

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

2024 #43

December 20, 2024

Please Note: The *ABC Newsletter* will not be published on Dec. 27th and Jan. 3rd. We will resume regular publication on Monday, Jan13th. Thank you for your continued interest.



ABC Submits Buffy Coat Method Comments to FDA

America's Blood Centers (ABC) has submitted comments to the U.S. Food and Drug Administration (FDA) in response to the agency's October 2024 <u>draft guidance</u> titled, "Recommendations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method."

In the December 13th comments, ABC urged the need for, "feasible solutions to the implementation of the Buffy Coat Method (BC)," while raising concerns regarding, "significant operational issues [that] would impair implementation of the BC in the U.S. under the proposed draft guidance.

ABC recommended that the FDA:

- "adopt alternate acceptance criteria for red blood cell components to accommodate outlier events; [and]
- approve holding whole blood for 24 hours at room temperature."

Additionally, the comments noted that FDA should be aware that, "at this time, manufacturers are unlikely to seek to obtain FDA approval or clearance to market blood collection, processing, and storage systems intended for the manufacture of blood components for transfusion using the BC method, until they have implemented the European Union's ban on di(2-ethylhexyl) phthalate (DEHP) in medical devices, <u>effective in 2030</u>.

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ABC Buffy Coat Method Comments to FDA (continued from page 1)

ABC expressed its appreciation that FDA, "is requiring manufacturers to 'conduct appropriate clinical studies or submit existing clinical data to demonstrate the safety and efficacy of blood components prepared using the BC method.' FDA's acceptance of international data for use in the approval of new products or technologies reduces unnecessary and burdensome regulation to support innovation and blood product availability."

The full comments are <u>available</u> on the ABC website.

(Source: ABC <u>Comments</u>, 12/13/24) •

ABC Comments to AHRQ Regarding Prehospital EMS Blood Transfusion and Fluid Interventions for Hemorrhagic Shock

America's Blood Centers (ABC) has responded to the Agency for Healthcare Research and Quality's (AHRQ) November 26th request for "Supplemental Evidence and Data Submission on Prehospital EMS Blood Transfusion and Fluid Interventions for Hemorrhagic Shock." In the comments to AHRQ, ABC highlighted the important role that its member blood centers play in prehospital blood transfusion programs nationwide and described impediments to implementing and maintaining such programs.

Specifically, the comments included aggregate survey data from ABC members regarding prehospital blood transfusion programs from 2022 to 2024 that demonstrated the impact of community blood centers to prehospital blood transfusion programs. Of note, ABC member blood centers have increased their participation in prehospital blood transfusion programs from 18 in 2022 to 34 member blood centers in 2024. The total number of reported blood products distributed via these programs also increased from 14,882 units in 2023 to 32,202 units in 2024 with low titer group O whole blood (LTOWB) making up 13,452 units in 2024 versus 5,015 in 2023.

ABC explained in the comments that, [t]he most consistent barrier for ABC member blood centers regarding prehospital blood transfusion programs, "is [a] lack of funding [with] operational costs at blood centers already [being] strained. [While additional barriers] that contribute to the reluctance by blood centers to implement a prehospital blood program are the risk of product wastage and the logistical burdens of rotating product between locations to prevent wastage."

The comments noted more, "clarification is needed on the definition of group O whole blood" including:

- leukoreduced vs. non-leukoreduced;
- cutoff values for low titer;
- age of units; [and]
- Rh (D) positive vs. Rh (D) negative.

ABC also recommended in the comments that, "a revision of the bag system to use an anticoagulant that would allow storage longer than 21 days that would preserve function of both red blood cells and platelets is worth further study, especially as new di(2-ethylhexyl) phthalate (DEHP) free bag systems are developed."

The full comments are <u>available</u> on the ABC website. Ensuring blood transfusions are available to all patients when and where they need blood is a top priority in ABC's <u>Advocacy Agenda</u>. ABC will continue to provide updates on its advocacy efforts as they become available.

(Source: AHRQ <u>Comments</u>, 12/13/24) •



Blood Community Thanks Donors Ahead of National Blood Donor Month

America's Blood Centers (ABC), the Association for the Advancement of Blood & Biotherapies (AABB), and the American Red Cross have issued a joint <u>news release</u> as National Blood Donor Month (NBDM) approaches in January. The news release thanks blood donors and also encourages eligible individuals to schedule appointments to donate blood, "[t]his [NBDM], we honor the exceptional generosity of the nearly 7 million individuals across the nation who selflessly donate blood each year," stated ABC Chief Executive Officer Kate Fry, MBA, CAE in the news release. "That simple yet powerful decision is a lifeline for those facing a health crisis or requiring a transfusion for disease management. We encourage all eligible individuals to make a life-saving impact in their community."

