

2025 #31

October 6, 2025

INSIDE:

WORD IN WASHINGTON	2
BRIEFLY NOTED	4
MEMBER NEWS	4
PEOPLE	5
INPUT REQUESTED:	
Participate in the ABC Strategic Planning Survey	6
ABC Member Prehospital Blood Utilization Survey Opens	6
Register Today for the <i>Rise & Lead Workshop</i> November 13 th -14 th	6
ABC Executive Fellows Program Call for Applicants Closes October 27 th	6
Input Requested: ADRP Member Satisfaction Survey	7
2025 International Showcase Set for November 12 th	7
GLOBAL NEWS	7
COMPANY NEWS	8
CALENDAR	9
POSITIONS	10

ABC Comments to FDA Regarding the Draft Guidance Eliminating the Requirement for HBsAg Testing

America's Blood Centers (ABC) has [submitted comments](#) to the U.S. Food and Drug Administration (FDA) in [response](#) to the draft guidance titled "[Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen \(HBsAg\)](#)" published by the agency in July 2025.

The September 26th ABC comments, "applau[d] FDA's proposal to remove the HBsAg testing requirement for whole blood and blood components" and urge the FDA to, "consider removing this testing requirement for Recovered Plasma as well." ABC explains that, [n]ot treating all plasma-derived medicinal product (PDMP) source materials equally creates a regulatory inconsistency for blood collectors and fractionators and contributes to fractionators' unwillingness to accept recovered plasma that has not been tested for HBsAg."

Additionally, the ABC comments encouraged the agency to, "update current testing requirements to one-time donor testing for antibodies to human T-lymphotropic virus types I and II (HTLV-I/II) coupled with effective leukoreduction for donors of whole blood and blood components intended for transfusion." Specifically, the comments noted that, "[t]he HTLV-I/II antibody testing requirement at each donation of whole blood and blood components intended for transfusion should be revised based on:

- the declining prevalence of HTLV-I/II infection in U.S. blood donors;
- the low incidence observed among U.S. repeat blood donors;
- the low likelihood of infection and disease in individuals receiving HTLV-I/II antibody-reactive whole blood and blood components;
- the efficacy of leukoreduction in reducing the infectivity of HTLV-I/II antibody-reactive donations; and
- the use of effective pathogen reduction technology (PRT) for some platelets."

ABC previously asked FDA in joint comments from the blood community [submitted in March 2025](#) to switch to a one-time testing requirement. Please [contact](#) ABC's Director of Regulatory Affairs and Public Policy Justine Coffey, JD, LLM with any questions. ABC will continue to provide updates on its advocacy efforts as they become available.

(continued on page 2)

ABC Comments Regarding Draft Guidance Eliminating Requirement for HBsAg Testing (continued from page 1)

ABC also joined the Association for the Advancement of Blood & Biotherapies (AABB), and the American Red Cross in submitting [joint comments](#) to FDA regarding the draft guidance eliminating the requirement for HBsAg testing. The joint comments are aligned with ABC's comments as the blood community requested FDA's, "consideration of a recognition that hepatitis B virus (HBV) nucleic acid testing (NAT), combined with robust pathogen inactivation (PI), is sufficient to reduce adequately and appropriately the risk of transmission of HBV from all PDMP source materials, not just Recovered Plasma. While FDA does not have regulatory authority over PDMP manufacturing in other countries, alignment on this point would be highly valuable. Supporting efforts to eliminate unnecessary HBsAg testing of all whole blood donations — especially when Recovered Plasma production cannot be predicted when testing is ordered — will help advance the spirit and intent of the Guidance within the U.S."

(Source: ABC [Comments](#), 9/26/25; Blood Community [Joint Comments](#), 9/26/25) ♦

WORD IN WASHINGTON

The U.S. federal government shutdown at midnight on October 1st. America's Blood Centers (ABC) continues to monitor the situation and provide updates to its member blood centers. Currently, ABC anticipates that the impact on blood centers and related operations should be minimal as most staff at the U.S. Food and Drug Administration (FDA) continue to work during a shutdown, due to the large number of positions funded by user fees. However, functions relating to review work, guidance development, and pre-approval inspections related to whole blood and blood components for transfusion will cease during a lapse in appropriations, except for work that is necessary to detect and address imminent threats to the safety of human life. Congress remains open though some staff may be furloughed or put on leave which varies dramatically from office to office. If you are reaching out to your congressional office, you may receive an out-of-office notice. If this happens, we encourage you to resend an email after the government shutdown concludes. The shutdown could also potentially be a great time to work with your congressional office, as their schedules tend to be lighter, giving them more time to dive into a specific issue. Please [contact us](#) with any questions. We will provide member blood centers with additional information and updates as they become available.

(continued on page 3)

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail. Contents and views expressed are not official statements of ABC or its Board of Directors. Copyright 2025 by America's Blood Centers. Reproduction of the *ABC Newsletter* is forbidden unless permission is granted by the publisher (ABC members need not obtain prior permission if proper credit is given).

