

A B C N E W S L E T T E R

URRENT EVENTS AND TRENDS IN BLOOD SERVICES

Visit ABC's Web site at: www.americasblood.org

2025 #1

January 13, 2025

Happy National Blood Donor Month! ABC and ADRP have provided resources to amplify your local efforts to celebrate and thank blood donors throughout January at: www.BloodDonorMonth.org.

First Executive Fellows Program Cohort Announced

America's Blood Centers (ABC) recently <u>announced</u> the first <u>cohort</u> of the <u>Execu-</u> <u>tive Fellows Program</u> (EFP). The participants will officially kick off the 2025-26 EFP in March during the ABC Annual Meeting and include:

- Heath Alls, Client Relations Manager, Carter BloodCare;
- JB Bowles, Senior Vice President of Business Development, OneBlood;
- Carlos Cockerham, Senior Director of Information Technology, LifeShare Blood Center;
- Stacey Connell, Senior Director of Human Resources, Community Blood Center of the Ozarks;
- Joy Duemke, Director of Marketing, North America, Terumo BCT;
- Darryl Elzie, Regulatory Affairs Manager, Inova Blood Donor Services;
- Amber Fuller, Senior Director of Technical Services, The Blood Connection;
- Dan Galasso, Chief Financial Officer, LifeSouth Community Blood Centers;
- Ruchika Goel, MD MPH, Senior Corporate Medical Director, Vitalant National Office;
- Shelley Harkey, Clinical Services and Research Manager, SunCoast Blood Centers;
- Mahtab Khan, Vice President of Finance and Procurement, New York Blood Center Enterprises;
- Kymberlie Kraemer, Manager of Manufacturing Operations and Product Management, The Community Blood Center;
- Jessica Lantz, Director of Quality Assurance and Regulatory Affairs, Bloodworks Northwest;
- Jennifer Lindburg, RN, Vice President, Quality Support Services, Impact-Life;
- Cliff Numark, Chief of Marketing, Vitalant;
- Theresa Pina, Vice President of Operations, Gulf Coast Regional Blood Center;
- Beau Robertson, Director of Blood Center Services, Cerus;
- Bob Scanlon, CEO, Blood Bank of Alaska;
- Grace Sese, MD, Medical Director, Inova Blood Donor Services and Medical Director, Inova Apheresis Services;

INSIDE:

CRED Dublishos 2025

Guidance Agenda2
REGULATORY NEWS3
WORD IN WASHINGTON
4
MEMBER NEWS5
DEADLINE EXTENSION: Join an ABC Committee for FY 2026 & 20276
Executive Compensation Report Available6
2025 ABC Annual Meeting Registration Is Open6
ABC Talking Points Released on DEHP and Blood Bags7
2025 ADRP Annual Conference Early Bird Registration & Call for Abstracts Are Open7
Register for the ABC & ADRP Webinar: "Gratitude in Action: Celebrating Blood Donors and Developing Strategic Partnerships".7
RESEARCH IN BRIEF7
GLOBAL NEWS8
COMPANY NEWS9
CALENDAR9
POSITIONS11



First Executive Fellows Program Cohort Announced (continued from page 1)

- Andrea Sign, Director of Marketing, Communications and Donor Relations, Carter BloodCare;
- Robert Simpson, Vice President of Hospital Services, San Diego Blood Bank;
- Floyd Wilson, Vice President of Biologics Operations, OneBlood; and
- Kate Witthaus, CEO, Northern California Blood Bank.

ABC congratulates all members of the inaugural cohort! The EFP is a groundbreaking new initiative that offers industry-specific, best-in-class leadership training to blood community executives, elevating individuals, organizations, and the nation's blood supply. Through the EFP, individuals will be uniquely equipped with the business acumen and executive skill set needed to succeed in the blood community's ever-evolving environment. The EFP features a week-long Leadership Residency at Vanderbilt each fall, three additional in-person learning immersions throughout the year, virtual seminars taught by Vanderbilt faculty, a 360leadership assessment, individual executive coaching, a capstone project, and more.

CBER Publishes 2025 Guidance Agenda

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) has <u>published</u> its guidance agenda for 2025. The agenda outlines the guidance and draft guidance documents that CBER "is considering for development" throughout the calendar year. Topics of note that the agency will look to address include:

- "Considerations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method; Guidance for Industry;
- Collection of Platelets by Automated Methods; Draft Guidance for Industry;
- Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; Draft Guidance for Industry;
- Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Draft Guidance for Industry; [and]
- Recommendations for the Evaluation of Blood Collection, Processing, and Storage Devices Using Non-Di(2-ethylhexyl) Phthalate (non-DEHP) Materials: Draft Guidance for Industry."

Topics categorized as therapeutic products that may be of interest include:

(continued on page 3)

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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. **America's Blood Centers**

Chief Executive Officer: Kate Fry Chief Medical Officer: Jed Gorlin Editor: Mack Benton Subscriptions Manager: Leslie Maundy Annual Subscription Rate: \$420

Send subscription queries to <u>memberservices@americasblood.org</u> America's Blood Centers 1717 K St. NW, Suite 900, Washington, DC 20006 Phone: (202) 393-5725 Send news tips to <u>newsletter@americasblood.org</u>. CBER Publishes 2025 Guidance Agenda (continued from page 2)

- "Frequently Asked Questions Cell and Gene Therapy Products; Guidance for Industry;
- Safety Testing of Human Allogeneic Cells Expanded for Use in Cell-Based Medical Products; Guidance for Industry;
- Post Approval Methods to Capture Safety and Efficacy Data for Cell and Gene Therapy Products; Draft Guidance for Industry;
- Recommendations to Reduce the Risk of Transmission of *Mycobacterium tuberculosis* by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Guidance for Industry;
- Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Guidance for Industry;
- Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry;
- Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry;
- Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry; [and]
- Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry."

America's Blood Centers (ABC) will continue to provide updates to member blood centers on its advocacy efforts regarding the CBER guidance agenda as they become available.

(Source: FDA <u>Announcement</u>, 1/3/25) ♦

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) has <u>announced</u> a February 25th webinar from 2-3 p.m. EST on the "Investigational Use Requirements for *In Vitro* Diagnostic Products (IVDs), including Laboratory Developed Tests (LDTs) Under 21 CFR 812." Registration is not required and interested individuals can join the virtual event via this link. The purpose of this webinar is to, "provide information on investigational use requirements for *in vitro* diagnostic products (IVDs), including laboratory developed tests (LDTs). This webinar will describe the Investigational Device Exemptions (IDE) Regulation (21 CFR Part 812) and the regulatory requirements it contains for the study of investigational devices, and FDA's typical review process for an IDE application."

(Source: FDA Announcement, 1/8/25)

The FDA has recently published four Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) draft guidances that apply to human cells and tissues recovered on or after May 25, 2005. The draft guidances include:

(continued on page 4)



-3-

<u>REGULATORY NEWS</u> (continued from page 3)

- "Recommendations for Determining Eligibility of Donors of HCT/Ps;
- Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by HCT/Ps;
- Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by HCT/Ps; [and]
- <u>Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by</u> <u>HCT/Ps</u>."

The agency also published two final guidances:

- "Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by <u>HCT/Ps;</u> [and]
- <u>Recommendations to Reduce the Risk of Transmission of Mycobacterium tuberculosis (Mtb) by</u> <u>HCT/Ps</u>."

ABC is reviewing the draft and final guidance documents and intends to submit comments by the February 6th deadlines. ABC members are encouraged to provide <u>feedback</u> to ABC Director, Regulatory Affairs and Public Policy Justine Coffey, JD, LLM by January 15th.

