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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2025 #2 **January 20, 2025**

INSIDE:

FDA Issues Malaria Draft Guidance

The U.S. Food and Drug Administration has published, "Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria Draft Guidance for Industry." The recommendations are applicable to the collection of whole blood and blood components, except source plasma. The Draft Guidance shifts away from current deferral-based strategies to a selective testing approach.

Under the agency's recommendations, blood establishments may implement one of the following procedures:

- "[a] selective testing strategy to:
  - test donations, using an FDA licensed donor screening NAT, from donors who have ever had malaria or resided in or traveled to a malaria-endemic country; and
  - test donations collected in regions of the U.S. that FDA identifies as having local, mosquito-borne malaria transmission; or
- implementation of pathogen reduction technology for platelets and plasma donations using an FDA-approved pathogen reduction device indicated for use against *P. falciparum*, when collected from donors who have had malaria or resided in or traveled to a malaria-endemic country or collected in regions of the U.S. that FDA identifies as having local, mosquito-borne malaria transmission."

The Draft Guidance also recommends:

- "[u]pdate donor history questionnaire and conduct a medical history interview at each donation;
- [d]efer a donor who is not in good health or who has clinical evidence of a relevant transfusion-transmitted infection, including malaria. Defer the donor for at least one year or until the donor is free of malaria if the donor reports symptoms of or is being treated for malaria;
- [t]est each donation from donors who report a history of malaria;
- [t]est at least one time a donor who reports they are a prior resident of a malaria-endemic country;
- [t]est each donation from a donor who reports travel to a malaria-endemic country in the past 12 months;
- [u]pon notification by FDA via a posting on the agency's website, test each donation collected in a region of the U.S. with local, mosquito-borne malaria transmission ;

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FDA Issues Malaria Draft Guidance (continued from page 1)

- [a]lternatively, for platelets and plasma donations, implement pathogen reduction technology using an FDA-approved pathogen reduction device when collected from donors who have had malaria or resided in or traveled to a malaria-endemic country or collected in regions of the U.S. that FDA identifies as having local, mosquito-borne malaria transmission. [d]efer donors with a reactive NAT result for Malaria for at least one year."

America's Blood Centers (ABC) previously submitted malaria testing recommendations in comments to the FDA Blood Products Advisory Committee (BPAC) in May 2024 that, "strongly recommended" that the agency delay publishing draft guidance until modeling studies are finished and additional malaria testing assays are approved and available."

ABC will submit comments to FDA by the March 17th deadline. Member blood centers are encouraged to share input with ABC Director of Regulatory Affairs and Public Policy Justine Coffey, JD, LLM by February 3rd.

OneBlood Receives FDA Approval for CCP for Immunocompromised COVID-19 Patients

OneBlood has announced that it has become the first blood center in the U.S. to be, "granted full U.S. Food and Drug Administration (FDA) approval to provide licensed high titer COVID-19 convalescent plasma (CCP) from people who have recovered from COVID-19 for use in individuals who are immunocompromised and unable to make their own antibodies to the virus." A January 13th news release explained that OneBlood collaborated with Johns Hopkins Medicine and the Johns Hopkins Bloomberg School of Public Health, the Mayo Clinic, the Association for the Advancement of Blood & Biotherapies (AABB), the COVID-19 Convalescent Plasma Project (CCPP19), and the COVID-19 Serologic Studies Consortium (CSSC-004) to, "provide the necessary data to the FDA to prove that convalescent plasma is safe and effective for patients who are immunocompromised."

OneBlood noted that individuals, "who have recovered from the coronavirus and/or who have been vaccinated for COVID-19 have developed antibodies to the virus that remain in the plasma portion of their blood. COVID-19 convalescent plasma from recovered patients with a high level of antibodies may be used to treat people diagnosed with COVID-19 who have a weakened immune system. The high titer antibody levels in the licensed CCP are more than 20 times greater than the levels required previously under the Emergency Use Authorization." The licensed high titer CCP is available for order to hospitals served by OneBlood (via BloodHub) and those not served by OneBlood (via: www.oneblood.org/ccp).