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

America's Blood Centers

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

Send subscription queries to memberservices@americasblood.org
America's Blood Centers
1717 K St. NW, Suite 900, Washington, DC 20006
Phone: (202) 393-5725
Send news tips to newsletter@americasblood.org.

WORD IN WASHINGTON (continued from page 2)

FDA recently published three draft guidances related to advanced therapies and regenerative medicine. The draft guidance documents are titled:

- [Innovative Designs for Clinical Trials of Cellular and Gene Therapy Products in Small Populations: Draft Guidance for Industry](#): “[which] provides recommendations to sponsors who are planning clinical trials of cell and gene therapy (CGT) products intended for use in a disease or condition that affects a small population — generally one that meets the definition of a rare disease or condition under section 526(a)(2) of the FD&C Act (21 U.S.C. 360bb(a)(2)). It describes FDA requirements and provides considerations for the use of various clinical trial designs and endpoints to generate clinical evidence to support product licensure. This guidance expands on principles described in FDA’s existing guidance documents related to this topic, by providing additional recommendations for the planning, design, conduct, and analysis of cell and gene therapy trials to facilitate FDA’s assessment of product effectiveness;”
- [Postapproval Methods to Capture Safety and Efficacy Data for Cell and Gene Therapy Products: Draft Guidance for Industry](#): “[the guidance discusses] methods and approaches for capturing postapproval safety and efficacy data for CGT products. Given the potential for long-lasting effects of CGT products, and the generally limited number of participants treated in clinical trials conducted to support approval of CGT products, postapproval monitoring is important for gathering data on product safety and effectiveness over time. This guidance does not address data collected for the purpose of expanding clinical indications;” and
- [Expedited Programs for Regenerative Medicine Therapies for Serious Conditions: Draft Guidance for Industry](#): “[the] guidance provides sponsors engaged in the development of regenerative medicine therapies for serious or life-threatening diseases or conditions with [FDA’s] recommendations on the expedited development and review of these therapies, including as provided under section 506(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by section 3033 of the 21st Century Cures Act (Cures Act). Under section 506(g) of the FD&C Act, a regenerative medicine therapy can be designated as a regenerative advanced therapy if it meets certain criteria. FDA refers to such designation as ‘regenerative medicine advanced therapy’ (RMAT). This guidance describes the expedited programs available to sponsors of regenerative medicine therapies for serious conditions, including those products designated as RMATs. To that end, the guidance provides information about the provisions in the Cures Act regarding the use of the accelerated approval pathway for regenerative medicine therapies that have been granted designation as an RMAT. Finally, the guidance describes considerations in the clinical development of regenerative medicine therapies and opportunities for sponsors of such products to interact with the Center for Biologics Evaluation and Research (CBER) review staff. As a general matter, this guidance addresses regenerative medicine therapies regulated by CBER as biological products under the FD&C Act, section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), and applicable regulations. This draft guidance, when finalized, will supersede the final guidance of the same title dated February 2019.”

(Source: FDA Guidances, [9/25/25](#); [9/25/25](#); [9/25/25](#)) 💧

Vinay Prasad, MD, MPH has resumed the role of Chief Medical and Scientific Officer in the Office of the FDA Commissioner according to the agency’s website. Dr. Prasad previously held this role after being appointed by FDA Commissioner Martin Makary, MD, MPH to the position in June. Dr. Prasad resigned in August from this role and his position as director of CBER before deciding to return later that month as CBER Director. In his role as chief medical and scientific officer, “Dr. Prasad advises the FDA

(continued on page 4)

WORD IN WASHINGTON (continued from page 3)

Commissioner and other senior officials on cross-cutting and emerging medical and scientific issues impacting regulatory science and public health. He provides strategic input and leadership on trans-center working groups and initiatives, ensuring scientific consistency and integration across FDA centers and builds partnerships with academic, governmental, and industry stakeholders. Dr. Prasad also provides senior medical and scientific input to the FDA Commissioner on cross-center medical policy and regulatory decisions and acts as a senior medical and scientific representative at national, international, or advisory committee meetings and forums related to public health, regulatory science, and innovation.”

(Source: FDA [Website](#), 9/10/25) 💧

BRIEFLY NOTED

The National Conference of State Legislators (NCSL) has [published](#) an article titled “Prehospital Blood Transfusions Give EMS Crews a Lifesaving Option.” America’s Blood Centers (ABC) worked with NCSL on the development of the article which includes sections on:

- “Pioneers in EMS Prehospital Blood Transfusion;
- State Actions on Prehospital Blood Programs; and
- Looking Ahead.”

ABC encourages all member blood centers to share the article with your state legislators to amplify your prehospital blood efforts through the ABC Council of States. ABC has participated in NCSL’s Legislative Summit exhibit hall since 2024 and has connected directly with legislators and staffers from several states, while sharing insights about the vital role community blood centers play in maintaining a safe and reliable blood supply.

