



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2024 #35

October 18, 2024

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FDA Releases Buffy Coat Method Guidance

The U.S. Food and Drug Administration (FDA) has [published](#) a draft guidance on October 17th titled “[Recommendations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method.](#)” The agency explained that the draft guidance is for manufacturers of blood collection, processing, and storage systems. The FDA noted in the draft guidance that, “[b]lood establishments in the U.S. are interested in using the buffy coat (BC) method to manufacture blood components for transfusion. Studies demonstrate that blood components prepared by using the BC method are comparable to blood components prepared using the platelet rich plasma (PRP) method, in terms of biochemical and physiological characteristics. In addition, use of the BC method may offer logistical advantages, which could result in higher plasma and platelet recovery and increased platelet availability, when compared to the PRP method.”

However, blood collection, processing, and storage systems currently marketed in the U.S. are only approved for the preparation of blood components from whole blood using the PRP method, and none are approved or cleared for the preparation of blood components using the BC method.

Recommendations from the FDA regarding the BC method include:

- “manufacturers should contact FDA to clarify the appropriate regulatory pathway for their blood collection, processing, and storage systems;
- when developing collection, processing, and storage systems that include anticoagulant or additive solutions for red blood cells (RBCs) and platelets, manufacturers should consider using solutions already approved by FDA;
- regulatory submissions for blood collection, processing, and storage systems should include:
 - the design of the collection, processing, and storage system;
 - a description of the established methods, facilities, and controls used for the manufacture of the blood collection, processing, and storage system;
 - biocompatibility studies and toxicologic risk assessments;
 - performance data that support sterility of the collection, processing, and storage system including sterilization validation, endotoxin testing, and container closure integrity evaluation;
 - performance data that support maximum shelf life of the collection, processing, and storage system;
 - results of studies evaluating the quality of blood components using the BC method throughout the duration of storage;

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FDA Buffy Coat Guidance (continued from page 1)

- if the collection, processing, and storage system includes a leukocyte reduction filter, you should provide results on the performance of the leukoreduction filter;
- manufacturers should conduct appropriate clinical studies or submit existing clinical data to demonstrate the safety and efficacy of blood components prepared using the BC method;
- FDA recommends manufacturers engage the Center for Biologics Evaluation and Research's (CBER) Office of Blood Research and Review (OBRR) early in product development and before submission of a drug or device application.”

America's Blood Centers (ABC) will submit comments to FDA on the draft guidance and encourages members to provide [feedback](#) to ABC Director of Regulatory Affairs and Public Policy Justine Coffey, JD, LL.M.

(Source: FDA [Draft Guidance](#), 10/17/24) 💧

Lorenzo Rodriguez Joins ABC Team

America's Blood Centers recently welcomed Lorenzo Rodriguez to the advocacy team as manager of Government Affairs. Mr. Rodriguez received his bachelor's degree in political science from Florida International University, and his master's degree in political science from American University. He has previously interned in the office of Rep. Diana DeGette (D-Colo.) and most recently worked as a part of the government affairs team at the Better Medicare Alliance. You can contact Mr. Rodriguez at: lrodriguez@americasblood.org. 💧

WORD IN WASHINGTON

A [report](#) from *Becker's Hospital Review* noted that **15 health systems and hospitals nationwide are delaying elective surgeries in the wake of the intravenous (IV) fluid shortage following an operations disruption due to damage at a Baxter facility in North Carolina in the aftermath of Hurricane Helene.** Baxter provided an [update](#) on the shortage on Thursday, October 17th explaining that U.S. IV solution allocation, “levels remain as previously communicated by Baxter on October 9th, including a 60 percent allocation for our highest demand IV fluids for both direct customers and distributors in the U.S. Customers should note that there is typically a one to two-week lag time for product to flow through the network. Based on the current status of our remediation efforts, our expectations regarding our ability to reallocate capacity from other Baxter facilities, and initiation of temporary importation on certain products, our goal

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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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WORD IN WASHINGTON (continued from page 2)

remains to return to 90 percent to 100 percent allocation of certain IV solution product codes by the end of 2024.” The U.S. Department of Health and Human Services (HHS) previously [announced](#) that the agency has, “invoked the Defense Production Act (DPA) to help Baxter obtain materials needed to clean and rebuild the facility, and the Administration for Strategic Preparedness and Response (ASPR) continues to actively pursue additional opportunities to invoke DPA authorities.”

(Sources: *Becker's Hospital Review*, “[15 systems delaying surgeries amid the IV shortage](#),” 10/17/24; Baxter [Announcement](#), 10/17/24)

The HHS Biomedical Advanced Research and Development Authority (BARDA) [announced](#) that it has awarded a \$32.1 million contract to Cerus Corp., “to advance the development of the INTERCEPT Blood System for red blood cells, based on Cerus’ pathogen reduction technology (PRT).” The agency stated in the announcement that, “[it] will continue to support [Cerus’] clinical studies and development of this next-generation PRT system to enable broad availability and ease of use for U.S. blood centers. PRT of red blood cells is an alternative method that takes a proactive approach to reducing transfusion-transmitted infections (TTI). This technology uses a small molecule to bind to the nucleic acids of contaminating pathogens (e.g., viruses, bacteria, and certain parasites), preventing their replication in donated blood.” BARDA also explained in the announcement that, “PRT has the potential to improve the safety and availability of blood transfusions for day-to-day use, in addition to increasing national emergency preparedness for mass casualty and nuclear incidents. Eventually, PRT could supplement or take the place of donor screening and testing, therefore broadening the potential pool of blood donors. In alignment with BARDA’s strategies to increase availability of agnostic testing and treatments, this technology also has the potential to reduce transmission of unknown emerging pathogens before donor screening tests become available. Importantly, PRT may also be approved for use in pediatrics, a key population to whom BARDA aims to make medical countermeasures available. This award is one component of BARDA’s Chemical, Biological, Radiological, and Nuclear (CBRN) Medical Countermeasures Division portfolio.”