(Source: OneBlood News Release, 1/13/25)

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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognizes the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the health care system; promote partnerships, policies, and programs that increase awareness about the need for blood donation; and serve as a thought leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

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SCABB and TABB Announce Affiliation

The South Central Association of Blood Banks (SCABB) and the Tennessee Association of Blood Banks (TABB) have "aligned as one under SCABB," according to a news release. Tennessee will become SCABB's District V with Sabah Ghazi, MBA, MSL, Msc, PhD of Tennova Healthcare (Clarksville, Tenn.) having been named as director of the new district. Other SCABB districts include:

- "District I (Texas);
- District II/III (Arizona, New Mexico, Colorado, Oklahoma, Arkansas, Louisiana, and Mississippi); and
- District IV (Florida)."

SCABB President Fran Carson explained in the news release, "[i]t was critical to both organizations to strengthen our abilities to continue to offer high quality education offerings, professional development, and peer to peer networking for our members on a regional platform. Bringing TABB into the South Central Association affords us all that ability for years to come!"

(Source: SCABB News Release, 1/14/25)

WORD IN WASHINGTON

The U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) Director Patrizia Cavazzoni, MD is retiring from the agency. According to a report from *Fierce Pharma*, she informed her colleagues at the agency via an internal memo, "'[l]eaving CDER was an extremely difficult decision, but the time has come for me to be more present for my family, who have taken the backseat over the past few years due to the demands of my role and our critically important public health work.' Dr. Cavazzoni became CDER director in 2021 following a long tenure at the department by FDA legend Janet Woodcock. After a career in industry, Dr. Cavazzoni joined the FDA in 2018, initially serving as deputy director of operations for CDER." January 18th was reported as her final day at the agency.

(Source: *Fierce Pharma*, "FDA's Patrizia Cavazzoni to retire as CDER chief in 2nd senior official's departure in span of weeks," 1/10/25)

The U.S. Department of Health and Human Services (HHS) has announced that it is providing, "$211 million in funding to the Rapid Response Partnership Vehicle (RRPV) Consortium to enhance mRNA platform capabilities so that the U.S. is better prepared to respond to emerging infectious diseases like avian flu." According to the agency news release, the funding will come from "the Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Administration for Strategic Preparedness and Response (ASPR), [and] will support development and long-term manufacturing capability of an RNA-based vaccine platform technology to combat evolving 21st century biothreats…The RRPV is a 10-year, multi-purpose acquisition vehicle and consortium partnership designed to support advanced research and development of medical countermeasures, such as vaccines, therapeutics, and diagnostics. The consortium leverages ASPR's authority to create flexible, strategic partnerships between government and industry that foster innovation and promote collaboration."

(Source: HHS News Release, 1/16/25)

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WORD IN WASHINGTON (continued from page 3)

The National Heart, Lung, and Blood Institute's (NHLBI) Blood Diseases & Disorders Education Program (BDDEP) has issued a request for proposals (RFP) via the 2025-2026 Community Subcontract Program for initiatives, "focused on promoting awareness of the importance of blood donor diversity and increasing blood donation among Black or African American communities." According to the announcement, funding for initiatives is available, "up to $50,000 each for up to three organizations."

NHLBI further explained that proposed projects should, "address three key goals:

- raise awareness about blood donation benefits and the importance of blood donor diversity within Black or African American communities;
- educate these communities about blood donation safety, eligibility, and the donation process, through culturally relevant efforts; and
- foster community involvement and help promote community events, such as health-oriented events and/or blood drives."

Submissions are due by February 21st at 3 p.m. EST.

(Source: NHLBI BDDEP RFP, 1/17/25)

STATE ADVOCACY BRIEFS

Senate Bill S.2994, "An Act to Increase Access to Blood Donation," has been signed into law by the Governor of Massachusetts. The bill amends existing law to allow, "organizations registered as blood establishments with the FDA," to establish and maintain a blood bank. The original statute limited blood collection to licensed hospitals, the American Red Cross, the Center for Blood Research, Inc., federal hospitals, and hospitals operated by the department of public health. This statutory restriction, unique to Massachusetts, posed significant barriers to building a robust and diverse blood donor pool and meeting the growing demand for lifesaving blood products.

HB1105 has been introduced in the Illinois General Assembly. The bill requires, "a blood bank to test or have tested donated blood for evidence of any COVID-19 vaccine and any other messenger ribonucleic acid (mRNA) vaccine components, and requires a blood donor to disclose during each blood donor screening process whether the blood donor has received a COVID-19 vaccine or any other mRNA vaccine during the donor's lifetime." A similar bill was introduced by the same Representative last year and failed. ABC is working with centers in Illinois to monitor and respond if necessary. If your center would like to be included in this group, please contact ABC Vice President of Government Affairs Diane Calmus, JD.