(Source: NCSL, “[Prehospital Blood Transfusions Give EMS Crews a Lifesaving Option](#),” 9/30/26) 💧

MEMBER NEWS

Héma-Québec recently [recognized](#) Jean Bernier for hitting the 1,700 blood donation milestone. An announcement from the blood center noted that, “Mr. Bernier has set an unparalleled record: according to [Héma-Québec ‘s] research, he is the first person in history — whether in Québec, Canada, or North America — to achieve such an extraordinary level of altruistic giving. Thanks to his generosity and unwavering commitment, he has helped save or improve the lives of thousands of people who required blood, plasma, or platelets.” Mr. Bernier is a former professor who taught for 35 years and began donating at the age of 18. “I never thought about setting a record [or] that I’d ever end up making 1,700 donations,” said Mr. Bernier in the announcement. “To me, it’s as if every one of those 1,700 donations was my first, because each donation carries unique importance for a patient in Québec and for their family. Young people are healthy and full of vitality — if we inspire them, they’ll want to share!” Mr. Bernier was also honored for achieving this milestone on October 5th, “during the Laval University Rouge et Or football game against Concordia University’s Stingers.”



(Source: Héma-Québec [News Release](#), 10/2/25) 💧

PEOPLE



Cliff Numark, JD has been [named](#) the next president and chief executive officer (CEO) of OneBlood effective November 17th. He succeeds George “Bud” Scholl who, “announced his decision to retire earlier this year.” Mr. Numark most recently served as the senior vice president of Donor Operations and Chief of Marketing at Vitalant where he has worked since 2019. According to a OneBlood news release, he has been, “recognized as a transformational strategic leader with a proven record of achieving operational growth, building strong teams, and creating and implementing innovative marketing and recruitment programs.” Prior to joining Vitalant, Mr. Numark, “spent more than 16 years at the American Red Cross where he was a senior executive responsible for leading donor services and operations at local, regional and national levels, including serving as CEO of the American Red Cross Southern California Region.” He currently serves on the America’s Blood Centers (ABC) Board of Directors and is part of the ABC Executive Fellows Program’s first cohort. Mr. Numark holds, “a law degree from University of California, Berkeley, has a Master’s in Public Affairs from Princeton University, a Master’s of Science from the University of Sussex in the United Kingdom, and has a Bachelor of Arts, magna cum laude, in Chemistry and Public Policy from Pomona College.” He will be based in Fort Lauderdale, Fla.

(Source: OneBlood [News Release](#), 9/26/25)

New York Blood Center Enterprises (NYBCe) has [announced](#) the recent appointments of **Andrea H. Cefarelli** as senior vice president and chief operating officer of Blood and Laboratory Operations and **Clay Rich** as senior vice president and deputy chief operating officer of Blood and Laboratory Operations. According to a blood center announcement, “Ms. Cefarelli has dedicated more than 30 years to NYBCe, most recently serving as senior vice president of Corporate Communications and Public Affairs. She has overseen end-to-end



blood and laboratory operations, including donor recruitment, collections, manufacturing, testing, and distribution, and has led NYBCe through public health crises including 9/11, Hurricane Sandy, and the COVID-19 pandemic. [Ms. Cefarelli has] pioneered signature donor engagement programs such as the Little Doctors Program®, Bloodstock®, and GiveBloodNYC, and played a key role in launching NYBCe’s new Rye, N.Y. campus. Mr. Rich, a U.S. Marine Corps veteran, most recently served as vice president of Supply Chain for NYBCe. Since joining the organization in 2016 through its merger with Innovative Blood Resources, he has advanced through roles in finance, production planning, and supply chain management. [Mr. Rich] played a pivotal role as a strategic partner in shaping NYBCe’s reporting and analytics platform, championing its adoption to improve inventory management and embed evidence-based decision-making across operations. His broader leadership was recognized with the President’s Award during the COVID-19 pandemic, and his military service included deployment to Afghanistan and earning the Navy and Marine Corps Achievement Medal.” NYBCe President and CEO Chris Hillyer, MD added in the NYBCe announcement, “[t]he strength of our leadership team is essential to ensuring exceptional stewardship of our organization, our people, and our mission. With over 30 years serving NYBCe, Andrea is a proven leader with unmatched knowledge of our lifesaving operations, and Clay brings extraordinary expertise in supply chain and innovation. Together, they will guide NYBCe into the next chapter of growth, and service for patients and communities across the country.”

(Source: NYBCe [Announcement](#), 9/23/25) ♦



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

INPUT REQUESTED: Participate in the ABC Strategic Planning Survey

America's Blood Centers (ABC) has launched a [Strategic Planning Survey](#) and invites all members to complete this brief survey prior to the October 17th deadline. Multiple submissions per blood center are welcome as this is an opportunity for individuals to inform the strategic direction of ABC in future years. The ABC Board of Directors will meet later this year to develop ABC's next [Strategic Plan](#) (for fiscal years 2027-2030). To ensure a full breadth of perspectives are captured during the planning process, we hope you will participate in this short survey designed to capture your valuable insights about the association. Please [contact us](#) with any questions or if you have trouble accessing the survey.