(Source: BARDA [Announcement](#), 10/16/24)

The U.S. Food and Drug Administration has [approved](#), “Hympavzi (marstacimab-hncq) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A without factor VIII inhibitors or hemophilia B without factor IX inhibitors (neutralizing antibodies).” According to an agency news release, “Hympavzi is a new type of drug that, rather than replacing a clotting factor, works by reducing the amount, and therefore, the activity of, the naturally occurring anticoagulation protein called tissue factor pathway inhibitor. This increases the amount of thrombin, an enzyme that is critical in blood clotting, that is generated. This is expected to reduce or prevent the frequency of bleeding episodes. Hympavzi’s approval is based on an open-label, multi-center study in 116 adult and pediatric male patients with either severe hemophilia A or severe hemophilia B, both without inhibitors. For the first six months of this study, patients received treatment with replacement factor either on-demand (33 patients) or prophylactically (83 patients). These patients then received Hympavzi prophylaxis for 12 months. The primary measure of efficacy of Hympavzi was the annualized bleeding rates of treated bleeds. In the patients receiving on-demand factor replacement during the first six months of the study, the estimated annualized bleeding rate was 38 compared to the estimated annualized bleeding rate during treatment with Hympavzi of 3.2, showing that Hympavzi was superior to on-demand factor replacement. In the initial six-month period during which patients received prophylactic factor replacement, the estimated annualized bleeding rate was 7.85 and was 5.08 during the subsequent 12 months on Hympavzi prophylaxis, showing that Hympavzi provided similar bleeding rates.”

(Source: FDA [News Release](#), 10/11/24) 💧



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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.

Registration Remains Open for the ABC WELC Rise & Lead Workshop

[Register](#) for the America's Blood Centers Women's Executive Leadership Community's (WELC) [Rise & Lead Workshop](#). This event will take place November 6th -7th in San Antonio, Texas at the Hyatt Regency Hill Country Resort. The full [agenda](#) is available and features speaker Vicki Guy, a strategist, coach, and facilitator with more than two decades of corporate experience in sales, management and leadership development who partners with corporate and non-profit organizations to optimize their talent and create high performing teams. Take advantage of this exclusive opportunity to boost your leadership journey as this workshop will ignite meaningful conversations and cultivate diverse perspectives. This event goes beyond traditional conferences by encouraging dynamic conversations that spark connections and drive personal and professional growth. At the Rise & Lead Workshop, you will delve into topics that matter, participate in interactive networking sessions, and walk away with tangible, real-life strategies to become a more resilient leader in today's ever-evolving world. Elevate your leadership journey with us!

October Blood Bulletin Available

ABC has published the October 2024 edition of the [Blood Bulletin](#) titled "Futility & Potentially Inappropriate Treatment in Massive Transfusion." This issue was written by Daniela Hermelin, MD, Chief Medical Officer at ImpactLife; Kirsten Alcorn, MD, Co-Chief Medical Officer at Bloodworks Northwest; Richard Gammon, MD, Chief Medical Officer at Carter BloodCare; Kip Kuttner, DO, Vice President and Medical Director at Miller-Keystone Blood Center; Louis Katz, MD, Chief Medical Officer Emeritus at ImpactLife; Nanci Fredrich, RN, BSN, MM, Transfusion Safety Officer, Versiti Blood Center of Wisconsin; Courtney Hopkins, DO, Senior Medical Officer at Vitalant; Timothy Pancioli, DO, Associate Medical Director at Versiti, Kevin Ha, MD, Associate Medical Director at Versiti; and Theresa Nester, MD, Co-Chief Medical Officer at Bloodworks Northwest. ABC thanks the following contributors for their expert guidance and insightful contributions to this [Blood Bulletin](#): Jed Gorlin, MD, MBA, Chief Medical Officer of America's Blood Centers; Walter Dzik, MD, Associate Professor of Pathology, Harvard Medical School; Steven M. Frank, MD, Professor, Anesthesiology/Critical Care Medicine, Johns Hopkins Medical Institutions; Diane Calmus, JD, Vice President of Government Affairs of America's Blood Centers; Joel Wu, JD, MPH, MA, HEC, Clinical Ethics Assistant Professor, Center for Bioethics, University of Minnesota; and Debra DeBruin, PhD, Director, Center for Bioethics, University of Minnesota. [Blood Bulletin](#) is a quarterly publication reviewed and edited by ABC's Scientific, Medical, and Technical (SMT) Publications Committee.