HB1179 has been introduced in the Illinois General Assembly. The bill would create, "an income tax credit of $250 for taxpayers who make four or more qualified donations of human whole blood or human blood components during the taxable year." A similar bill was introduced by the same Representative last year through the work and support of ABC member centers in the state.

HB1120 has been introduced in the Illinois General Assembly. The bill removes "a provision that requires the Secretary of State to designate on each driver's license issued a space where the licensee may indicate his blood type and Rh factor."

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STATE ADVOCACY BRIEFS (continued from page 4)

HB140 has been introduced in the Kentucky General Assembly. The bill would, in part: require blood establishments to test for spike proteins, antibodies to the nucleocapsid protein on the SARS-CoV-2 virus, and synthetic mRNA, require adding the results of these tests to the blood label, and prohibit transfusion of units that test positive on any of these tests (though there is a provision allowing for the transfusion of a unit positive for synthetic mRNA with patient informed consent); require additional screening questions for blood donors and not allow donation if a donor has "received genetically engineered blood or blood products; Has received experimental therapies or medications of any kind including but not limited to: a. Engineered cell therapy; b. Genetically modified or engineered blood products; c. Drugs, blood, or blood-derived pharmaceuticals; or d. Monoclonal antibody treatments, stem cell therapy, or any other human cell derived medication, treatment, or therapy;" provide that a person shall not be compelled to donate blood; require blood establishments to inform donors of the potential uses for donations; require blood to be sold to hospitals before any other entity; strengthen existing language around the right of a patient to receive a directed or autologous blood donation. A similar, though less comprehensive, bill was introduced last year and failed. ABC is working with centers in Kentucky to monitor and respond, if necessary.

HB155, "An Act Relating to Blood Donations," has been introduced in the Kentucky General Assembly to strengthen an existing right in Kentucky law to autologous and directed donation. The bill would require, "a health facility that facilitates autologous or directed blood donations [to] comply with a health care provider's order prescribing an autologous or directed blood donation for an individual." Additionally, the health care facility would be required to, "allow an individual on whom a medical procedure is to be performed to provide an autologous or directed blood donation ordered by a health care provider for the medical procedure." ABC is working with centers in Kentucky to monitor and respond, if necessary.

Senate Bill S765, "An act to amend the public health law, in relation to certificates of qualification for clinical laboratories and blood banks," was filed in New York. The purpose of the amendment is, "to clarify provisions related to updating the standards of certificates of qualification for clinical laboratories and blood banks and work standards for cytotechnologists." The Assembly version of the bill, A1468, has also been filed.

HB1239 has been introduced in the Illinois General Assembly. The bill amends, "the Illinois Identification Card Act and the Illinois Vehicle Code [by requiring] the Secretary of State to provide an option to an applicant for an original, reissued, or renewed identification card, driver's license, or driver's permit to indicate the applicant's blood type. If an applicant chooses to indicate the applicant's blood type, the Secretary of State shall print the identified blood type on the applicant's identification card, driver's license, or permit."

HB239 has been introduced in Mississippi. The bill would, "specify the required and optional identifying information to be included on drivers' licenses issued by the department, including the option to indicate the licensee's blood type if medical documentation verifying such is presented at the time of [the] license's issuance."

HB0135, relating to autologous or direct[ed] blood donations, was introduced in the Wyoming House. The bill would require a hospital or other licensed healthcare facility to, "allow a person on whom a medical procedure is to be performed at the facility to donate a health care provider-ordered autologous or direct[ed] blood donation before the medical procedure if the facility performs blood donations…A blood bank may charge not more than their regular fee to facilitate an autologous or direct[ed] blood donation ordered by a health care provider…The blood bank may charge a fee to store the donated blood until it is used by the person meant to receive it."

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STATE ADVOCACY BRIEFS (continued from page 5)

HB0152 has been introduced in the Wyoming House regarding, "donated blood-mRNA disclosure. The bill would require, "blood donors to disclose vaccination status as specified; requir[e] blood packaging to be marked as specified; allo[w] a person who receives a blood transfusion to request the use of certain blood."