Resources that can be used to recognize NBDM are available from ABC and ADRP at <u>www.BloodDonor-Month.org</u>.

(Source: Blood Community <u>News Release</u>, 12/18/24) •

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) has published a communication titled, "Update to Important Information about Young Donor Plasma Infusions Offered for Profit." The agency warns that, "establishments have continued to market "young plasma" for a variety of medical conditions. We are not aware of evidence that demonstrates any clinical benefit of the infusion of plasma from young donors in the prevention of conditions such as aging or memory loss, or for the treatment of such conditions as dementia, Parkinson's disease, multiple sclerosis, Alzheimer's disease, heart disease, or post-traumatic stress disorder. Some establishments claim to be registered with FDA and have studies of "young plasma" for these types of medical conditions listed on the clinicaltrials.gov database. The inclusion of a study of "young plasma" for certain uses in the clinicaltrials.gov database or the fact that an establishment has registered with FDA does not mean that "young plasma" is approved by FDA for such uses, or that the establishment has met applicable statutory or regulatory requirements for conducting research involving human subjects." The FDA also noted that, "[i]n patients with one or more of the indications for administration of plasma listed in the FDA-recognized *Circular of Information*, the benefits of treatment with plasma outweigh its risks... The Circular of Information describes risks of plasma transfusion such as transmission of infectious disease, allergic reactions, and respiratory complications. The administration of plasma collected exclusively from young donors for indications other than those listed in the FDArecognized Circular of Information must be performed by a qualified investigator or sponsor who has an active Investigational New Drug application (IND) with the FDA."

(Source: FDA <u>Communication</u>, 12/6/24) •

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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

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WORD IN WASHINGTON

David Goff Jr., MD, PhD has been <u>named</u> deputy director for Precision Medicine and Data Science at the National Institutes of Health (NIH) National Heart, Lung, and Blood Institute (NHLBI) as of December 16th. According to an agency announcement, in this role, Dr. Goff will, "lead efforts to harness cutting-edge data science approaches to strategically drive and accelerate advancements in personalizing the prevention, detection, and treatment of heart, lung, blood, and sleep conditions. This new position will be located within the Office of the Director as part of strategic initiatives to advance data science and precision medicine research. Dr. Goff will work with a forthcoming senior advisor for data science, appointed in 2025, to lead, plan, and implement these initi-



atives and to modernize NHLBI's data resource ecosystem. He will also oversee NHLBI's BioData Catalyst and Trans-Omics for Precision Medicine (TOPMed) programs." Dr. Goff previously, "served as Director of the Division of Cardiovascular Sciences (DCVS) since 2016."

(Source: NHLBI Announcement, 12/16/24)

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER), Office of Therapeutic Products (OTP) will hold a virtual scientific public workshop on February 25th titled "Cell Therapies and Tissue-Based Products: A Public Workshop on Generating Scientific Evidence to Facilitate Development." This virtual event will take place via Zoom from 8:30 a.m. to 5:00 p.m. EST. Registration is open and required. This workshop aims to, "identify and discuss the current state of the science, development, and regulation for cellular therapies and tissue-based products. FDA 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 Announcement, 12/18/24)

The Centers for Medicare & Medicaid Services (CMS) has published national health expenditure (NHE) data for 2023. According to an agency fact sheet, NHEs grew 7.5 percent to \$4.9 trillion in 2023, or \$14,570 per person, and accounted for 17.6 percent of Gross Domestic Product (GDP). Private health insurance spending grew 11.5 percent to \$1,464.6 billion in 2023, or 30 percent of total NHE. Out of pocket spending grew 7.2 percent to \$505.7 billion in 2023, or 10 percent of total NHE. Hospital expenditures grew 10.4 percent to \$1,519.7 billion in 2023, faster than the 3.2 percent growth in 2022. The largest shares of total health spending were sponsored by the federal government (32 percent) and the households (27 percent). The private business share of health spending accounted for 18 percent of total health care spending, state and local governments accounted for 16 percent, and other private revenues accounted for 7 percent." Additionally, CMS is projecting that, "[0]ver 2023-32 average NHE growth (5.6 percent) is projected to outpace that of average GDP growth (4.3 percent), resulting in an increase in the health spending share of GDP from 17.3 percent in 2022 to 19.7 percent in 2032. NHE spending is expected to have grown 7.5 percent in 2023, faster than GDP growth of 6.1 percent. Health price growth remains modest, though faster than pre-pandemic. Over 2027-32, personal health care price inflation and growth in the use of health care services and goods contribute to projected health spending that grows at a faster rate than the rest of the economy."