Save the Date: SMT Journal Club on December 2nd

The next ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar will take place on December 2nd from 4-5 p.m. EST. The webinar is free to all ABC members. An email announcement with a registration link and the articles to be reviewed on the webinar will be available soon. A Continuing Medical Education (CME) credit (1.0) is now offered for all ABC SMT Journal Club webinars.

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INSIDE ABC (continued from page 4)

Registration Opens for 2024 ADRP International Showcase

Join ADRP for the [2024 ADRP International Showcase](#) taking place on November 13th from 1-2:30 p.m. EST. [Registration](#) is open. Blood center professionals worldwide are encouraged to take part in this annual event that provides them a forum to share, connect and learn from each other. Topics this year include:

- The “License to Save Lives” campaign, low-budget but highly effective “guerrilla” marketing strategy that resulted in a 20 percent increase in new donors by Eva Petra Gómez Sjunnesson, Head of Communication and Marketing, Blood and Tissue Bank (Catalonia);
- Artificial Intelligence (AI) in blood donation: Implementation of an automated and efficient system to optimize the call of donors in three hospitals in Catalonia. Iris Garcia, PhD, Blood and Tissue Bank (Catalonia);
- Breaking through the white noise: how community leaders can amplify our voice. Chelsey Smith, Director of Public Relations, New York Blood Center Enterprises;
- Using AI to increase efficiency on social media (while staying human and full of empathy)? Yes we can. Patrice Lavoie, Director of Public Relations and Outreach, Hema-Quebec; and
- Plasmattaque: a successful friendly competition between universities. Brigitte Bernier, Senior Advisor, Donor Recruitment, Hema-Quebec.

ADRP October Webinar: Recruit, Retain, & Realize the Impact

Join ADRP on Wednesday, October 23rd at 1 p.m. EDT for the [ADRP “Recruit, Retain, & Realize the Impact”](#) webinar. [Registration](#) is open as this event will include a discussion of targeted tactics recently used in the blood community to recruit and retain donors while engaging blood center staff. Speakers include:

- Adam Testa (Strategic Communications Manager at Vitalant);
- John Eben (Manager of Marketing Insights and Operations at Versiti);
- Kelli Rai Smith (Director of Training and Customer Experience at Versiti); and
- Tara Matheson (Director of Donor Recruitment at ImpactLife).

They will share insights into the recruitment and retention of first-time donors, the use of artificial intelligence in donor recruitment, and strategies for fostering employee engagement through creativity. Don't miss out on learning different approaches blood centers can use to address challenges in their employee engagement and donor recruitment and retention efforts. 💡

INFECTIOUS DISEASES UPDATE

Dengue

Officials in California have [reported](#) two additional cases of locally acquired dengue infections in Los Angeles County according to a report from the Center for Infectious Disease Research and Policy (CIDRAP) within the University of Minnesota. This comes in the wake of a [warning](#) from health officials earlier this month of “unprecedented” local transmission for the region. The latest cases in Los Angeles are, “part of a cluster of cases from Baldwin Park, for a total of five since September 9th. None of the affected patients had a history of travel to tropical regions endemic for the mosquito-borne virus.” In 2023, the California Department of Public Health [reported](#) two cases of locally acquired dengue in Los Angeles. “This small local outbreak raises concerns about the ongoing spread of dengue and the potential for spread to other areas of Los Angeles County,” [said](#) Los Angeles Public Health on X. “Everyone in Los Angeles County should take action to prevent mosquito bites and mosquito breeding.”

(Source: CIDRAP, [“California’s Baldwin Park dengue cluster grows by 2,”](#) 10/16/24) 💡

RESEARCH IN BRIEF

Community Screening of Iron Deficiency in Females of Childbearing Age. A [study](#) in *Vox Sanguinis* “aimed to develop a non-invasive, low-cost screening tool that could [used] in the community.” The researchers conducted, “five all-day data collection events [in] Perth, Western Australia.” The paper noted that, “[w]omen between 18–49 years [of age] were recruited to complete a self-report questionnaire on risk factors for iron deficiency (ID).” The study’s primary outcome was, “the acceptability of screening, assessed by the feasibility of reaching the study sample size.” The researchers explained that, “[s]econdary outcomes included relevant history on diet, pregnancy, blood donation, symptoms of iron deficiency, any prior diagnosis or treatment for ID or an[em]ia and prevalence of heavy menstrual bleeding (HMB)...For those with Hb <130 g/L and no history of iron therapy in the past two years, referrals were given for venous testing.” The authors noted that, “[t]hose with ferritin <30 µg/L were classified as ID.” The researchers stated that in the paper that, “[t]he mean age of the cohort [of 640] was 33.5 ± 9.2 years...The mean Hb was 132.4 ± 11.9 g/L. [Additionally,] [i]n the past two years, 335 (52 percent) had a diagnosis of ID or an[em]ia; 322 (50 percent) had taken oral iron and 210 (33 percent) had an intravenous iron infusion. Vegetarian diets were followed by 89 (14 percent); 40 (6 percent) were regular blood donors; 290 (45 percent) had a previous pregnancy.” The study found that, “those with HMB were more likely to report a history of ID or an[em]ia in the past two years (67 vs. 47 percent, $p < 0.001$) and were more likely to have received iron therapy (iron infusion: 43 vs. 29 percent, $p < 0.001$; oral iron: 58 vs. 47 percent, $p=0.022$). Aside from chest pain, all symptoms of ID were significantly more frequently reported in those with HMB compared with those without.” The paper also explained that, “[n]either HMB nor an[em]ia status impacted maximum grip strength ($p>0.05$); however, linear regression analysis of Hb against maximum grip strength showed a positive relationship (adjusted $R^2 = 0.012$, $p = 0.004$)...Of 150 referrals given to those with Hb <130 g/L, 51 women went for further venous blood [where] ID (ferritin <30 µg/L) was detected in 20 women (39 percent).” The authors discovered that, “[s]imilarly, linear regression analysis showed a positive relationship between maximum grip strength and log-transformed ferritin (adjusted $R^2 = 0.135$, $p = 0.005$).” The researchers concluded in the paper that the “protocol for ID screening was well accepted by women in the [community.] There appears to be a relationship between ID, HMB and grip strength which should be considered for further development of a screening tool.”