RESEARCH IN BRIEF

Freeze-Dried Plasma and Damage Control Resuscitation. The goal of a study published in *Transfusion* "was to determine whether freeze-dried plasma (FDP) was comparable to fresh plasma and to assess whether it can serve as a logistically feasible and stable alternative in the absence of whole blood for pre-hospital resuscitation." The paper explained that, "FDP was reconstituted according to manufacturer guidelines (OctaplasLG Powder) [and the] intrinsic and extrinsic rotational thromboelastometry (ROTEM) clot profiles and parameters between FDP were comparable to plasma controls." Additionally, the researchers noted that, "[t]he extrinsic (prothrombin thrombin, PT) and intrinsic (partial thromboplastin time, PTT) pathways, fibrinogen concentration, D-dimer fragments produced by clot degradation, coagulation factors (F)V and FVIII, antithrombin, plasminogen, and proteins C and S were analyzed using STAGO, demonstrating comparable physiological functions in FDP and plasma controls. PT and PTT values were consistent with the ROTEM clotting profiles, demonstrating that the coagulation function of the reconstituted FDP was equivalent to plasma after lyophilization and during six-month storage...Von Willebrand factor (VWF) multimer analysis of reconstituted FDP compared to plasma control showed similar size distribution, but increased concentration." Additionally, the study found that, "VWF activity in FDP was comparable to plasma control [and] ADAMTS13 antigen levels in FDP were lower compared to the plasma control [while total] protein concentration of FDP was in agreement with that of plasma control." The paper further explained that, "[t]he thermodynamic parameters of reconstituted FDP mixing in fresh plasma were examined [and] demonstrate enthalpy-driven exothermic mixing processes, suggesting spontaneity of homogenized mixing processes…Titration of saline controls did not generate a significant heat of mixing, consistent with dilution of plasma." The researchers noted that an, "[a]nalysis of FDP powder showed 1.2 percent ± 0.5 percent (w/w) water content. This finding indicated that the sealed FDP powder did not show changes in moisture content after six-month storage at room temperature under passive humidity conditions. [Differential] calorimetry analyses of isobaric excess heat capacity as a function of temperature demonstrated similar thermal stability profiles for FDP and plasma control." The authors wrote that, "to study the effect of FDP on platelet adhesion *ex vivo*, the ligand-binding properties of platelet receptors GPIbα and GPIIbIIIa were studied in FDP and plasma control…The values between activated GPIIbIIIa- and GPIbα-binding affinities in reconstituted FDP were comparable to that observed with the plasma control." The paper concluded that, "FDP exhibits characteristics comparable to those of FFP used for human transfusion, while providing significant logistical and storage advantages. [Ultimately,] timely surgical hemostasis remains essential for definitive treatment, but the availability of FDP can bridge the gap until whole blood resuscitation can be initiated."

Citation: Shoara, A.A, Singh, K., Peng H.T., *et al*. "Freeze-dried plasma: Hemostasis and biophysical analyses for damage control resuscitation." *Transfusion*. 2025.

Contributed by Richard Gammon, MD

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INSIDE ABC

The programs and services described in the Inside ABC section are available to ABC member blood centers and their staffs only, unless otherwise specified.

2025 ABC Annual Meeting Schedule Available

Join us for the 63rd America's Blood Centers (ABC) Annual Meeting in Arlington, Va. Registration is open and the schedule is available. Hear *POLITICO's* Director of Regulatory Research Laura DiAngelo, MPH deliver the keynote as she addresses the impact of the 2024 Presidential and Congressional elections on the regulatory and congressional landscape. Meeting attendees will gain insights into how the administration's policy agenda and approach to regulation will impact the blood community, allowing your organization to stay ahead of the curve. This event will also explore the latest developments in advocacy, leadership, operations, science, and medicine, connecting and preparing your c-suite and senior leadership for the most critical topics facing your blood center. Following the success of last year's revamped format and expanded content offerings, we will continue this approach in 2025. Book your rooms by Friday, February 14th to secure the hotel group rate. Sponsorship opportunities are also available. Please contact us with any questions as we look forward to seeing you!

Executive Compensation Report Available

ABC has published the 2024 Executive Compensation Survey Report. This resource is available complimentary to participating ABC member blood centers. Non-participating member blood centers may purchase the report which is an important tool for blood center chief executive officers (CEOs) and their boards for setting executive salaries/benefits, as well as meeting the Internal Revenue Service Form 990 requirements to demonstrate comparability of CEO compensation. Please contact us with questions.