ABC Member Prehospital Blood Utilization Survey Opens

ABC is encouraging all members to take part in the [ABC Member Prehospital Blood Utilization Survey](#). This annual survey collects and provides statistically significant information to our members and supports ABC's prehospital blood [advocacy efforts](#). Please complete the survey by October 24th. The opportunity for prehospital blood transfusion to save lives has become increasingly popular. As part of ABC's [Advocacy Agenda](#), we have developed partnerships with EMS organizations and government agencies by way of the [Prehospital Blood Transfusion Coalition](#) (PHBTC) to address the barriers limiting widespread availability of prehospital blood transfusions, including scope of practice and reimbursement. As a member of the PHBTC, ABC is focused on improving the access of this lifesaving initiative to those who need it. Please [contact us](#) with questions or if you have trouble accessing the survey.

Register Today for the Rise & Lead Workshop November 13th-14th



[Registration](#) is open for the America's Blood Centers (ABC) 2025 ABC Women's Executive Leadership Community (WELC) [Rise & Lead Workshop](#) taking place November 13th-14th in San Antonio, Texas at the Westin Riverwalk. [Book now](#) to secure the discounted rate by the October 21st deadline. Check out the [schedule](#) as this workshop is designed for women in leadership positions, emerging leaders, and professionals seeking personal and career growth. It also welcomes individuals who want to cultivate diverse perspectives. Attendees will engage in an intimate, engaging, and interactive environment focused on networking, mentorship, and meaningful discussions on leadership and growth. Please [contact us](#) with questions.

ABC Executive Fellows Program Call for Applicants Closes October 27th

[Apply](#) to participate in the 2026 [ABC Executive Fellows Program \(EFP\)](#) by the October 27th deadline. ABC is partnering with Vanderbilt University's Owen School of Management. This groundbreaking initiative offers industry-specific, best-in-class leadership training to blood community executives, elevating individuals, organizations, and the nation's blood supply. The program will accept an annual cohort of up to 25 fellows who will participate in:



(continued on page 7)

INSIDE ABC (continued from 6)

- “a week-long leadership residency at Vanderbilt;
- three additional in-person learning immersions;
- virtual seminars taught by Vanderbilt faculty;
- a 360-leadership assessment;
- individual executive coaching; and
- a capstone project presented at ABC Annual Meeting 2027.

The EFP strives to accept participants from a wide variety of backgrounds and leadership roles. Final selections for the 2026 cohort will occur by December 2025. An independent selection committee is responsible for choosing each year’s cohort. Senior leaders from ABC member blood centers, hospital-associate members, affiliate organizations, and industry partners are encouraged to apply. The Foundation for America’s Blood Centers (FABC) is pleased to announce up to \$20,000 in partial scholarships for individuals employed by ABC active member blood centers. Additional information regarding tuition rates is available [here](#).

Input Requested: ADRP Member Satisfaction Survey

Take part in shaping the future of ADRP by completing the [ADRP Member Satisfaction Survey](#)! We encourage all ADRP members to participate as this is your opportunity to let your voice be heard, as your input will help shape our strategic priorities for the next three years. ADRP values and welcomes all member feedback and are asking you to please complete the survey by Monday, October 27th. If you have any questions or have trouble accessing the survey, please [contact us](#).

2025 International Showcase Set for November 12th

[Registration](#) is now open for the [2025 ADRP International Showcase](#) and complimentary for all blood center staff! This virtual event will take place on Wednesday, November 12th at 1 p.m. EST and includes blood community professionals worldwide taking part in our annual forum to share, connect, and learn from each other! Stay tuned for additional details in the coming weeks as the International Showcase is a unique, cross-cultural exchange that fosters new connections and perspectives on donor motivation and retention strategies that can potentially be adaptable across the global blood community. A recording of this event will be made available to all registrants. 💧

GLOBAL NEWS

A paper [published](#) in *PLOS Global Public Health*, “**outlines the results of invasive mosquito surveillance conducted by United Kingdom Health Security Agency (UKHSA) from 2020 to the end of 2024.**” The agency’s reported findings indicate that, “[b]etween 2020 and 2024 surveillance effort significantly increased with the number of polystyrene blocks returned from ovitraps increasing each year, with slight variations in the start date due to limitations in staff resources. [The United Kingdom has] already recorded isolated detections of *Aedes albopictus* [mosquito] at transport hubs, underscoring the role human activity plays in facilitating arthropod vector introductions. This trend highlights the importance of proactive measures, such as enhanced surveillance at ports of entry and public awareness campaigns to mitigate risks associated with invasive mosquito species. Both *Aedes aegypti* and *Aedes albopictus* are significant vectors globally and the economic cost of *Aedes*-borne diseases is rising, with cost of damage being 10 times higher than that of the cost of management, highlighting the importance of and requirement for [the] Medical Entomology and Zoonoses Ecology group at UKHSA [and their] ongoing surveillance progra[m] in the UK. [These repeat detections also underscore] the need for sustained investment in surveillance and

(continued on page 8)

GLOBAL NEWS (continued from page 7)

control. Strengthening monitoring networks, developing climate-resilient vector management strategies, and deploying innovative tools are crucial to preventing establishment of exotic arthropod vectors.” The *Aedes* species of mosquito can transmit viruses such as dengue and chikungunya.