Citation: MacLean, B., Lim, J., Fuller, J., *et al.* “[Community screening for iron deficiency in reproductive aged women: Lessons learnt from Australia.](#)” *Vox Sanguinis*. 2024.

Contributed by Richard Gammon, MD, Chief Medical Officer at Carter BloodCare 💧

MEMBER NEWS

Blood Assurance recently [received](#) a \$450,000 grant from the Commonwealth Transfusion Foundation (CTF). The funds will be awarded over a three-year period, “to support the Commonwealth Transfusion Foundation Specialist in Blood Banking (SBB) Program at Blood Assurance,” according to a CTF news release. “It is important that we support SBB certification, especially as many healthcare systems have transitioned to using generalists in the laboratory,” said Blood Assurance President and Chief Executive Officer (CEO) Liz Culler, MD in the news release. “There remains a significant need for blood bank experts within hospital systems and blood centers to develop policies and procedures, as well as to oversee complex case evaluations, particularly when specialized testing is involved.” CTF President and CEO Robert Carden, PhD added in the news release, “[t]here remains a significant need for blood bank experts within hospital systems and blood centers to develop policies and procedures, as well as to oversee complex case evaluations, particularly when specialized testing is involved.”



(Source: CTF [News Release](#), 10/14/24) 💧

GLOBAL NEWS

The University of Nottingham and Action on Blood, “a United Kingdom (UK) and Nigeria-based social enterprise that recruits, nurtures, mobile[z]es, and showcases Black people participating in activities like blood donation and health research,” have [announced](#) the publication of [data](#) in *Transfusion* demonstrating that, “[a] series of community made videos have proven to be an effective way to encourage Black people to donate blood.” According to the organizations, the videos, “[were] tested and evaluated and 90 percent of the target audience who were shown the videos stated that they would be convinced to donate blood.” The videos featured, “different themes:

- [\[c\]lometry](#);
- [\[r\]eciprocity](#),
- [\[d\]onor-\[r\]ecipient](#); and
- [\[s\]liding \[d\]oors](#).

Each had its own storyline developed over two one-day workshops in London.” The videos were, “scripted, acted and produced by Black professional artists in London.” Professor Eamonn Ferguson of the University of Nottingham School of Psychology added in the news release, “[t]his research shows the power of involving the intended communities in the co-design of healthcare promotion from the start and the real positive impact this can have, by enhancing trust and engaging people emotionally. It highlights why co-design with ethnic minorities has a vital role within healthcare and healthcare delivery to address wider health needs and health inequalities and health. Ensuring people are involved, engaged and listened, to develop arts-based approaches, could really help with boosting much needed blood supplies by engaging people’s emotions.”

(Source: University of Nottingham [News Release](#), 10/14/24)

The Department for the Execution of Judgments of the European Court of Human Rights announced that the Committee of Ministers has, “[ended](#) its supervision of the execution of the [Drelon v. France judgment](#).” According to the announcement, “[t]his case concerns the disproportionate interference with the applicant's right to respect for his private and family life (Article 8 of the Convention), as a result of the collection in 2004 and retention by the Établissement Français du Sang (French Blood Establishment) of personal data containing information about his alleged sexual orientation, which had led to several refusals to accept the applicant as a blood donor. The applicable legislation has been amended several times, and since a decree March 16th, 2022, sexual orientation is no longer considered a contraindication to donating blood. It is therefore now forbidden to collect data on this subject. Data collected prior to 2022 will continue to be kept by the Établissement Français du Sang, but will only be accessible to a very limited number of medical practitioners, and they will be kept for 15 to 30 years from the last blood donation, depending on the nature of the data.”

(Source: Department for the Execution of Judgments of the European Court of Human Rights [Announcement](#), 10/15/24) ♡

Upcoming ABC Webinars & Virtual Events – Don’t Miss Out!

- **ADRP Webinar: Recruit, Retain, & Realize the Impact** – Oct. 23rd at 1 p.m. EDT. [Registration](#) is open. More information available [here](#).
- **2024 ADRP International Showcase** – Nov. 13th. [Registration](#) is open. More information available [here](#).
- **ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar** – Dec. 2nd at 4 p.m. EST. More information is coming soon.