(Source: CMS <u>NHE Fact Sheet</u>, 12/18/24)



America's Blood Centers^{*} It's About Life. 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.

Join an ABC Committee for FY 2026 & 2027

ABC has opened the call for Fiscal Years 2026 & 2027 ABC Committee Nominations. We invite individuals to submit your interest by completing <u>this form</u> by Wednesday, January 8th. ABC and its <u>Board of</u> <u>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.

28th Annual Awards of Excellence Nominations Deadline Extended

The <u>nomination</u> deadline for the 28th Annual *Awards of Excellence* has been extended until Tuesday, December 31st. Submit a nomination for the following awards:

- ABC Outstanding Blood Drive of the Year;
- Outstanding Public Relations Campaign;
- Corporation of the Year Award;
- Larry Frederick Award;

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- ITxM Award for Excellence in Technical Operations; and
- Thomas F. Zuck Lifetime Achievement Award (A listing of past winners is <u>available</u>.)

This is a chance to honor and recognize supporters of blood donation nationally. More information including <u>descriptions</u> of each award can be found <u>here</u>. Please <u>contact us</u> with any 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 be released in the coming weeks, an overview of the schedule is available:

- Sunday, March 9 Committee and Council meetings. Formal invitations are forthcoming if you have not already received them from ABC committee and council liaisons;
- 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 on the latest developments and research in advocacy, leadership, operations, and science and medicine. 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;

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• 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!

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

<u>Register now</u> for the <u>2025 ADRP Annual Conference</u> 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 <u>book your hotel room</u> 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.

Also, remember to submit an <u>abstract</u> to present your work through abstract lectures, quick hit topics, or posters. ADRP welcomes submissions on:

- collaboration between blood center departments for best outcomes;
- industry innovations;
- donor journey/donor management;
- marketing/public relations strategies;
- staff retention and satisfaction;
- leadership and staff development;
- social media applications in blood centers/TikTok use/social interaction;
- donor recruitment, engagement, and retention;
- collections technical and operational topics;
- social sciences and donor behaviors;
- artificial intelligence; and
- cellular therapies.

The abstract submission deadline is December 31st. Please contact us with any questions.

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INSIDE ABC (continued from page 6)

Call for ADRP Board Nominations Is Open

ADRP, The Association for Blood Donor Professionals invites interested individuals to consider <u>applying</u> to serve on the <u>ADRP Advisory Board</u> for the term beginning in May 2025. This is your chance to amplify your voice and help shape the future of your association! The ADRP Advisory Board is responsible for providing guidance towards, and prioritization of, the <u>strategic direction</u> of the organization and its mission to educate and empower blood banking professionals worldwide who are committed to donor recruitment, donor experience, and donor management. ADRP is looking for individuals that are team-oriented with leadership skills, and technical knowledge and expertise. The application deadline is December 31st. Please <u>contact us</u> with questions.

RESEARCH IN BRIEF

A Study on the Prevalence of Emerging Infectious Diseases in Brazil. A study in Transfusion Medicine "aimed to evaluate blood donations from different Brazilian regions for the presence of three endemic arboviruses by nucleic acid testing (NAT)." The researchers explained that, "[b]lood donations were collected from February 7th to April 4th, 2020, originating from four out of the five Brazilian geographical regions - [a] period [that] corresponds to the end of the summer to fall transition, where historically, the largest number of arbodisease cases take place in the country." The paper noted that, "[o]verall, 21,341 samples, corresponding to 21,341 individual donors, were analy[z]ed. [and an] extra plasma preparation tube was obtained from participating donors for the investigation of arbovirus RNAs." NAT was performed for the detection of chikungunya (CHIKV), dengue (DENV) and zika (ZIKV) virus RNA. The authors wrote that, "[a]ll samples found to be viremic when individually tested were submitted to ancillary molecular assays...All 38 samples that tested positive by NAT (including the 33 (0.15 percent) cases of dengue and 5 cases of zika) were further subjected to serological analysis." The study found that, "[w]hen split by region, the highest prevalence of DENV (0.29 percent) was found among samples from the South...Five samples (0.02 percent) were confirmed CHIKV positive by NAT. Three of them came from donors from the Northeast, representing the region with the highest observed frequency, of 0.12 percent (3/2498)." The researchers noted that, "[n]one of the samples were positive for ZIKV RNA [and the] highest incidence of dengue was verified in the South and Southeast regions whilst chikungunya was more inciden[ce] in the Northeast, thus, mirroring [the] findings among blood donors." The authors explained that, "[i]t is clear that, at the peak, there are many recipients being transfused with viremic units, raising the chance that a rare event, such as symptomatic transfusion-transmitted (TT)-arbodisease takes place." They also noted that, "[f]or both TT-zika and TT-chikungunya, overt clinical impact in recipients is the missing piece of evidence that would fav[o]r the balance to some kind of intervention in endemic regions. Dengue requires a deeper reflection since it is clear that its TT may cause significant morbidity to recipients." They concluded that, "the current study shows that NAT was able to avoid TT of dengue and chikungunya to many patients without delaying or somehow impacting the supply of blood components. Thus, it can be incorporated into regular screening of blood donors when and where decided to be appropriate."