Citation: Johnston, C.J., Edwards, A.C., Vaux, A.G.C., *et al.* “[Invasive mosquito surveillance in the United Kingdom 2020 to 2024: First detection of *Aedes aegypti* eggs in the UK and further detection of *Aedes albopictus*.](#)” *PLOS Global Public Health*. 2025

Australian Red Cross Lifeblood and Metallica are [partnering](#) to encourage blood and plasma donation as part of the band’s Australian tour. According to a news release, “the collaboration in conjunction with Metallica’s foundation All Within My Hands, will see Aussie donors, who donate [at select donor centers] in the week before each tour stop, receive a limited-edition Metallica t-shirt designed by the band’s iconic artist SQUINDO. The one-of-a-kind design for Aussie donors features the band’s famous ‘A Sea of Hearts Beat As One’ lyric, encapsulated within a blood drop, as well as a visual nod to Aussie Metallica fans.” Australian Red Cross Lifeblood Executive Director of Donor Experience Cath Stone added in the news release, “Metallica and their foundation’s commitment to making every tour stop a better place, by rallying fans to donate blood and plasma, is a selfless act that will have a lifesaving impact on so many individuals and their families. With demand for blood at a 12-year-high and plasma demand at record levels, we hope this partnership will fuel an influx of Metallica fan donors that we can welcome home to our donor cent[ers].”

(Source: Lifeblood [News Release](#), 9/23/25) 💧

COMPANY NEWS

Cellphire Therapeutics, Inc. has recently [shared](#) that it has received, “the final topline results from its “Randomized Controlled Trial Comparing Dimethyl Sulfoxide Cryopreserved Platelets to Liquid Stored Platelets in Patients Undergoing Cardiopulmonary Bypass Surgery” (CRYPTICS) clinical study and is pleased to report that it met the study’s primary efficacy endpoint.” The company plans to report on the topline results during a presentation at the Association for Advancement of Blood & Biotherapies (AABB) Annual Meeting on Sunday, October 26th. According to Cellphire Therapeutics, CRYPTICS investigated, “the hemostatic efficacy and safety of CLPH-511 in comparison to room temperature platelets (RTP) for the treatment of acute hemorrhage in patients undergoing cardiopulmonary bypass surgery. The results of the CRYPTICS study demonstrated:

- [n]oninferiority of CLPH-511 to room temperature platelets based on the primary endpoint measure, 24-hour chest tube drainage (Difference in LS Means was 142.0 mL; 95.576 percent confidence interval of volume difference lower than noninferiority margin);
- [s]ensitivity analyses of the primary endpoint were consistent and supportive;
- [c]omprehensive review of the study efficacy data based on clinically relevant secondary endpoints further supports noninferiority of CLPH-511 to room temperature platelets; [and]
- [a]dverse events were well balanced between the two treatment groups.”

In April, Cellphire Therapeutics [announced](#) that the phase II/III multicenter, randomized, controlled trial of its investigational cryopreserved platelet product (CPP) was ending early after meeting its primary efficacy endpoint following a pre-planned interim analysis by an independent data monitoring committee (IDMC).

(Source: Cellphire Therapeutics, Inc. [News Release](#), 10/1/25)

(continued on page 9)

COMPANY NEWS (continued from page 8)

Valneva SE has [reported](#) “positive antibody persistence data four years after vaccination with a single dose of its chikungunya vaccine Ixchiq.” According to a company news release, “[t]he results are in line with Valneva’s expectations for this vaccine, confirming a strong and long-lasting antibody persistence across all age groups investigated. The four-year persistence data are in line with previous persistence data. [Among the 254 healthy adults] still followed in the trial, 95 percent maintained neutralizing antibody titers well above the seroresponse threshold four years after the single-dose vaccination. Persistence of antibodies in older adults (age 65+) was comparable to younger adults (18-64 years of age) in terms of geometric mean titers (GMTs) and seroresponse rates (SRRs). Trial VLA1553-303, which has received funding support from the Coalition for Epidemic Preparedness Innovations (CEPI) and the European Union’s (EU) Horizon Europe program, also collected long-term safety data up to two years, including Adverse Event of Special Interest (AESI) from the preceding trial and any new-onset Serious Adverse Events (SAEs). No safety concerns were reported or identified and no AESI were ongoing at the time of participant enrollment in the trial. Per trial protocol, antibody persistence is planned to be collected up to ten years after vaccination.” In August, the U.S. Food and Drug Administration’s (FDA) Center for Biologics Evaluation and Research (CBER) announced that it had, “[suspended](#) the biologics license for Valneva Austria GmbH’s Ixchiq (Chikungunya Vaccine, Live),” as of August 22nd. An agency communication explained that, “[t]his vaccine was initially approved by FDA under the accelerated approval pathway in November 2023 for the prevention of disease caused by the chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. CBER’s decision is based on serious safety concerns related to the vaccine, which appears to be causing chikungunya-like illness in vaccine recipients. There has been one death from encephalitis directly attributable to the vaccine (CSF PCR was + for the vaccine strain of the virus) and over 20 reported serious adverse events that were consistent with chikungunya-like illness. Reported serious adverse events have included 21 hospitalizations and 3 deaths. Furthermore, the clinical benefit of the vaccine has not yet been verified in confirmatory clinical studies. CBER’s benefit-risk analysis broadly shows the vaccine does not have benefits outweighing risks, under most plausible scenarios. For these reasons, CBER believes this vaccine is not safe and that continued administration to the public would pose a danger to health.”