COMPANY NEWS

Cerus Corp. [provided](#) an update this week on their CE Mark application submission under Europe’s Medical Device Regulation (MDR) for the use of pathogen-reduced red blood cells using the Intercept system. According to company news release, the submission was not approved. The Cerus news release explained that, “[f]or Cerus’ MDR application in Europe, Cerus’ Notified Body, TÜV-SÜD, reviewed the modules for clinical, non-clinical, manufacturing and quality and found them to be satisfactory. However, the Competent Authority, CBG-MEB, reviewed the active pharmaceutical ingredient module and concluded that the data included in the module were insufficient to support the proposed classification of the impurity profile of the final product, necessitating TÜV-SÜD’s closure of Cerus’ MDR application without an approval. The Company, in collaboration with TÜV-SÜD, is assessing strategies for a potential enhanced new regulatory submission and the associated timeline.” Cerus Senior Vice President Carol Moore added in the news release, “[w]e continue to believe strongly in the need for pathogen inactivated RBCs and the regulatory dossier we filed in Europe. In addition to how we address the new questions CBG has raised, we want to take this opportunity to be thoughtful about leveraging the additional data that we have accumulated since our original CE Mark submission. For example, we believe the positive results from our U.S. Phase III ReCePI trial substantially expand the data available to evaluate the clinical safety and efficacy of INTERCEPT RBCs. We will be assessing how these data could allow us to propose a broader clinical indication in a potential new CE Mark submission in consultation with TÜV.”

(Cerus Corp. [News Release](#), 10/16/24)

• **FRESENIUS KABI** • **National Blood Donation** • **Hall of Fame**

Fresenius Kabi has [announced](#) the new inductees into the National Blood Donation Hall of Fame for 2024. This year marks the 26th year of the honor and the company’s collaboration with blood centers around the country. The National Blood Donation Hall of Fame recognizes individuals who have shown exemplary, “commitment to donating blood

and/or encouraging blood donation,” according to a news release from Fresenius Kabi. This year’s inductees include several donors from ABC member centers:

- J. David Myers, Blood Bank of Delmarva;
- Ana Cruz Hollingsworth, Carter BloodCare;
- Monte Engh, LifeServe Blood Center;
- Alejandro Herrera, OneBlood;
- Ray Lebron, San Diego Blood Bank;
- Judith Lamusga, Solvita Blood Center;
- The Fontanez Family, Versiti Blood Center of Illinois; and
- Bertha Axtman, Vitalant.

Additional information including all the 2024 inductees and those from previous years are also located at the Fresenius Kabi Donation Hall of Fame [website](#).

(Source: Fresenius Kabi [News Release](#), 10/17/24) ♦

Rise & Lead

A WOMEN'S LEADERSHIP WORKSHOP

Elevate your leadership journey!

Join us in San Antonio, TX
November 6th & 7th

Register Now

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.)

2024

Oct. 19-22. **Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting. Houston, Texas.** More information available [here](#).

Oct. 23. **ADRP, the Association for Blood Donor Professionals Webinar: Recruit, Retain, & Realized the Impact.** [Registration](#) is open. More available [here](#).

Oct 24. **U.S. Department of Health and Human Services (HHS) Office of Infectious Disease and HIV/AIDS Policy (OIDP) Tick-borne Diseases and Associated Illnesses and Conditions (TBDAIC) Community Engagement Session (Virtual).** [Registration](#) is open. More information available [here](#).

Oct. 23-26. **Sickle Cell Disease Association of America (SCDAA) Annual National Convention. Atlanta, Ga.** [Registration](#) is open. More information available [here](#).

Oct. 28. **U.S. Centers for Disease Control and Prevention (CDC) Sickle Cell Data Collection Summit (Virtual).** [Registration](#) is open. More information available [here](#).

Oct. 28. **Reagan-Udall Foundation for the FDA Webinar: Record Keeping and Adverse Event Reporting: Medical Device Reporting, Corrections and Removals and Quality System Complaint Requirements (LDT Industry Education) (Virtual).** [Registration](#) is open. More information available [here](#).

Oct. 28. **Centers for Disease Control & Prevention (CDC) Sickle Cell Data Collection (SCDC) Summit 2024 (Virtual).** [Registration](#) is open. More information available [here](#).

Oct. 30. **FDA Patient Engagement Advisory Committee Meeting on Patient-Centered Informed Consent in Clinical Study (Virtual).** More information available [here](#).

Nov. 6-7. **America's Blood Centers Women's Executive Leadership Community (WELC) Workshop. San Antonio, Texas.** [Registration](#) is open. More information is available [here](#).

Nov. 6-7. **Centers for Disease Control and Prevention (CDC Clinical Laboratory Improvement Advisory Committee (CLIAC) Meeting (Virtual).** More [information](#) is available [here](#).

Nov 8. **FDA Webcast: Informed Consent — More than Just Another Document to Sign? (Virtual).** [Registration](#) is open. More information available [here](#).

Nov. 13. **2024 ADRP International Showcase.** [Registration](#) is open. More information available [here](#).

Nov 14. **2024 FDA Broad Agency Announcement (BAA) Day Webinar (Virtual).** [Registration](#) is open. More information available [here](#).

Nov. 19-20. **Trauma Hemostasis & Oxygenation Research (THOR) Network Emergency Transfusion in Females with Childbearing Potential: Mitigating the Risks of Hemolytic Disease of the Fetus and Newborn Meeting. Bethesda, Md.** [Registration](#) is open. More information available [here](#).

