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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2022 #23 **June 24, 2022**

INSIDE:

Blood Community Sends Joint Letter to FDA for Update on HBV Testing Recommendations

America's Blood Centers, the Association for the Advancement of Blood & Biotherapies (AABB), and the American Red Cross submitted a joint letter to the U.S. Food and Drug Administration (FDA) this week to "request an update on the current testing recommendations for hepatitis B virus (HBV)." The letter recognizes recent efforts by the agency to make "evidence-based changes to regulatory requirements and recommendations" citing guidances for variant Creutzfeldt-Jakob Disease (vCJD) and CJD, donor blood pressure and pulse, and donation suitability, donor eligibility and source plasma quarantine hold requirements.

The blood community stated that "[c]onsistent with CBER's evidence-based updates to donor eligibility, we believe the hepatitis B surface antigen (HBsAg) testing requirement for whole blood and blood components intended for transfusion should be removed because HBsAg testing, is one of three tests currently required for HBV, and (1) does not increase transfusion safety; (2) is outdated, and (3) is overly burdensome because other required testing methods have proven to be highly effective in identifying HBV risk in donors for years."

Thus, the organizations requested that the FDA "consider the following information supporting the removal of the current HBsAg testing requirement. Currently, in the United States (U.S.) the risk of HBV transfusion transmission is reduced by testing all blood donations for three FDA-required markers: HBsAg (since 1971), antibody to hepatitis B core antigen (anti-HBc, since 1986), and HBV DNA by minipool nucleic acid testing (NAT, since 2006-2009). As judged by the absence of reported confirmed cases of HBV transfusion transmission, the policy has been successful."

The letter also references studies conducted in Europe and in the U.S. by the American Red Cross as further evidence for a change. It concludes that "another consideration is the growing use of FDA-licensed pathogen reduction technology (PRT) of platelets in the U.S.; platelets are most often transfused to immunosuppressed patients in whom low levels of HBV infectivity if such exists following screening, would be the most at risk, where PRT adds an additional layer of safety. Weighing the established evidence demonstrating the sensitivity of HBV NAT and anti-HBc testing of blood, we respectfully request the discontinuation of HBsAg testing of whole blood and blood components intended for transfusion in the U.S. We believe that the elimination of HBsAg testing is a first step in an ongoing dialogue of how to streamline the qualification of blood donations that maintains safety while eliminating unnecessary testing."

(Blood Community Joint Letter, 6/21/22) ♦

13 Members of Congress Sign Letter to FDA Regarding Temporary Donor Deferral Changes Made During COVID-19 Public Health Emergency

A June 22nd letter sent to U.S. Food and Drug Administration Commissioner (FDA) Robert Califf, MD included 13 signatures from members of Congress "urging" the FDA to make permanent the current temporary blood donor deferral changes, which were implemented during the COVID-19 public health emergency (PHE). The letter was led by Rep. Mariannette Miller-Meeks (R-Iowa).

America's Blood Centers (ABC) previously notified member blood centers on May 25th of the letter circulating within the U.S. House of Representatives and asked member blood centers to contact their members of the U.S. House of Representatives to request that they show their approval by signing the letter.

The final version of the letter specifically "urged FDA to finalize the revised recommendations to reduce the risk of transfusion-transmitted malaria and for reducing the risk of human immunodeficiency virus (HIV) transmission by blood and blood products, including source plasma, released April 2020. It noted that the agency's "guidance in effect under the COVID-19 Public Health Emergency (PHE) has prevented potential donors from being deferred and has allowed for thousands of individuals to re-enter [the] donor pool who had been previously deferred."

The letter explained that "[although the PHE is still in effect, blood centers are aware the existing guidance is tied to the PHE declaration, resulting in uncertainty about the future applicability of these guidance documents…Finalizing these guidance documents prior to the conclusion of the PHE will eliminate unnecessary uncertainty, allow blood centers to produce contingency plans should the temporary guidance not be replaced with permanent guidance, and avoid donor confusion. We urge FDA to finalize these important guidance documents that have safely expanded the donor base to assist blood centers in their essential job of ensuring all patients in need of lifesaving blood have a safe product available when needed."