(Source: Valneva SE [News Release](#), 9/30/25)

Takeda Pharmaceutical has [announced](#) that it will, “stop its cell therapy initiatives and seek a partner to advance its research and clinic-ready programs in this field” according to an article published by *Reuters*. The publication reported that, “Takeda had discontinued the development of its blood cancer cell therapy candidate, TAK-007, last year, calling it a ‘data-driven decision.’ The drugmaker said it will now focus on other treatment types, including small molecule drugs, biologics and antibody-drug conjugates — areas it believes can deliver innovative medicines to patients more quickly and at greater scale.”

(Source: *Reuters*, “[Takeda Pharmaceutical to exit cell therapy research](#),” 10/1/25) ♦

CALENDAR

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

2025

Oct. 12-15. **American Association of Tissue Banks (AATB) Annual Meeting.** Atlanta, Ga. [Registration](#) is open. More information available [here](#).

(continued on page 10)

COMPANY NEWS (continued from page 9)

Oct. 14-15. **International Protein Forum. Old Town Alexandria, Va.** [Registration](#) is open. More information is available [here](#).

Oct. 22. **FDA CBER OTP Town Hall: “Gene Therapy Manufacturing CMC and Facility Readiness for BLAs and Post-licensure Changes” (Virtual).** [Registration](#) is open. More information is available [here](#).

Oct. 25-28. **AABB Annual Meeting. San Diego, Calif.** [Registration](#) is open. More information is available [here](#).

Oct. 26-29. **Blood 2025 and the ISBT 36th Regional Congress. Perth, Australia.** More information available [here](#).

Nov. 6-7. **National Institutes of Health’s (NIH) National Heart, Lung, and Blood Institute (NHLBI) Cardiopulmonary Complications of Hematopoietic Stem Cell Transplantation (HCT) and Gene Therapy Workshop (Hybrid).** [Registration](#) is open. More information is available [here](#).

Nov. 12. **2025 ADRP International Showcase.** [Registration](#) is open. More information is available [here](#).

Nov. 13-14. **2025 ABC Women’s Executive Leadership Community (WELC) Rise & Lead Workshop.** [Registration](#) is open. More information available [here](#).

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

2026

Feb. 11-12. **4th Biennial International Plasma and Fractionation Association (IPFA) & EBA Symposium on Plasma Collection and Supply. Leuven, Belgium.** [Registration](#) is open. More information is available [here](#).

Mar. 9-12. **2026 ABC Annual Meeting. Tucson, Ariz.** More information is coming soon.

May 12-14. **2026 ADRP Annual Conference. Minneapolis, Minn.** More information is 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

Cell Therapy Technologist (Carter BloodCare). The Cellular Therapy Technologist (CTT) participates in activities in the Cellular Therapy Laboratory. These activities include, but may not be limited to, cellular therapy (CT) processing, performing and troubleshooting quality control of reagents and equipment, participating in educational instruction of students and new employees, familiarity and full compliance with all CT and general laboratory regulations, and participating in design and implementation of new methodology for processing CT products. A CTT ensures daily operations within the department meet and follow all established guidelines and provide excellence in service and patient care. Ability to work a flexible schedule, long and/or odd hours with little notice. Regular full-time attendance is required during normal working hours. This position requires a valid driver’s license. **Education:** MT (ASCP), MLS (ASCP)

or equivalent, or eligible with certification obtained within 90 days of hire. Bachelor of Science Degree in Clinical Laboratory Science, Medical Laboratory Science, Medical Technology, or a related field in laboratory science. **Experience:** Minimum of one year of experience as an MT/MLS. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job Cell Therapy Tech or Cell Therapy Technologist (MLS).

Manager of Product Quality Control (Carter BloodCare). The Manager of Product Quality Control will be responsible for all Product Quality Control related activities of the blood center. These activities may include, but

(continued on page 11)

POSITIONS (continued from page 10)

are not limited to, equipment/instrument maintenance and quality control, product testing, review of testing results, review of donor center activities, as related to Product Quality Control testing, training, and education of Product Quality Control testing staff. The Manager will monitor budget and other administrative activities for the department, as assigned by the Technical Director. Additionally, the position will be actively involved in strategic planning and collaborating with other blood centers on projects and other corporate initiatives. The Manager will report to the Technical Director. Regular full-time attendance is required during normal working hours. **Education:** Bachelor of Science Degree, or related field. MT (ASCP), MLS (ASCP) or equivalent. **Experience:** Minimum three (3) years general laboratory experience, required. Minimum one (1) year of blood banking, required. Minimum one (1) year of supervisory experience, preferred. Previous management experience, preferred. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job Manager of Product Quality Control (MLS).