Nov. 19-20. **Plasma Protein Forum. Washington, D.C.** More information available [here](#).

Dec. 2. **ABC Scientific, Medical, and Technical (SMT) Journal Club Fall Webinar.** More information coming soon.

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CALENDAR (continued from page 9)

2025

Mar. 10-12. **ABC Annual Meeting, Arlington, Va.** More information available [here](#).

May 6-8. **2025 ADRP Annual Conference, Oklahoma City, Okla.** 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 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.** 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

Associate Director, Member Programs. The Associate Director of Member Programs will play a crucial role in the development and oversight of member programs for America's Blood Centers (ABC) and our international division, ADRP: The Association for Blood Donor Professionals. This key position will provide strategic guidance on emerging trends in association management and the blood community and shape strategies that drive value and promote growth. Working closely with the leadership team, the Associate Director will be at the forefront of decision-making processes to ensure that member programs align with the organizational objectives. The role involves collaborating with stakeholders from both ABC and ADRP to create engaging and impactful member programs that meet the evolving needs of the blood community. The successful candidate will foster innovation and excellence in program development and execution. This position is remote. ABC employs talented individuals whose passion, drive and skills are necessary to fulfill our mission. ABC offers a salary commensurate with experience as well as an excellent benefit

package including medical, dental, LTD, and 401k contribution. We are a virtual office that promotes a flexible work environment. Applicants must be able to maintain a safe, separate workspace in which they can complete their work that is free from distraction and live in an area where they can obtain reliable internet service. This is a full-time staff position including benefits and a stipend for internet and telephone services. ABC prohibits discrimination and provides equal employment opportunities to all employees and applicants for employment without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state, or local laws. Learn more [here](#). Interested applicants should send a cover letter and resume to careers@americasblood.org.

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POSITIONS (continued from page 10)

Inventory Coordinator MLT. Have you been looking for purposeful work that contributes to a lifesaving mission? We are currently looking for a full-time Inventory Coordinator to join our team in Johnston, Iowa. This position ensures the highest level of customer satisfaction to our hospitals through our inventory management resources and expertise. Key responsibilities: Daily reporting of inventory. Daily evaluation of inventory. Anticipates impact of inventory on external factors such as holidays or weather, and coordinates stakeholders to develop action plans. Communicates with hospital blood bank staff, leaders, and expired product vendors. Schedules and organizes all assigned exporting operations. Negotiates price on ad hoc shipments. Requirements: Bachelor's degree required. Medical Technology (MT), Medical Laboratory Specialist (MLS), or at minimum Medical Lab Technology (MLT) certification required. Four years sales, customer service, or directly-related experience preferred. Experience working with inventory management is preferred. Hospital transfusion service experience is ideal. Interested applicants should visit our [website](#). LifeServe Blood Center is fully committed to equal employment opportunity. All applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, age, sexual orientation, gender identification, genetic information, marital status, pregnancy, disability, veteran status, or any other legally protected status.

Donor Recruitment Manager. Blood Assurance is seeking a **Donor Recruitment Manager** to lead field recruitment efforts that build new and existing business in and around our Nashville region. Primary responsibilities include direct leadership of Account Managers in expanding blood drive activity on mobiles primarily, and in facilities as needed, based on growth strategy in a specific type of blood product recruitment and collection. Assist in developing long-term community business partnerships, and coordinating internally with all leadership levels to support or expand Blood Assurance recruitment efforts. Work closely with Donor Services leadership to ensure recruitment and collection teams are working together toward meeting overall product collection goals. Qualified applicants will have: Bachelor's degree-preferably in business, marketing, or related field. Seven to 10 years sales experience, preferably in blood banking. Three to 5 years sales staff management. Advanced communication skills. Public presentation and networking skills. Advanced organizational, customer service and teamwork skills. We offer many benefits including: Health/Dental/Vision Insurance, Flexible Spending Account, Employee Assistance Program for you and your family, Paid Time Off, 401K and a Wellness Program. Qualified candidates are encouraged to email a resume to katiemarye@bloodassurance.org. Blood Assurance is an Equal Opportunity Employer and a Tobacco Free Environment.

LAN Administrator II. Join Gulf Coast Regional Blood Center's team of heroes as a **LAN Administrator II!** We are seeking a detail-oriented professional responsible for planning and deploying major service upgrades and providing enterprise-level support for hardware, software, operating systems, and network infrastructure. In this role, you will oversee Windows Server management, file and print sharing, and network support. You'll also serve as the technical lead for projects, ensuring seamless network infrastructure installation and support for key systems like Exchange, Virtualization, and Active Directory. Additional responsibilities include maintaining system documentation, assisting with Wide Area Network (WAN) management, and providing backup support for MS back-office services and the organizational Help Desk. Ideal candidates will have a Bachelor's Degree in Computer Science or a related field and at least five years of experience in enterprise-level server and network support. Proficiency in Windows Active Directory, TCP/IP, and Microsoft Office is essential, and certifications such as MCSE, MCSA, or VCP are highly preferred. This role offers exciting career advancement opportunities, a competitive compensation package, and the chance to make a real difference in a mission-driven organization. If you're a problem-solver with great interpersonal skills and a passion for IT, [apply now!](#)