Members of Congress who signed the letter included:

- Rep. Susan Wild (D-Penn.);
- Rep. William R. Timmons, IV (R-S.C.);
- Rep. Nancy Mace (R-S.C.);
- Rep. Marilyn Strickland (D-Wash.);
- Rep. Deborah K. Ross(D-N.C.);
- Rep. Jake Auchincloss (D-Mass.);
- Rep. Brian Fitzpatrick (R-Penn.);
- Rep. Rick Larsen (D-Wash.);
- Rep. Bruce Westermann (R-Ark.);
- Rep. Barbara Lee (D-Calif.);
- Rep. Don Bacon (R-Neb.); and
- Rep. Kat Cammack (R-Fla.).

Ensuring permanence of the guidance documents beyond the PHE is one of ABC's top three advocacy agenda issues. This letter directly addressed concerns raised by ABC member blood centers during the March 2022 Advocacy Day where individuals from ABC member blood centers virtually met with members of Congress and their staff. ABC thanks all members for their assistance with this advocacy initiative. For more information, please contact ABC's Senior Director of Federal Government Affairs Diane Calmus, JD.

(Source: Congressional Letter to FDA, 6/22/22)

CBER Issues Update to 2022 Guidance Agenda

This week, the U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) has published an updated guidance agenda for 2022. The agenda outlines the guidance and draft guidance documents that CBER "is considering for development" throughout the calendar year. The agency added a tissues and advanced therapies topic that was not included in the May announcement of the agenda:

- "Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial; Guidance for Industry."

Other topics of note that the agency intends to address that remain from the earlier announcement for blood and blood components include:

- "Alternative Procedures for Cold-Stored Platelets Intended for Transfusion Draft Guidance; for Industry;
- Collection of Platelets by Automated Methods; Guidance for Industry; and
- Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry.

The topics listed for tissues, advanced therapies, and vaccines of note included:

- "Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) – Small Entity Compliance Guide; Guidance for Industry;
- Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies; Draft Guidance for Industry and Staff;
- Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry;
- Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products; Draft Guidance for Industry; [and]
- Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridioides difficile* Infection Not Responsive to Standard Therapies; Guidance for Industry."

America's Blood Centers will continue to provide updates to member blood centers on its advocacy efforts regarding the CBER guidance agenda as they become available. Please contact ABC Director of Regulatory Affairs Jill Mastin with questions.

(Source: FDA Announcement, 6/22/22)

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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 recognize 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

The House passed legislation this week to create the Advanced Research Projects Agency for Health—modeled after a Pentagon entity for developing national security technologies. ARPA-H would fund applied research with short-term teams to solve major challenges, such as a vaccine to prevent most cancers. H.R. 5585 "would give Congress more power to oversee the new agency's structure, which is still in the early stages of development. The Biden administration proposed a $4 billion increase for ARPA-H in fiscal 2023, although congressional appropriators have expressed concern about a plan that pours billions into the new agency while leaving about a $270 million increase for the NIH over 2022."

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) is requesting comments on a "pilot program for sponsors of CBER premarket notification (510(k)) submissions that wish to use the voluntary Electronic Submission Template and Resource (eSTAR) Pilot Program. CBER's voluntary eSTAR Pilot Program is intended to improve consistency and efficiency in both industry's preparation and FDA's review of premarket notification (510(k)) submissions. During CBER's voluntary eSTAR Pilot Program, participants will have the opportunity to provide input to FDA on the eSTAR Pilot Program for submissions to CBER." The Comment period closes on August 22nd.

(Source: Federal Register Notice 6/21/22)

The FDA issued a draft guidance titled "Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies; Draft Guidance for Industry." The draft guidance "describes a standards recognition program for regenerative medicine therapies (SRP-RMT) at FDA's Center for Biologics Evaluation and Research (CBER) designed to identify Voluntary Consensus Standards (VCS) to facilitate the development and assessment of regenerative medicine therapy (RMT) products regulated by CBER when such standards are appropriate. The voluntary use of recognized VCS can assist stakeholders in more efficiently meeting regulatory requirements and increasing regulatory predictability for RMT products. The program is modeled after the formal standards and conformity assessment program (S-CAP) for medical devices." Comments on the draft guidance are due September 14th.

