



# 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

<b>9:00- 9:15</b>	<b>Welcome and Introduction</b> Anne Eder, M.D. PhD Director, Office of Blood Research and Review (OBRR)  <b>Moderator</b> Wendy Paul, MD Director, Division of Blood Components and Devices (DBCD), OBRR
<b>9:15- 9:45</b>	<b>Regulatory Requirements for Blood and Blood Components, including Source Plasma</b> Jennifer Scharpf, MPH Associate Director for Policy, OBRR
<b>9:45- 10:15</b>	<b>Blood Establishment Registration and Facility Relocations</b> Carmelita Bibby, MS, MLS(ASCP)BB Consumer Safety Officer, Blood and Plasma Branch, DBCD/OBRR
<b>10:15-10:45</b>	<b>Submitting a BLA for Blood and Blood Components or Source Plasma</b> Miriam Montes, MS, MT(ASCP)SBB Acting Branch Chief, Blood and Plasma Branch, DBCD/OBRR
<b>10:45-11:00</b>	<b>Break</b>
<b>11:00-11:30</b>	<b>BLA Review Process</b> Camilla Smith, BS, BB(ASCP)SBB, CQA(ASQ) Team Lead, Blood and Plasma Branch, DBCD/OBRR

<b>11:30-12:00</b>	<b>FDA/OBRR Inspection Process/ Expectations/ Common Citations</b> Catherine McGraw, MSN, RN Consumer Safety Officer, Blood and Plasma Branch, DBCD/OBRR
<b>12:00-12:30</b>	<b>Donation Testing, Deferral, Requalification, and Notification</b> Yeowon Kim, MD, MHS Medical Officer, OBRR
<b>12:30-12:45</b>	<b>Break</b>
<b>12:45-1:45</b>	<b>Questions submitted to FDA</b> All speakers
<b>1:45-2:00</b>	<b>Closing Remarks</b> Anne Eder, M.D. PhD, OBRR