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

Office of Blood Research and Review (OBRR),
Center for Biologics Evaluation and Research (CBER), FDA

AGENDA

May 12, 2026, 9.00 am to 2.00 pm Eastern

9:00- 9:15	**Welcome and Introduction** Anne Eder, M.D. PhD Director, Office of Blood Research and Review (OBRR) **Moderator** Wendy Paul, MD Director, Division of Blood Components and Devices (DBCD), 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	**Donation Testing, Deferral, Requalification, and Notification** Yeowon Kim, MD, MHS Medical Officer, OBRR
10:15-10:45	**Blood Establishment Registration and Facility Relocations** Carmelita Bibby, MS, MLS(ASCP)BB Consumer Safety Officer, Blood and Plasma Branch, DBCD/OBRR
10:45-11:00	**Break**
11:00-11:45	**Submitting a BLA for Blood and Blood Components or Source Plasma** Miriam Montes, MS, MT(ASCP)SBB Branch Chief, Blood and Plasma Branch, DBCD/OBRR

11:45-12:15	**BLA Review Process** Camilla Smith, BS, BB(ASCP)SBB, CQA(ASQ) Team Lead, Blood and Plasma Branch, DBCD/OBRR
12:15-12:45	**FDA/OBRR Inspection Process/ Expectations/ Common Citations** Catherine McGraw, MSN, RN Consumer Safety Officer, Blood and Plasma Branch, DBCD/OBRR
12:45-1:00	**Break**
1:00-1:45	**Questions submitted to FDA** Miriam Montes, MS, MT(ASCP)SBB Camilla Smith, BS, BB(ASCP)SBB, CQA(ASQ)
1:45-2:00	**Closing Remarks** Anne Eder, M.D. PhD, OBRR