Public Webinar: FDA Review of Biologics License Applications for Blood and Source Plasma

Office of Blood Research and Review, CBER, FDA

AGENDA

February 19, 2025, 9.00am to 2.00pm

9:00- 9:15	**Welcome and Introduction** Anne Eder, M.D. PhD Director, Office of Blood Research and Review (OBRR)
9:15- 9:45	**Regulatory Requirements for Blood and Blood Components, including Source Plasma** Jennifer Scharpf, MPH Associate Director for Policy, OBRR
9:45- 10:15	**Blood Establishment Registration and Facility Relocations** Orieji Illoh, MD Deputy Director, OBRR
10:15-10:45	**Submitting a BLA for Blood and Blood Components or Source Plasma** Miriam Montes, MS, MT(ASCP)SBB Team Lead, BPB/DBCD/OBRR
10:45-11:00	**Break**
11:00-11:30	**BLA Review Process** Camilla Smith, BS, BB(ASCP)SBB, CQA(ASQ) Team Lead, BPB/DBCD/OBRR
11:30-12:00	**FDA/OBRR Inspection Process/ Expectations/ Common Citations** Richard McBride, MS, MT(ASCP)SBB Branch Chief, BPB/DBCD/OBRR
12:00-12:30	**Donation Testing, Donor Deferral, Requalification, and Notification** Anne Eder, M.D. PhD Director, Office of Blood Research and Review (OBRR)

12:30-12:45	**Break**
12:45-1:15	**BPB Commonly asked questions** Camilla Smith and Miriam Montes
1:15-1:45	**Q/A-** (will address questions submitted by registrants)
1:45-2:00	**Closing Remarks**