Citation: Langhi D.M., Levi J.E., Sanches S., *et al.* "<u>A prospective, multi-centric study on the prevalence</u> of dengue, zika and chikungunya in asymptomatic blood donors from different geographical regions of <u>Brazil</u>." *Transfusion Medicine*. 2024

Contributed by Richard Gammon, MD 🍐



GLOBAL NEWS

ABC Newsletter

NHS Blood and Transplant (NHSBT), the national blood provider for England and transplant services for the United Kingdom (UK), scientists recently published research in eBioMedicine on their development of, "a way of assessing the ability of red blood cells to deliver oxygen by measuring their shape." In a news release, the organization described, "FlowScore - a formula [created] at Oxford University in collaboration with NHSBT [that] predicts how quickly red blood cells release their oxygen." The organization noted that, "[d]uring routine blood counts, h[e]matology analy[z]ers use flow cytometry — a method that passes cells through a laser beam to study their characteristics. When light hits a cell, the pattern of scattering reveals information about their size and shape. It was found that this information accurately predicts oxygen release from red blood cells, and the predictive formula was called FlowScore. The innovation makes measurements of red cell oxygen transport simpler, faster, and more accessible for laboratories worldwide. Blood banks can now use FlowScore as a quality-control measure during processing and storage. For example, FlowScore was able to quantify the beneficial effects of rejuvenation and detect periods of blood handling outside blood bank-grade conditions. The latter may be critical in monitoring stored blood quality in developing countries with higher ambient temperatures. FlowScore could also provide a way to check the quality of blood for specific vulnerable patient groups, should future research show patient benefit."

(Source: NHSBT News Release, 12/19/24)

Kuwait has <u>implemented</u> a radio frequency identification (RFID) system to improve the precision of tracking blood products from donors to recipients. In an article published by the *Arab Times*, Kuwait's Minister of Health Dr. Ahmad Al-Awadhi explained that the RFID system will, "help reduce human errors in patient identification or blood type mismatches by automating tracking and verification processes, thus enhancing patient safety and the quality of health services." The system upgrades are part of the country's Blood and Transfusion Services Department digital transformation and the Ministry of Health's strategic vision, "to improve the quality of health services and ensure their sustainability, in line with the latest scientific advancements and international standards," according to the news outlet.

(Source: *Arab Times*, "<u>Kuwait's new RFID system improves blood donation efficiency and safety: Official</u>," 12/12/24) ♦

COMPANY NEWS

Incept recently <u>launched</u> an, "Advanced Conversational Artificial Intelligence (AI) Voice Agent" named Betty BloodTM. According to a company news release, the product is designed to, "enhance donor interactions and boost engagement [by] making appointment reminder calls and answering common donor inquiries. Additionally, Betty BloodTM, created in partnership with **Gridspace**, proactively reaches out to potential donors, gauging their willingness to donate and seamlessly transfer[s] interested individuals to a scheduling specialist, creating a streamlined and donor-friendly experience that combines the best in AI technology with seamless human interaction."

(Source: Incept <u>News Release</u>, 12/13/24)

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<u>COMPANY NEWS</u> (continued from page 8)

Vertex Pharmaceuticals Inc. has <u>reported</u> additional longer-term data for its gene therapy (CasgevyTM) to treat individuals with severe sickle cell disease (SCD) or transfusion-dependent beta thalassemia (TDT). In the data released during the American Society of Hematology (ASH) Annual Meeting and Expo, the company noted that:

- "[i]n SCD, 39/42 (93 percent) evaluable patients (those with at least 16 months of follow-up) were free from vaso-occlusive crises (VOCs) for at least 12 consecutive months (VF12) in CLIMB-121 and CLIMB-131 combined. The mean duration of VOC-free was 30.9 months, with a maximum of 59.6 months;
 - [t]he three evaluable patients who have not achieved VF12 have derived meaningful clinical benefit including by reducing their rate of hospitalization for VOCs by 91 percent, 71 percent and 100 percent;
- [i]n TDT, 53/54 (98 percent) evaluable patients (those with at least 16 months of follow-up) achieved transfusion-independence for at least 12 consecutive months with a weighted average hemoglobin of at least 9 g/dL (TI12) in CLIMB-111 and CLIMB-131 combined. The mean duration of transfusion independence was 34.5 months, with a maximum of 64.1 months;
 - \circ [t]he one evaluable patient who has not yet achieved TI12 has been transfusion free for 8.2 months;
- [b]oth SCD and TDT patients reported sustained and clinically meaningful improvements in their quality of life, including physical, emotional, social/family and functional well-being, and overall health status;
- [t]he safety profile of CASGEVY continues to be generally consistent with myeloablative conditioning with busulfan and autologous hematopoietic stem cell transplant; [and]
- [p]atients continue to demonstrate stable levels of fetal hemoglobin (HbF) and allelic editing across all ages and genotypes in the trials."

Additionally, Vertex explained that, "[t]he longest follow-up for both SCD and TDT patients now extends more than 5 years, with a median of 33.2 months and 38.1 months, respectively." The therapy is currently approved for, "both SCD and TDT in the U.S., the European Union, Great Britain, Canada, Switzerland, Bahrain and the Kingdom of Saudi Arabia, and Vertex plans to make submissions in the United Arab Emirates and Kuwait."

(Source: Vertex Pharmaceuticals Inc. News Release, 12/8/24)

Updated long-term data has been <u>shared</u> by **bluebird bio**, **Inc.** during the ASH Annual Meeting and Expo on its gene therapy treatment (LyfgeniaTM) for individuals with SCD who have a history of vaso-occlusive events (VOEs). According to the reported findings, "[a]s of July 2024, 70 patients were treated across the full LyfgeniaTM clinical development program, with follow-up beyond 9 years in the earliest treated patients. [The latest efficacy results] continue to support sustained, transformational impact on VOE burden and hematologic markers of disease...VOEs and severe vaso-occlusive events (sVOEs) were eliminated or significantly reduced in all patients. Specific findings include:

- 36/38 (94.7 percent) of evaluable patients achieved complete resolution of severe VOEs (sVOE-CR) in the 6-18 months post infusion, maintained for a median (min, max) of 42.3 months (12.2, 70.5);
- 33/38 (86.8 percent) of evaluable patients achieved complete resolution of VOEs (VOE-CR), maintained for a median (min, max) of 42.4 (12.2, 70.5) months;
- 10/10 (100 percent) pediatric patients achieved complete resolution of VOEs and sVOEs;

<u>COMPANY NEWS</u> (continued from page 9)

- [t]he safety profile of the LyfgeniaTM treatment regimen was generally consistent with underlying sickle cell disease and the known effects of myeloablative conditioning. There were no cases of graft failure or graft-versus-host disease (GVHD), no vector-related complications, and no insertional on-cogenesis; [and]
- [d]ata from patients with sickle cell disease and a history of overt stroke show no recurrence of stroke following treatment with LyfgeniaTM."

(Source: bluebird bio, Inc. <u>News Release</u>, 12/8/24) ♦

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>.

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. U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (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 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. More information coming soon.

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.

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CALENDAR (continued from page 10)

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 <u>here</u>.

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. More information coming soon.

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

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 <u>https://obi.org/about/careers/</u>.

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,

<u>POSITIONS</u> (continued from page 11)

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: <u>https://obi.org/about/careers/</u>

Vice President, Quality & Regulatory Affairs (VPORA). The Vice President, Quality & Regulatory Affairs (VPQRA) leads the Organization's adherence to regulations and standards established by governing agencies (AABB, FDA, CLIA, State, OSHA, NRC, EU, etc.). Kentucky Blood Center is seeking qualified candidates to fill this key executive leadership role which is responsible for our Quality Assurance (QA) program and regulatory compliance activities. The position has oversight of the QA department and team, and reports to the CEO. Qualifications include MLS/CLS (ASCP) with preference given to candidates with a graduate degree, and blood banking experience. Relocation to the Lexington, Kentucky area required (assistance provided). For more information or to apply, visit https://www.kybloodcenter.org/about-us/careers.

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.



Immunohematology Reference Lab Medical Technologist (2nd Shift/Evenings). LifeSouth Community Blood Centers is looking for an experienced Laboratory Medical Technologist, 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 IRL Medical Technologist will resolve 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 blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Immunohematology Reference Lab Medical Technologist (2nd Shift). LifeSouth Community Blood Centers is looking for an experienced Laboratory Medical Technologist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Jacksonville, FL. 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. This individual 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 blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!