Regional Consultation Lab Services Tech III. Join our team of heroes! Gulf Coast Regional Blood Center is seeking a **Regional Consultation Lab Services Tech III** in Nacogdoches, TX! This unique role combines laboratory services, phlebotomy, and community engagement. You'll prepare special blood components, perform patient testing, and serve as hospital services support. Additionally, you'll participate in blood collection during facility and mobile operations, ensuring a high level of customer service with both hospital staff and donors. Key responsibilities include performing serological testing, interpreting complex antibody identification, and preparing consultation reports. You'll also rotate on-call duties to provide after-hours consultation and support hospital services. In donor collections, you'll handle pre-donation screening, venipuncture, and post-donation care, with all necessary training provided. The ideal candidate will have a certification as an MLT or MLS, with blood bank and immunohematology experience preferred. A valid Texas Driver's License and reliable commute to the Nacogdoches facility are required. This position offers career growth, a competitive compensation and benefits package, and the rewarding opportunity to save lives. If you're precise, astute, and passionate about using your talents to support the community, this is the perfect role for you! Training in donor collections is provided for those without phlebotomy experience. What are you waiting for? [Apply Now!](#)

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Business Development Manager. Join Gulf Coast Regional Blood Center's team of heroes as a **Business Development Manager!** We're seeking an energetic self-starter passionate about making a difference through outstanding client service and business growth. In this role, you'll initiate new client onboarding, prospecting, and account management for our diverse product lines, including biotech/research, laboratory testing, and cellular therapy products and services. You'll be responsible for identifying top prospects, strategizing sales and marketing approaches, and managing CRM processes. This in-office position collaborates with the marketing team which is key to developing engaging materials for B2B and online campaigns. We offer a competitive compensation package, career advancement opportunities, and the chance to work in a dynamic, mission-driven environment that saves lives. Ideal candidates will have a Bachelor's degree or five years of related experience. Industry sales experience or a background in life science is preferred. Candidates must have a valid Texas driver's license and reliable transportation. This position also offers mileage reimbursement and free parking near NRG Stadium. If you're adaptable, driven, and passionate about helping others, this role is for you. Join us in embodying our core values of Commitment, Integrity, and Respect while creating life-saving experiences every day. [Apply Now!](#)

Consultation Lab Specialist. Join Gulf Coast Regional Blood Center as a **Consultation Lab Specialist!** This life-saving role performs complex and routine serological investigations and testing, requiring precision, attention to detail, and the ability to work diplomatically with both internal and external customers. You'll be responsible for resolving serological problems, interpreting complex antibody cases, and preparing consultation reports among additional intricate laboratory services. If you take pride in delivering high-quality service and are passionate about making a difference in the community, this is the perfect role for you. We offer a competitive compensation package, career advancement and technical development opportunities. Talent in this department has the chance to work in a dynamic, mission-driven, and patient-first environment. Ideal candidates will have a Bachelor's degree in a laboratory science field with an ASCP MT, MLS or SBB certification and recent immunohematology, reference lab experience. Sign-on bonus and relocation packages available. If you're precise, astute, and passionate about using your talents to support the community, this is the perfect role for you! What are you waiting for? [Apply Now!](#)

Consultation & Reference Laboratory Assistant Manager. Gulf Coast Regional Blood Center is seeking a **Consultation & Reference Laboratory Assistant Manager!** This pivotal role involves overseeing laboratory operations, supervising staff, and ensuring compliance

with all policies, procedures, and quality control standards. Reporting to the Consultation & Reference Manager, the Assistant Manager will be instrumental in maintaining effective relations with both internal and external departments and customers. This opportunity is perfect for individuals who value precision, enjoy problem-solving, and are dedicated to delivering high-quality service to the community. You will assist with budget management, monitor lab performance, and contribute to the development and revision of department SOPs. Additionally, the role requires regular communication with the Medical Director and participation in internal and external assessments. **Why join us?** You'll enjoy a competitive compensation package, free parking at the Texas Medical Center, and opportunities for career growth—all while contributing to life-saving work. Sign-on bonus and relocation opportunities available. **Qualifications** include an SBB Certification (ASCP), 6+ years of recent blood banking experience, 3+ years in an Immunohematology Reference Lab, and at least 2 years of management experience. If you embody integrity, commitment, and respect, we encourage you to [apply now](#) and help make a difference!

Quality Assurance Director. Gulf Coast Regional Blood Center is seeking an experienced **Quality Assurance Director** to lead and oversee all aspects of Quality Assurance and Compliance. Reporting to the Associate Vice President of Quality Services, this pivotal role ensures that the blood center maintains the highest standards of safety and quality in alignment with FDA regulations, AABB standards, and other key accrediting bodies. As the Quality Assurance Director, you will be responsible for implementing and monitoring quality systems, leading audits, ensuring compliance with international and domestic regulations, and fostering a culture of continuous improvement. This role is ideal for individuals with strong leadership and problem-solving skills, and a deep understanding of quality management principles like Lean and Six Sigma. You will develop quality training programs, oversee incident reports, and serve as the FDA designee for the organization, ensuring that all processes meet regulatory standards. **Qualifications** include a Bachelor's degree (Graduate degree preferred) and at least 7 years of progressive management experience in a regulated industry. Preferred certifications include ASCP, ASQ, and Six Sigma Green Belt or better. If you are ready to make a lasting impact in a mission-driven organization, we encourage you to [apply today!](#)