Senior Manager of Technical Operations (Carter BloodCare). The Senior Manager of Technical Operations (SMTO) provides leadership and oversight across Distribution/Hospital Services, Product Quality Control (PQC), Component Production, and Testing and Labeling departments in North, East, and Central Texas. The SMTO serves as a key operational leader with delegated authority from the Technical Director, ensuring continuity of operations, consistency of processes, and compliance with all regulatory standards. The SMTO directly supervises managers across all departments and locations, guiding daily operations, hiring, and developing staff, managing training programs, and ensuring high performance standards. In partnership with the Technical Director, the SMTO leads the implementation of departmental procedures, validations, and regulatory requirements. Periodic travel between assigned work areas in North, East and Central Texas is required. **Education:** Bachelor of Science Degree or related field. MT (ASCP), MLS (ASCP) or equivalent. **Experience:** Minimum of four (4) years of experience in blood bank management or supervisory position with an emphasis on inventory management and hospital services. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job Senior Manager of Technical Operations (MLS).

Reference Lab Manager. OneBlood is currently recruiting for a Lab Manager in our AABB-Accredited Immunohematology Reference Laboratory. This position provides leadership and technical expertise, manages staff, and performs training and quality activities for the staff responsible for performing basic through advanced

testing procedures on patient and/or donor samples. Applicants must have a bachelor's degree in medical technology, biological science or related scientific field from an accredited college or university. Five or more years in a clinical laboratory, preferably blood banking environment, or an equivalent combination of education, certification, training and/or experience. Applicants must have SBB certification, as well as a valid and current Florida Clinical Laboratory Supervisor license, or eligible, in Immunohematology or Blood Banking. To apply and view a complete Job Description of this position, go to www.oneblood.org and click on the **Careers** tab. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

Director of Laboratory and Technical Services. The Blood Bank of Alaska is looking for a Director of Laboratory and Technical Services. The Director of Laboratory and Technical Services is responsible for ensuring alignment of organizational goals and compliance with regulatory guidelines within the laboratory environment. This position participates as a member of the blood bank's management team in planning, program formulation and decision making with reference to the role, functions and technical support of the blood collection and processing operations throughout the Blood Bank of Alaska. Ensures all procedures are followed and promotes a positive work environment. This position is full-time exempt. The Blood Bank of Alaska offers competitive wages and an exceptional benefits plan. We offer medical, dental, vision, life, and short/long term disability programs to qualified employees. Paid time off (PTO), paid sick leave (PSL), holidays and a 401 (k) program are also available. The Blood Bank is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status or any other legally protected status. Interested candidates can please apply online at: <https://bloodbankofalaska.apscareerportal.com>. A complete job description can be found there as well.

Medical Director. Blood Assurance is seeking to fill a job opening for **Medical Director** based in our downtown Chattanooga home office. The Medical Director will provide medical and professional guidance to employees of the company and to area medical professionals. Minimum qualifications for consideration include: MD degree required; board certification or eligibility in pathology required (board certification must be secured within 1 year of hire); Transfusion Medicine board certification or eligibility preferred. Must be licensed to practice medicine in the states of our fixed facilities if required by that state (state licensure can be secured after hire). Blood bank management and advanced therapy experience preferred. Success in this role

(continued on page 12)

POSITIONS (continued from page 11)

will require advanced skills in all of the following areas: verbal and written leadership communications with a servant-leadership philosophy, staff management/development, customer service, conflict resolution, decision-making, strategic planning, collaborative teamwork, flexibility, and adaptability. Proficiency in making Board room presentations and resolving complex medical issues is also required. We offer many benefits including: Health/Dental/Vision Insurance, Flexible Spending Account, Employee Assistance Program for you and your family, Company Paid Time Off, 401K with Company Match, Wellness Program, and Relocation Assistance. Qualified candidates are encouraged to submit an online application for consideration at www.bloodassurance.org. Blood Assurance is an Equal Opportunity Employer and a Tobacco Free Workplace.

Hematology - Quality Control Specialist. Gulf Coast Blood is seeking a Hematology - Quality Control Specialist! This key role supports quality assurance by preparing and testing blood component samples to ensure safety and effectiveness for patients and hospitals throughout the Texas Gulf Coast region. It's ideal for detail-driven individuals who uphold high standards and contribute meaningfully to patient outcomes. Showcase your expertise by performing advanced quality control testing, managing lab operations in the absence of supervisors, and responding to critical situations such as positive bacterial cultures. You'll initiate recall procedures, track and trend QC results, train new hires, coordinate workflow, and recommend process improvements, all while ensuring compliance with lab standards and supporting patient safety. **Why join us?** We offer a competitive salary, full benefits, free parking at the Texas Medical Center, and opportunities for a sign-on bonus and relocation assistance to support a smooth transition. Enjoy professional development and career advancement opportunities while making a meaningful difference every day. **Qualifications:** MT/MLS certification (ASCP or equivalent) with at least two years of hematology experience. Flow cytometry experience is a plus. This role operates Monday through Friday, 7:00 AM to 3:00 PM. If you embody integrity, commitment, and respect, [apply now](#) and help make a difference!