ABC Talking Points Released on DEHP and Blood Bags

ABC has updated talking points focused on di(2-ethylhexyl) phthalate (DEHP) use in blood collection, technical requirements for blood bags, and challenges in transitioning to DEHP-free materials. The talking points underscore the limited availability of such alternatives and the complexity of the approval process. An archive of all talking points developed by ABC are available here.

Register for the 2025 ADRP Annual Conference

Register now for the 2025 ADRP Annual Conference in Oklahoma City, Oklahoma, from May 6th to 8th at the Omni Oklahoma City Hotel. Remember to book your hotel room by April 11th for the discounted rate. This conference offers a chance to learn about industry trends, share ideas, and connect with other donor recruitment, donor services, collections, marketing, and communications professionals. Join more than 400 of your peers by participating in pre-conference workshops, attending compelling educational sessions, engaging in roundtable discussions, and exploring an expansive exhibit hall filled with innovative solutions. Seize this extraordinary opportunity to learn, share, and grow within the blood community.

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INSIDE ABC (continued from page 7)

Register for the ABC & ADRP Webinar: "Gratitude in Action: Celebrating Blood Donors and Developing Strategic Partnerships"

Join ABC and ADRP on Wednesday, January 22nd at 1 p.m. EST for the January webinar titled "Gratitude in Action: Celebrating Blood Donors and Developing Strategic Partnerships." Registration is open. Hear speakers Joey Powell, director of Public Relations and Marketing at Dickerson Park Zoo, and Matt Swanson, manager of Marketing Partnership Programs at Versiti, share insights on creating valuable partnerships and recognizing the individuals who help support blood donation.

2025 ADRP Call for Award Nominations Opens

ADRP encourages you to recognize the work of individuals on your staff, donors, and organizations who go above and beyond with their exceptional service and leadership in support of blood donation by submitting a nomination for the 2025 ADRP Awards. This year's awards include:

- Franzmeier Lifetime Achievement Award;
- Ronald O. Gilcher, MD Award;
- Donor Experience Professional of the Year Award;
- Rolf Kovenetsky Leader of the Year Award;
- ADRP Volunteer of the Year Award;
- Media Partner Award;
- Blood Drive Partner of the Year Award; and
- School Partner of the Year Award.

Award winners will be honored during the 2025 ADRP Annual Conference in Oklahoma City, Oklahoma at the Omni Oklahoma City Hotel and receive a complimentary conference registration. You may view a description of each award here and a listing of the 2024 winners. Please contact us with questions.

GLOBAL NEWS

The European Centre for Disease Prevention and Control (ECDC) recently held the second meeting of the Substances of Human Origin network's (SoHO-Net) Blood group in Stockholm, Sweden. According to the agency, the meeting featured representatives from the World Health Organization (WHO), European Blood Alliance (EBA), European Directorate for the Quality of Medicines & HealthCare (EDQM), Directorate-General for Health and Food Safety (DG SANTE, EC), and the European Medicines Agency (EMA) and focused on, "critical issues related to blood safety and the prevention of transfusion-transmitted infections [including:]

- [u]pdates on ECDC's scientific activities and outputs: Focus on blood safety in the context of the new SoHO Regulation;
- [i]nput gathering from participants for the SoHO network prioriti[z]ation of pathogens for upcoming technical guidelines;
- [e]xamination of the risk of dengue virus transmission through blood transfusion, including the implications for blood safety measures and supply across European Union (EU)/European Economic Area (EEA) countries;
- [d]iscuss[ion] of the application of a risk model for variant Creutzfeldt–Jakob disease (vCJD) in transfusion to support country decision-making on the geographic deferral of donors due to the risk of vCJD; [and]
- Shar[ing] feedback on ECDC's surveillance tools for vector-borne diseases and explored and provided input on adaptations of rapid risk assessment methodology tailored for SoHO."