VP, Regional Operations. Reporting to the Chief Operating Officer (COO), the position is responsible for executing the New York Blood Center Enterprises (NYBCE) strategy for the Mid-Atlantic Region (BBD and RIBC). The role will coordinate regional efforts with the centralized enterprise functions to attain objectives and

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KPIs for the region. The VP, Regional Operations will support NYBCe stature as “best in class” by achieving strategic goals and driving tangible, measurable outcomes. The candidate will join the Senior Leadership Team and be the enterprise ambassador for NYBCe in the Mid-Atlantic region, represent the enterprise at official events and meetings with community leaders. The home site is RIBC (Providence, RI) or BBD (Newark, DE). Minimum one week on site presence required monthly at the non-home site. Education: Bachelor’s degree in STEM, economics, business administration, or health administration. MBA preferred. Experience: 15 + years of previous operations management experience in a healthcare, hospitality, or service sector. Travel: Ability to travel 25-30% including overnight stays. For applicants who will perform this position in Rhode Island the annual salary is \$285,000.00p/yr. to \$290,000.00p/yr. salary reflects local market rate and be commensurate with the applicant’s skills, job-related knowledge, and experience. Please click [here](#) to apply.

Executive Director, Comprehensive Client Relations. Reporting to the B&LO Vice President of Strategy and Business Operations, the *Executive Director, Comprehensive Client Relations* (ED-CCR) will act as the leading executive responsible for driving the commercial strategy and execution of B&LO products and services. The ED-CCR is responsible for the end-to-end design and management of the interface with commercial customers, with the goal of maximizing current accounts and acquiring new ones. The ED-CCR will develop, plan, and execute the overall customer sales strategy for B&LO. The mandate of the ED-CCR includes prospecting, market development, value proposition formulation, pricing/volume/product mix optimization, RFI/RFQ/RFP preparation, negotiations, contracting, customer service, and service recovery. The ED-CCR is responsible for leading, motivating, coaching, developing, and retaining a diverse team of individuals. **Education:** BS/MS in marketing, sales, business, economics, STEM, or applied social sciences. MBA would be an advantage. **Experience:** 12 or more years of sales experience, including 57 years of commercial leadership experience or corporate account management experience in BioPharma, medical devices, and/or related healthcare field. Hospital sales experience is required. **Travel:** Ability to travel 25 percent with occasional overnight stays. **Unless otherwise specified, all posted opportunities are in the New York or Greater Tri-State office locations. Click [here](#) to apply.**

Marketing Executive. LifeSouth Community Blood Centers is looking for a highly skilled leader with a solid understanding of marketing principles and techniques, a data-driven approach, and a passion for innovation, to join the team as Marketing Executive in Gainesville, FL. This position is responsible for the overall marketing

strategy across the organization. This position requires active communication with executive leadership and department directors within the organization to ensure adequate planning and execution of strategic marketing plans. This position is dedicated to advancing the organization’s objectives in blood donation, cord blood services, cellular therapy, new business development, and meeting patient needs. 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](#)!

Immunohematology Reference Lab Medical Technologist. 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 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](#)!

Immunohematology Reference Lab Medical Technologist. 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 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](#)!

 **Massachusetts General Hospital**
Founding Member, Mass General Brigham

Assistant/Associate Director, Blood Transfusion Service (Massachusetts General Hospital; Boston, Massachusetts). The Department of Pathology at the Massachusetts General Hospital (MGH), a founding hospital of Mass General Brigham, and a major teaching

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affiliate of the Harvard Medical School, seeks a full-time, early- or mid-career, academically oriented transfusion medicine physician. The successful candidate will combine clinical and teaching activities with a research program in a field relevant to transfusion medicine, hematology, or hemostasis. The Blood Transfusion Service at MGH encompasses an FDA-licensed donor center, therapeutic apheresis, an outpatient transfusion/infusion clinic, a transfusion service, and progenitor cell collection and processing. We collaborate closely with colleagues in bone marrow and solid organ transplantation, CAR-T cell therapy, cardiac surgery, trauma and critical care, neurology, and pediatrics. Our faculty also works closely with transfusion medicine faculty within the MGB network. Service and teaching responsibilities will be shared with two full- and several part-time staff physicians. Candidates must be BC/BE in Transfusion Medicine, with primary training in either Pathology or Hematology/Oncology (adult or pediatric). Academic rank as Associate Professor, Assistant Professor or Instructor and salary will be commensurate with experience and accomplishments. Interested candidates should send a personal statement with research interest, three potential referees and *Curriculum Vitae* to: Dr. Robert Makar; Director, Blood Transfusion Service; Department of Pathology; Massachusetts General Hospital; 55 Fruit Street, GRJ 148; Boston, MA 02114. Email: rmakar@mgh.harvard.edu C/O Diane Savickas dsavickas@mgb.org. We are an equal opportunity employer, and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability status, protected veteran status, gender identity, sexual orientation, pregnancy, and pregnancy-related conditions, or any other characteristic protected by law.



HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL