transportation to Hotel**

Day 2

Thursday, August 22, 2019

8:30 a.m. **13. Scope of Work for >1000 General Chapter**

Goal: Define the scope of work for the >1000 (informational) General Chapter

- a. Discussion

All

10:00 a.m. **Break**

10:15 a.m. **14. Scope of Work for <1000 General Chapter**

Goal: Define the Scope of work for the <1000 (method) General Chapter

- a. Discussion

All

11:45 a.m. **15. Meeting Summary**

- a. Meeting Summary
- b. Reminder of next EC meeting

Dr. Alai
Ms. Casino

12:00 p.m. **Adjourn & Lunch**