

PPTA DHQ Workshop

Agenda

June 14, 2010

Reston, VA

- 8:30 a.m. Introduction and Welcome
Joshua Penrod, PPTA VP Source
- 8:40 a.m. History of Development: The Long Winding Road to Today
Mary Gustafson, PPTA VP, Global Regulatory Policy
- 9:00 a.m. The Donor History Questionnaire Tools
a. Evolution of Questions, *Dr. Toby Simon, CSL Plasma*
b. Full Length Questionnaire, *Dr. Jon Knowles, CSL Plasma*
c. Abbreviated Questionnaire, *Richard Amador, Biotest Pharmaceuticals*
- 9:45 a.m. BREAK**
- 10:00 a.m. The Donor History Questionnaire Tools (Cont'd)
a. Directions for Use, *Dr. Maria Gudino, Baxter*
b. Use of Posters and Lists, *Dr. Robert Kratzel, Talecris*
c. Improvements over earlier questionnaires, *Dr. Toby Simon*
d. Differences between US and EU, *Dr. Maria Gudino*
- 11:45 a.m. Q and A Session
- 12:00 p.m. LUNCH (On your own)**
- 1:30 p.m. PPTA's Role in Managing the PPTA DHQ
Bridget Elis, PPTA Assistant Director, Regulatory Policy
Michelle Mason, PPTA Associate, Global Regulatory Policy
a. Website Overview
b. Document policy, revisions – how we will communicate changes to membership
- 2:00 p.m. FDA Expectations
Judy Ciaraldi, FDA, Division of Blood Applications, OBRR, CBER
a. Overview of the process of DHQ acceptance
b. How to submit documents to FDA – pas v. annual report
c. Tips for implementation and acceptance
- 2:45 p.m. Q and A Session

3:00 p.m. BREAK

3:15 p.m. The AABB Experience
Dr. Joy Fridey, AABB
a. The AABB DHQ Task Force
b. How AABB Manages the AABB DHQ
c. Implementation challenges—experience learned

3:45 p.m. Automating the PPTA DHQ: Collection Facilities Experiences
Roger Brinser, Baxter

4:30 p.m. Q and A session

4:45 p.m. Wrap-up