Assistant Lab Manager, RRPL. Gulf Coast Blood is seeking an Assistant Lab Manager, RRPL! This key role leads operations in the Research and Recovered Product Laboratory, overseeing staff, blood component production, and research products to ensure quality, compliance, and timely delivery. Ideal for organized, detail-driven leaders who uphold high standards and contribute meaningfully to patient care and research. Lead the RRPL team to deliver high-quality blood components and research products while maintaining cGMP, AABB, and FDA compliance. Manage lab operations, optimize workflows, and allocate resources to meet client needs

and production goals. Serve as the primary liaison for internal systems, client communications, and quality audits, using data-driven insights to track KPIs and enhance productivity. **Why join us?** Competitive pay, full benefits, career advancement opportunities, and the chance to make a tangible difference in patient outcomes and research. **Qualifications:** Bachelor's in Biology, Chemistry, or related field with three years of lab or blood. Component manufacturing experience (plasma a plus). MT/MLS (ASCP or equivalent) strongly preferred. Minimum two years of supervisory or management experience. Strong knowledge of quality concepts, cGMP, AABB, and FDA regulations. If you embody Commitment, Integrity, and Respect, [apply now](#) to help save lives every day!

Medical Director (Miller-Keystone Blood Center (MKBC)). Are you a mission-driven leader seeking to integrate patient care with public health while improving work-life balance? Join MKBC, where we save lives daily by supplying blood to hospitals across Pennsylvania (PA) and New Jersey (NJ). As **Medical Director**, you'll lead clinical oversight for transfusion medicine and ensure the safety, quality, and regulatory compliance of our blood services. You'll guide donor eligibility, review protocols, supervise lab operations, advise on complex medical issues, and collaborate with hospitals and public health partners. You'll also support staff education, represent MKBC in professional forums, and provide executive leadership to promote excellence and innovation. **Requirements:** M.D. or D.O. with Board Certification in Clinical Pathology, Internal Medicine, or Hematology. Board Certified or Eligible in Transfusion Medicine. Five to seven plus years in healthcare with a focus in blood banking. Medical licensure in PA & NJ. Strong knowledge of AABB, FDA, CLIA, and cGMP standards. **Benefits include:** Medical/Dental/Vision, FSA, Life Insurance, Disability, PTO, Retirement Plan & more. Make a lasting impact—apply today to join our lifesaving mission and see the full position description here <https://hcsc.isolvedhire.com/jobs/1583606>.

Chief Scientific Officer. A national search is underway to recruit a recognized executive with exceptional vision and leadership abilities to become the next Chief Scientific Officer (CSO) of Gulf Coast Blood, headquartered in Houston, Texas. Reporting to the CEO, the CSO serves as the senior medical and scientific leader of Gulf Coast Blood. They are responsible for ensuring the highest standards in quality, clinical and operational excellence, and innovation across all laboratory and blood services, in addition to ensuring compliance with regulatory and accreditation standards. As a physician and strategic thought leader, the CSO drives the organization's quality and continuous improvement agenda while also serving as the medical expert to advise on future investments in the blood research investment fund which will advance

(continued on page 13)

POSITIONS (continued from page 12)

translational initiatives. The CSO also oversees the scientific coordination of research partnerships, leads the medical advisory committee, serves as a part of the diligence team, and champions laboratory strategy and performance. This role is instrumental in aligning operational excellence with a forward-looking research and innovation agenda that supports the mission to save and sustain lives. To be considered for the role, inquiries, nominations, and applications (detailed CV for now) should be submitted electronically in confidence, to: charlotte.fredericks@kornferry.com.

Medical Director. Central California Blood Center is seeking a Medical Director who shall work to promote the mission of Central California Blood Center (CCBC) while being responsible for overseeing the medical activities of the organization. This scope of duties will be accomplished within 20-25 hours per week remotely and/or in person at CCBC's headquarters in Fresno, Calif. The Medical Director oversees all processes and SOPs of CCBC relating to donor selection, eligibility, collection, processing, testing and distribution of blood products, donor safety and other roles guided or mandated by local, state, federal, and international regulatory agencies. Qualifications and skills: must be a Doctor of Medicine Degree or Doctor of Osteopathic Medicine Degree, with a license in good standing; must be licensed in the State of California with sub-specialty training in Hematology (IM) or Transfusion Medicine (Pathology); excellent verbal and written communication skills; must be proficient in Microsoft Office products and virtual meeting technology platforms; strong people skills; superior leadership skills; and superb judgment, problem-solving and cognitive skills. Learn more and apply [here](#). 💧