WORD IN WASHINGTON

The National Heart, Lung, and Blood Institute's (NHLBI) Blood Diseases & Disorders Education Program (BDDEP) is set to launch, "the 2025-2026 Community Subcontract Program." According to the announcement, "[w]ith awards up to \$50,000 each for up to three organizations, this program will support initiatives that increase awareness of the importance of blood donor diversity and that increase blood donation among Black or African American communities." NHLBI further explained that the 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."

The request for proposals will be issued on January 17th with submissions due by February 21st at 3 p.m. EST.

(Source: NHLBI <u>Announcement</u>, 1/6/25)

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER), Office of Therapeutic Products (OTP) is holding a virtual public workshop on February 25th titled, "Cell Therapies and Tissue-Based Products: A Public Workshop on Generating Scientific Evidence to Facilitate Development." Registration is open and this virtual event will take place from 8:30 a.m.-5 p.m. EST. The agency is, "convening this public workshop with relevant stakeholders to discuss best practices on generating scientific data necessary to further facilitate the development of stem cell and other cellular therapies."

(Source: FDA <u>Announcement</u>, 12/18/24)

(continued on page 5)

WORD IN WASHINGTON (continued from page 4)

The FDA's CBER, OTP is <u>hosting</u> a webinar on January 30th from 1-2 p.m. EST titled "RegenMedEd Roundtable with FDA's OTP." <u>Registration</u> is open and the webinar will feature, "OTP's Super Office Director, Dr. Nicole Verdun, and other leaders across OTP "[s]har[ing] how the office has enhanced its capabilities to address the exponential growth in the cell and gene therapy space; [p]rovid[ing] an update on OTP's goals, priorities, and activities for 2025; [e]ngag[ing] directly with patients, caregivers, and members of the patient community to provide information about OTP's patient engagement and outreach efforts."

(Source: FDA <u>Announcement</u>, 12/20/24)

MEMBER NEWS

The Blood Emergency Readiness Corps (BERC) <u>announced</u> an activation earlier this month, "in response to the attack [in] New Orleans, La. that took place during the early morning hours of New Year's Day. The BERC activation [provided] blood components needed to replenish the region's blood supply in the immediate aftermath of the attack." According to a BERC news release, "[b]lood components shipped to New Orleans have helped supplement the local supply maintained by **The Blood Center** (New Orleans, La.). These shipments have helped ensure blood components are available for ongoing patient care in the region." The Blood Center also, "opened its doors on New Year's Day to address the critical blood supply needs following [the] mass casualty event that killed at least 15 people and injured at least 35 others," according to *The Times-Picayune*. "Obviously, this is a mass casualty event, and we are reaching out to organizations throughout the country to help, but it really is going to be our local community that's going to make a big difference," explained Paul Adams, manager of Public Relations at The Blood Center, to the publication. The following ABC members were "on call to ship blood components in the BERC activation:

- Blood Bank of Hawaii;
- Houchin Community Blood Bank;
- ImpactLife;
- Inova Blood Donor Services;
- LifeStream Blood Bank;
- Mississippi Blood Services;
- Northern California Community Blood Bank;
- South Texas Blood & Tissue;
- Stanford Blood Center;
- Vitalant; and
- We Are Blood."

(Sources: BERC <u>News Release</u>, 1/7/25; *The Times-Picayune*, "<u>Blood donations needed after Bourbon</u> <u>Street attack in New Orleans, facilities say</u>," 1/1/25)

San Diego Blood Bank has begun <u>celebrating</u> its 75th anniversary this month with the opening of a new location in the Clairemont Mesa neighborhood. This is the blood bank's 10th donor center according to the *Times of San Diego*. Douglas Morton, chief executive officer of the blood bank, added, "[w]e are a home-grown community nonprofit, founded 75 years ago on the need for San Diego to have a central organization that would collect and supply blood for hospitals locally. The official opening of our new permanent Clairemont Mesa location expands our reach to diverse residents of various ethnic backgrounds, enabling improved blood matches for patients in San Diego and in Southern California. We're fulfilling our vision of making blood donation accessible to everyone in San Diego. You can now find a San Diego Blood Bank blood donation center anywhere in San Diego within a 10-minute drive."

(Source: *Time of San Diego*, "<u>SD Blood Bank begins 75th anniversary celebration with opening of new</u> <u>donation location</u>, 1/3/25) ♦





ABC Newsletter

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

DEADLINE EXTENSION: Join an ABC Committee for FY 2026 & 2027

America's Blood Centers (ABC) has extended the deadline for the call for Fiscal Years 2026 & 2027 ABC Committee Nominations to Wednesday, January 15th. We invite individuals to submit your interest by completing <u>this form</u>. ABC and its <u>Board of Directors</u> depend on committee volunteers from member blood centers to guide and accomplish the work of the <u>ABC Strategic Plan</u>. Committee terms are for two years, starting April 1st, 2025. Please review the listing of committees and <u>their descriptions</u> to determine interest in serving on a particular committee. Selection notifications will be sent out in early March. Please contact <u>ABC Member Services</u> with questions.

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 <u>purchase</u> 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 <u>contact us</u> with questions.

2025 ABC Annual Meeting Registration Is Open

America's Blood Centers has launched <u>registration</u> for the <u>2025 Annual Meeting</u>. Join us in Arlington, Va., March 10th-12th, as we address 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. <u>Book your rooms</u> by Friday, February 14th to secure the hotel group rate. While the full agenda will soon be released, an overview of the schedule is available:

- Sunday, March 9 Committee and Council meetings;
- Monday, March 10 General sessions, featuring speakers from *POLITICO*, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and more. The day concludes with the Celso Bianco Lecture;
- **Tuesday, March 11** ABC Members Meeting and concurrent breakout sessions. Session topics will focus on artificial intelligence, disaster planning, donor deferrals, pre-hospital blood, new and emerging technologies, stakeholder engagement, workforce trends, and more. The day will culminate with the *Awards of Excellence* on Capitol Hill where we will honor this year's recipients alongside meeting attendees, members of Congress and their staff, and our federal agency partners;
- Wednesday, March 12 Meetings with the Council of States, <u>Executive Fellows Program</u>, and the Blood Centers of America (BCA) Medical Directors Workshop.

<u>Sponsorship opportunities</u> are also available. Please <u>contact us</u> with any questions as we look forward to seeing you!

(continued on page 7)



-6-

INSIDE ABC (continued from page 6)

ABC Talking Points Released on DEHP and Blood Bags

ABC has updated our <u>talking points</u> 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 <u>here</u>.

2025 ADRP Annual Conference Early Bird Registration & Call for Abstracts Are Open

<u>Register now</u> for the 2025 ADRP Annual Conference in Oklahoma City, Oklahoma, from May 6th to 8th at the Omni Oklahoma City Hotel. Secure early bird rates by registering before January 17th and 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, exploring an expansive exhibit hall filled with innovative solutions. <u>Seize this extraordinary opportunity</u> to learn, share, and grow within the blood community.

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 <u>January webinar</u> titled "Gratitude in Action: Celebrating Blood Donors and Developing Strategic Partnerships." <u>Registration</u> 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.

RESEARCH IN BRIEF

The Relationship Between Blood Tests and Vasovagal Reactions. Authors of a paper in Vox Sanguinis explained that, "[b]ecause dehydration increases the likelihood of vasovagal reactions (VVR)," their study , "examined whether elevated levels of hemoglobin (Hb), hematocrit (Ht), total protein (TP), and albumin (Alb), which are markers of h[e]moconcentration and are considered surrogate markers for dehydration, are associated with an increased likelihood of VVRs." The researchers noted that, "It he Japanese Red Cross Fukuoka Blood Cent[er] received 847,813 whole blood donations, including 847,614 donations of 400 mL and 199 donations of 200 mL, between April 1st, 2016, and December 2021." Of those, a "total of 7,080 donations [from] 1,873 eligible donors who donated multiple times with and without a VVR were analy[z]ed." The authors observed that, "[t]he mean and median age of the donors were 30.1 and 25 years, respectively. A total of 250 first-time donors experienced a VVR (13.3 percent). The mean and median number of donations per donor during the study period were 3.8 and 3.0, respectively, with the highest number of donations from a single donor being 17...The <29 years age group had the highest number of donations. The mean values of pulse rate were higher in VVR donations than in non-VVR donations, whereas the opposite was observed for systolic blood pressure and diastolic blood pressure. The study found that, "Hb, Ht, TP and Alb concentrations prior to donation were higher in VVR donations than in non-VVR donations for each age group and sex. Specifically, Hb values were approximately 0.1–0.3 g/dL higher in VVR donations relative to non-VVR donations." "In addition, the difference in Hb and Ht values between VVR and non-VVR donations was largest in the >50 years group for both men and women. Statistically

<u>RESEARCH IN BRIEF</u> (continued from page 7)

significant positive associations between Hb, Ht, TP, Alb and VVR were observed in all combinations of age groups and sex." The authors noted that, "[t]he OR of Hb (per 0.5 g/dL) was the highest in women aged \geq 50 years (OR [95 percent CI]: 1.844 [1.457, 2.333]), and there was a significant interaction between age group and Hb value (p value= 0.036) in women." The authors concluded that in, "practice, at the donation site, comparing the predonation Hb value to that of the past values for the same donor would help raise awareness of the risk of VVR."

Citation: Chijiiwa, T., Hirata, A., Okui, T., Iwasaki, J., Nakashima ,N., Kumagawa, M. "<u>The relationship</u> between blood test results and vasovagal reactions: An intra-individual comparative retrospective analysis of blood donor data in Japan." *Vox Sanguinis*. 2025.

Contributed by Richard Gammon, MD 🍐

GLOBAL NEWS

RedC Biotech, an Israeli startup, <u>announced</u> the development of, "a technology that could revolutionize blood supply by producing high-quality, safe, and cost-effective red blood cells (RBCs) on a mass scale using stem cell technology," according to *Y Net News***. The report explained that the company's product, "involves manufacturing RBCs from stem cells in a lab. [It] uses specialized stem cells. Stem cells are remarkable — they can divide indefinitely and transform into any type of cell the body needs. By replicating the body's natural processes, particularly in bone marrow, [the company] guide[s] these cells to develop into red blood cells. It's similar to growing lab-based meat, where stem cells or fibroblasts are turned into muscle, fat, and connective tissue. We do the same thing but produce RBCs." The startup aims to, "create universal RBCs that are compatible with any recipient without testing, free from contaminants or risky donor-derived residues. RedC Biotech's ambitious vision is to address the global blood shortage crisis within the next five years."**

(Source: *Y Net News*, "Israeli startup creates lab-grown blood cells without donors in major breakthrough," 12/25/24)

Q News recently reported that Just.Equal Australia Inc.'s "Let Us Give" campaign continues to encourage Australia's national blood provider (Australian Red Cross Lifeblood) and the country's regulators to revise blood donation policies for sexually active gay and bisexual men and transgender women who are deferred for 3 months. The news organization attributed a statement from a spokesperson from the campaign who explained that a policy shift could help eliminate blood shortages in Australia, "[w]e estimate there would be over 12,000 new donors and over 50,000 new donations per year, if the current ban was lifted. We want Australia to adopt the same donor policy as the United Kingdom, U.S., and Canada where all donors, gay and straight, are screened for the safety of their sexual activity, not the gender of their sexual partner. [While] we welcome Lifeblood's in-principle support for this reform in Australia, change is taking too long and, as a result, lives are being put at risk." Lifeblood previously announced, "[i]n December 2023 [that] it supports lifting the current ban. It has since applied to the Therapeutic Goods Administration (the country's regulatory authority) for permission. [There] is no indication how long this will take or when [sexually active] gay men, and bisexual men and transgender women, will be able to donate under the same conditions as everyone else," reported *Q News*.

(Source: *Q News*, "Let Us Give Campaign: 'Lifting gay blood ban will save lives,'" 1/8/25)



COMPANY NEWS

Vascarta Inc. recently <u>announced</u> findings from a study <u>published</u> in *Scientific Reports* which found that red blood cell storage lesions, "can be mitigated by adding a highly concentrated biocompatible curcumin gel developed [by the company] for transdermal treatment of inflammation and oxidative stress." According to the Vascarta news release, the study's findings demonstrated that the, "addition of a single dose of Vascarta transdermal curcumin gel ("VAS-101 or Vasceptor®") to stored red blood cells reduces oxidative damage by about 50 percent and increases ATP by about 40 percent. ATP is crucial in allowing red blood cells to contribute to vascular homeostasis. Treating human red blood cells with VAS-101 increased viable red cell refrigerated storage time by one week." The company further explained that the research was conducted by scientists at the U.S. Food and Drug Administration's Laboratory of Biochemistry and Vascular Biology at the Center for Biologics Evaluation and Research, along with colleagues from the University of California San Diego and Albert Einstein College of Medicine." Richard Prince, MD, chief executive officer at Vascarta Inc., added in the news release, "[t]he benefits shown by Vasceptor® in improving the health of red cells led us to prioritize human clinical testing of Vasceptor® in sickle cell disease, which will begin in early 2025."

(Source: Vascarta Inc. <u>News Release</u>, 1/7/25)

Beam Therapeutics recently shared new data from an ongoing trial of its investigational genetically modified cell therapy to treat severe sickle cell disease (SCD). According to the company, "more than 35 patients have cleared screening and enrolled in the BEACON [p]hase I/II clinical trial, and of these, 11 patients have been dosed with BEAM-101. As of an October 2024 data cut-off, a total of seven patients with severe SCD were treated with BEAM-101 and included in the safety and efficacy analysis with followup ranging from 1 to 11 months. All patients achieved endogenous hemoglobin F (HbF) levels exceeding 60 percent and reduction in corresponding sickle hemoglobin (HbS) below 40 percent that was durable. A pancellular distribution of HbF was observed after the elimination of transfused blood. Total hemoglobin levels increased rapidly with resolution of anemia in patients after elimination of the transfused blood. All patients achieved the minimum target cell dose in either 1 or 2 cycles of mobilization (average: 1.4). The mean time to neutrophil engraftment was 17.1 days (range: 15-21), with a low mean duration of neutropenia (6.3 days). The mean time to platelet engraftment was 19.1 days (range: 11–34). Key markers of hemolysis, including indirect bilirubin, haptoglobin, lactate dehydrogenase and reticulocytes, normalized or improved in all patients following BEAM-101 treatment. The safety profile of BEAM-101 was consistent with busulfan conditioning and autologous hematopoietic stem cell transplantation (HSCT). The most common treatment-emergent adverse events (TEAEs) were consistent with busulfan conditioning, including febrile neutropenia, stomatitis, and anemia. One patient died four months after BEAM-101 infusion due to respiratory failure that was determined by the investigator to be likely related to busulfan conditioning and deemed unrelated to BEAM-101. No VOCs were reported post-engraftment."

(Source: Beam Therapeutics <u>News Release</u>, 12/7/24) ♦

CALENDAR

Note to subscribers: Submissions for a free listing in this calendar (published weekly) are welcome. Send information to <u>newsletter@americasblood.org</u>. (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. <u>Registration</u> is open. More information available <u>here</u>. <u>CALENDAR</u> (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). <u>Registration</u> is open. More information available <u>here</u>.

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. <u>Registration</u> is open. More information available <u>here</u>.

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). <u>Registration</u> is open. More information available <u>here</u>.

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). <u>Registration</u> is open. More information available <u>here</u>.

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. <u>Registration</u> is open. More information available <u>here</u>.

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. <u>Registration</u> is open. More information available <u>here</u>.

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. <u>Registration</u> is open. More information available <u>here</u>.

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 nonprofit 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 <u>here</u> 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/