(Source: ECDC SoHO-Net Meeting, 12/17/24)

COMPANY NEWS

The U.S. Food and Drug Administration (FDA) has granted 510(k) clearance to **Roche Diagnostics** for software changes to cobas pro serology solution for the Elecsys Syphilis, Elecsys Anti-CMV, cobas pro serology solution. According to an approval letter from the agency, the cobas pro serology solution is, "a combination of the cobas pro serology controller, cobas pro integrated solutions (cobas e 801 analytical units only) and applicable licensed blood screening assays. The system automates electrochemiluminescence immunoassay test processing, result interpretation, and data management functions for screening of donations of whole blood and blood components using plasma or serum samples." Elecsys Syphilis is, "an *in vitro* immunoassay for the qualitative detection of total antibodies (IgG and IgM) to Treponema pallidum in human serum and plasma. Elecsys Syphilis is intended to screen individual human donors, including volunteer donors of whole blood and blood components." The FDA letter described the Elecsys Anti-CMV as an, "*in vitro* immunoassay for the qualitative detection of antibodies to [c]ytomegalovirus in human serum and plasma. Elecsys Anti-CMV is intended to screen individual human donors, including volunteer donors of whole blood, and blood components." The cobas pro serology solution, Elecsys Syphilis, and Elecsys Anti-CMV assays received FDA clearance in November 2024.

(Sources: FDA Letter, 1/10/25, FDA Letter, 11/6/24)

Haemonetics Corporation has announced the completion of the sale of its whole blood assets to **GVS, S.p.A**. According to the news release regarding the transaction, "GVS has acquired Haemonetics' portfolio of proprietary whole blood collection, processing and filtration solutions, along with Haemonetics' manufacturing facility in Covina, Calif. [and] Tijuana, Mexico." Haemonetics also explained in the announcement that its blood center business unit will continue to, "manufacture and provide customers with its full line of apheresis solutions for automated blood collection. These include devices and disposable kits that support a variety of apheresis collections, including platelets, plasma, and red cells, and ensure efficient blood center operations."

(Source: Haemonetics News Release, 1/14/25)

The **American Hospital Association (AHA)** has published its 2025 Advocacy Agenda which includes mitigating blood shortages. Specifically, the resiliency and preparedness section states, "[p]revent and address shortages of critical medical drugs, devices, blood and blood products, and supplies, including working with Congress and the federal government to bring about policy changes that will avert future shortages by strengthening the medical supply chain."

(Source: AHA Advocacy Agenda, 1/16/25)

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@americasblood.org. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2025

Jan. 22. **America's Blood Centers and ADRP Webinar: Gratitude in Action: Celebrating Blood Donors and Developing Strategic Partnerships.** Registration is open. More information available here.

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CALENDAR (continued from page 9)

Jan. 30. **U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER), Office of Therapeutic Products (OTP) RegenMedEd Roundtable with FDA's OTP Webinar (Virtual).** Registration is open. More information available here.

Feb. 4-6. **Department of Defense (DoD) Combat Casualty Care Research Program, the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA) Radiation/Nuclear Medical Countermeasures Program, and the Medical Technology Enterprise Consortium (MTEC) Platelet and Platelet-like Products State of Technology Meeting. Bethesda, Md.** Registration is open. More information available here.

Feb. 19. **FDA CBER Office of Blood Research and Review (OBRR) Public Webinar: FDA Review of Biologics License Applications for Blood and Source Plasma (Virtual).** Registration is open. More information available here.

Feb. 25. **FDA Investigational Use Requirements for In Vitro Diagnostic Products (IVDs), including Laboratory Developed Tests (LDTs) Under 21 CFR 812 Webcast (Virtual).** More information available here.

Feb. 25. **FDA CBER Office of Therapeutic Products (OTP) Cell Therapies and Tissue-Based Products: A Public Workshop on Generating Scientific Evidence to Facilitate Development (Virtual).** Registration is open. More information available here.

Mar. 10-12. **ABC Annual Meeting. Arlington, Va.** Registration is open. More information available here.

May 6-8. **2025 ADRP Annual Conference. Oklahoma City, Okla.** Registration is open. More information available here.

May 14-15. **International Plasma and Fractionation Association (IPFA)/Paul-Ehrlich Institut[e] (PEI) 30th International Workshop on Surveillance and Screening of Blood-borne Pathogens. Heidelberg, Germany.** Registration is open. More information available here.

May 20-21. **International Plasma Protein Congress. Warsaw, Poland.** More information is coming soon.

June 1-4. **International Society of Blood Transfusion (ISBT) 35th Regional Congress. Milan, Italy.** Registration is open. More information available here.

June 10-11. **ABC Advocacy Workshop. Washington, D.C.** More information is coming soon.

June 25-26. **HHS OIDP TBDAIC Community Engagement Meeting (Hybrid). Portland, Maine.** More information coming soon.

June 30-July 1. **HHS Administration for Strategic Preparedness and Response (ASPR) Biomedical Advanced Research and Development Authority (BARDA) Industry Day 2025 (Hybrid). Washington, D.C.** More information available here.

Oct. 12-15. **American Association of Tissue Banks (AATB) Annual Meeting. Atlanta, Ga.** More information is coming soon.

Oct. 25-28. **AABB Annual Meeting. San Diego, Calif.** More information is coming soon.

Nov. 17-20. **American Society for Clinical Pathology (ASCP) Annual Meeting. Atlanta, Ga.** Registration is open. More information available here.

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: newsletter@americasblood.org

POSITIONS

Associate Medical Director/Medical Director (Versiti Blood Center of Ohio). Serve as the physician face of Versiti and Versiti Ohio, translating complex medical issues to educate other physicians, support staff and the public. Opportunities in educational initiatives and clinical/applied research are available within Versiti and with our affiliated health systems. As part of the Versiti physician team you will have the opportunity to participate in clinical research projects with investigators at our world-renowned diagnostic laboratory and blood research institute. Joining our Medical Science Institute transfusion medicine physician team will provide you with a uniquely diverse and collaborative experience. Requirements: MD or DO Degree. Board certified/eligible in Blood Banking/Transfusion Medicine. At least three years of experience in blood center/transfusion medicine practice preferred. Licensed or eligible for an Ohio and Indiana; other state licenses may be required. Driver's License in good standing. Please click here to read the full job description and apply.

Chief Operations Officer (Oklahoma City, Oklahoma). Our Blood Institute (OBI), America's largest, self-sufficient blood center is seeking a seasoned, successful, and inspiring Chief Operations Officer (COO). The COO will provide leadership, guidance, and oversight for core blood center operations to include Donor Recruitment; Donor Services; Technical Operations; Client Relations/Contracting; 8 Subcenter, and 9 Satellite operations. This position will assure donor and product safety. He/She will recruit and foster the talent required to staff a dependable, high performance, engaged, and innovative team now and for the future. They will develop annual budgets at the organizational level (demand planning) and for supervised departments, with an eye to maximizing efficiencies and expanding revenue streams. They will also recommend new technologies and capital expenditures that are necessary to keep the organization's operations at the leading edge of performance. They will maintain productive industry collaborations and relationships via group purchasing organizations and professional/industry associations while working with executive leadership to shape strategic plans to benefit the organization's principle functions of blood product acquisition, processing, and distribution. Salary Range: Competitive salary with excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. **How to apply:** https://obi.org/about/careers/

Operations Manager. Blood Assurance is seeking an **Operations Manager** to manage our collection efforts in the Georgia area. This position will be responsible for operational oversight of collection services for multiple collection teams in an assigned territory. Supervises staff in coordination with other department leaders and ensures compliance with all Standard Operating Procedures, FDA and AABB regulations. Monitors performance in the areas of productivity, proficiency and customer service. Operations Manager Requirements: A bachelor's degree with some prior supervisory/ management experience in blood banking is required. Advanced skills in leadership, teamwork, analytics, and communications are also required. We offer many benefits including: Health/Dental/Vision Insurance, Flexible Spending Account, Employee Assistance Program for you and your family, Generous Paid Time Off, 401K with company match and Wellness Program. Blood Assurance is a non-profit organization with a workforce of more than 300 employees. At Blood Assurance, our values are centered around LIFE: Laughter, Integrity, Family and Excellence. These values are embedded in our company culture. Come and join our team to be a part of this rewarding environment! Qualified candidates are encouraged to submit an online employment application for consideration at //bloodassurance.org/careers. Blood Assurance is an Equal Opportunity Employer and a Tobacco Free Workplace.

Medical Laboratory Scientist - Blood Bank (2nd Shift/Evenings). LifeSouth Community Blood Centers is looking for an experienced Medical Laboratory Scientist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Atlanta, GA. The position is responsible for following established policies and procedures, identifying problems that may adversely affect test performance or reporting of test results, and either correct the problems or immediately notify a supervisor, manager, or director. The Medical Laboratory Scientist will resolve complex immunohematology and compatibility problems to provide the safest donor blood for the patients in our community. We focus on providing the best possible customer service. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Assistant/Associate/Full Professor, Clinical Track (Hoxworth Blood Center). Hoxworth Blood Center (HBC) was founded in 1938 and serves more than 30 hospitals in 18 counties in Ohio, Kentucky, and Indiana. Annually, HBC collects more than 100,000 units of blood from local donors to help save the lives of patients in area hospitals. HBC is located within the University of Cincinnati (UC), College of Medicine, and is seeking an academic physician to advance clinical services and research in Blood Banking and Transfusion Medicine. The rank of the clinical track appointment is open and will be commensurate with the experience and professional accomplishments of the selected applicant. Essential Functions: Provide clinical blood banking/transfusion medicine coverage in an active academic transfusion service supporting a robust academic teaching hospital

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POSITIONS (continued from page 11)

specializing in hematology/oncology, high risk obstetrics, organ transplantation and surgery; including a Level I Trauma Center. Provide medical coverage for a large regional independent blood collection center with an active apheresis program supporting cell therapy collections. Engage in the training of Transfusion Medicine fellows, pathology residents, and rotating fellows, residents, and medical students. Minimum Requirements: MD or MD/PhD; Board eligibility or Board certification in Blood Banking/Transfusion Medicine; and active or eligible for a State of Ohio Medical License. Click here to view the full job description and apply. EOE

Vice President, Corporate Medical Director. At Vitalant, our mission is to transform lives and strengthen communities through the gift of blood. We are seeking a Vice President, Corporate Medical Director to play a vital role in advancing this mission. In this leadership position, you will be the primary resource for regional and corporate physicians and Vitalant personnel, providing medical expertise and guidance on donor suitability, blood product preparation, and ensuring the safety of both donors and recipients. Additionally, you will oversee the operational functions of our central office Medical Affairs Department, driving excellence and innovation in support of our life-saving work. As VP, Corporate Medical Director, you'll get to: Lead and develop your team by hiring, training, supervising, and evaluating personnel, fostering a collaborative and high-performing work environment. Shape strategic planning and manage budgets. Oversee key Medical Affairs functions, including donor counseling and transfusion-related investigations. Serve as a medical advisor to field directors, hospitals, donors, and patients. Collaborate on donor medical policy development and implementation. Improve technologies, policies, and blood center services. Direct operations in Manufacturing, Training, Quality Management, and Regulatory Affairs. Publish research, represent Vitalant in professional organizations, and maintain industry connections to advance innovation. Please click here to view the full job description and apply.

Donor Recruitment Field Training Specialist (Oklahoma, Texas, or Arkansas). Our Blood Institute is looking for a **FIELD TRAINING SPECIALIST** who will be a key member of our Donor Recruitment team, helping to identify skill gaps and develop training paths to fill those gaps. The trainer must be both data and metrics driven, as well as hands-on with excellent communication and donor development skills. Working with our Donor Recruitment Management Team, the Field Training Specialist will oversee sales calls, including prospects and existing donor groups, and work with individual Recruitment team members to develop their skills to achieve their goals and targets. The role will also act as an advocate to promote the voice of Drive Champions (DC) and ensure DC effectiveness by coaching account consultants on DC engagement strategies. A successful candidate must have 3 years' experience in sales and/or training. This position requires 60 percent travel across Oklahoma, Texas, and Arkansas. Must be 21 years of age or older with clean MVR. Salary Range: Competitive salary with excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off and holiday https://obi.org/about/careers/.

Associate Medical Director (Oklahoma City, OK). Our Blood Institute (OBI) seeks an Associate Medical Director for its Oklahoma City headquarters location. The Associate Medical Director is a licensed physician with shared responsibility for the medical, technical, and clinical leadership and direction of OBI's operations. This position will help direct and supervise key staff and processes to ensure the safety and well-being of all blood donors, the quality of all blood products manufactured, and the provision of premier laboratory and patient services. Ample complex medical care and professional growth opportunities arise from our Therapeutic Apheresis, AABB accredited IRL, and FACT accredited cell therapy operations. Numerous clinical research, public health, and product development initiatives can inspire projects ranging from community health surveillance to entrepreneurial start-ups. Empowering resources including clean rooms, a high-volume donor testing laboratory, and sizable software engineering skunkworks. OBI has a variety of outstanding opportunities to propel your career in a nimble, supportive, and friendly environment. Management experience and business skill acquisition is guaranteed in a complex, 1100-employee non-profit organization. Salary Range: Competitive salary with excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. How to apply: https://obi.org/about/careers/