(FDA Draft Guidance, 6/16/22)

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste and published after editorial review. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 899-2621. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

RESEARCH IN BRIEF

Impact of Incorporating Whole Blood into Hemorrhagic Shock Resuscitation. A study published in the *Journal of the American College of Surgeons* "investigate[d] [the] survival benefit of whole blood (WB) across a diverse population of bleeding trauma patients." The authors explained that "[a]ll level-1 adult trauma patients transported to Memorial Hermann Hospital from November 2017 to September 2020 who received emergency-release, uncrossmatched products in the prehospital or emergency department setting

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RESEARCH IN BRIEF (continued from page 4)

were evaluated…Patients were divided into those who received any low-titer group O whole blood (LTOWB) (WB arm) and those who received only component therapy (COMP), consisting of red blood cells, plasma, and platelets…The coprimary outcomes of interest were survival to discharge and 24-hour blood product use. Secondary outcomes were transfusion reactions, acute renal failure, sepsis, respiratory failure, venous thromboembolic events (VTE), overall hospital-free days, intensive care unit (ICU)-free days, ventilator-free days, and blood product use by patient location…A total of 1,377 "patients received emergency-release blood in the prehospital and or emergency department setting (840 WB, 537 COMP)." The study found that "[r]eceiving WB during the course of resuscitation was associated with an odds ratio (OR) of 4.1 for 30-day survival ($p<0.001$)…In addition, WB transfusion was associated with a 60 percent reduction in 24-hour transfusion volumes…WB transfusion was also associated with a decrease in the composite outcomes of death or sepsis and death or acute respiratory distress syndrome (ARDS)." The authors noted that "[a]mong survivors, WB was associated with decreased hospital days and there were no differences in ventilator or ICU days…Transfusion-related acute lung injury (TRALI), transfusion-associated circulatory overload (TACO), and general transfusion reactions were uncommon and similar between the two groups." There was no difference in incidence of acute renal failure ($p=0.909$) nor a statistically significance difference in VTE ($p=0.428$). "In both settings (prehospital and inpatient), LTOWB transfusion was associated with a significant increased likelihood of survival (receiving only prehospital products: OR 3.73, $p = 0.002$; and receiving only inpatient products: OR 5.20, $p = 0.001$)." The authors concluded that "WB transfusion to resuscitate patients in hemorrhagic shock from major trauma is associated with a survival benefit that extends to 30 days in a large cohort…These patients receiving WB also require fewer component products later in the resuscitation."

Citation: Brill, J.B., Tang, B., Hatton, G., *et al*. Impact of Incorporating Whole Blood into Hemorrhagic Shock Resuscitation: Analysis of 1,377 Consecutive Trauma Patients Receiving Emergency-Release Uncrossmatched Blood Products, *J Am Coll Surg*. 2022.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The calendar of events includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!

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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 staff only, unless otherwise specified.

Webinar Recording and Slides Available: U.S.-Wide Red Blood Cell Antibody Exchange Project

A recording and slides of the May 10th America's Blood Centers (ABC) webinar on the "U.S.- Wide Red Blood Cell Antibody Exchange Project" are now available to ABC members. The webinar featured Jeanne Hendrickson, MD, medical director of the Apheresis Service and associate medical director of the Transfusion Medicine Service at Yale New Haven Hospital, providing background information and a status update on the project and its future direction. This project focuses on antibody exchange at the hospital level. ABC members can find the recording and slides in MCN 22-051. Contact us to receive a copy of the MCN.

Registration Opens for MD Workshop and Summer Summit

Registration is open for the ABC Medical Directors Workshop and ABC Summer Summit taking place August 2-4 in Minneapolis, Minn. A preliminary program is available. Over the course of two days, attendees will hear case study rounds, engaging discussions, and have many networking opportunities to connect with peers and colleagues. Hotel reservations can be made now through the ABC block until July 8th to receive the group rate.

MEMBER NEWS

Photo courtesy of San Diego Blood Bank.

San Diego Blood Bank recently held a ribbon-cutting ceremony to celebrate the opening of a ninth donation center. The new Chula Vista location replaces a temporary donation site that opened in December 2020 in Chula Vista's Terra Nova Plaza to help collect blood at the height of the pandemic. During the ribbon-cutting ceremony, the San Diego Woman's Club presented the blood bank with a check for $25,000 to support the needs of this new site. Speakers included San Diego Blood Bank Chief Executive Officer (CEO) Doug Morton and Sharp Chula Vista CEO, Dr. Pablo Velez. This new location is expected to collect more than 400 donations each month, potentially impacting more than 114,000 lives every year.

(Source: San Diego Blood Bank Announcement, 6/8/22)

We Are Blood opened a new location this week in Cedar Park. A public ribbon-cutting ceremony took place on June 22nd at the new donor center, which features "seven donor beds, including three for platelet donations, four for whole blood donors, [and] hand-painted murals by Austin, Texas artist Avery O. Houser," according to KVUE-ABC.

(Source: KVUE-ABC, We Are Blood opening Cedar Park location, 6/22/22)

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MEMBER NEWS (continued from page 6)

Rock River Valley Blood Center opened a new 8,7000 square foot donor center this week, according to WIFR-CBS 23. "We are proud to be a part of this community as the only local supplier of blood and blood products," said Lisa Entrikin, CEO of the Rock River Valley Blood Center to the news station. "We invite everyone to celebrate with us all year long and schedule a donation to honor the opening of this amazing facility and most importantly, save up to three lives… We are absolutely thrilled to be opening our new donor center in the same neighborhood we have been in since the 1960s. We feel a huge sense of community here and wanted to continue to be a convenient place for our dedicated donor base to visit. We were excited to recognize some of our top donors today by inviting them to be among the first to donate at the new facility."

(Source: WIFR-CBS 23, New RRVBC facility ready for donors in Rockford, 6/21/22)

OneBlood held a ribbon-cutting ceremony in Leesburg, Fla. to recognize the grand opening of a new donor center this month. The local Chamber of Commerce took part in the ceremony. The center located near the Leesburg International Airport previously held a "soft" opening prior to the official grand opening.

(OneBlood Announcement, 6/24/22)

PEOPLE

Javier Castillo has been named vice president of Marketing at San Diego Blood Bank. Mr. Castillo brings more than 15 years of marketing, design, and development experience to the organization, in addition to seven years of leadership experience in health and life sciences. He earned his Executive MBA from the Quantic School of Business and Technology with a focus on business, management, and marketing. In this role, he will oversee the blood bank's marketing and branding efforts while shaping its communications strategies to amplify their efforts.

(Source: San Diego Blood Bank Announcement, 6/22/22)

GLOBAL NEWS

NHS Blood and Transplant (NHSBT), the national blood provider for England and transplant services for the United Kingdom (UK) recently unveiled a new five-year blood service strategy as it celebrates its 75th anniversary for the blood service. The strategy includes "plans to recruit up to a million new donors and double the number of regular donors with the rarest blood types." NHSBT's four strategic priorities will be:

- "to use our expertise to save patient lives we will innovate and collaborate to develop and deliver a portfolio of components and services that meets the demands of our customers;
- to deliver great donor engagement and experiences, in order to grow and diversify our donor base to collect the right blood components to meet individual patient needs;
- to be the best at what we do, we will build a modern, resilient, and efficient integrated supply chain to deliver the right components, on time; [and]
- to ensure colleagues feel included and that everyone counts, we will invest in our people and culture."

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GLOBAL NEWS (continued from page 7)

Stephen Cornes, director of Blood Supply at NHSBT, added in a news release, "[c]urrently we can only meet around half of the demand for R_o blood through our existing donor base and demand for this rare blood type is rising. This means many sickle cell patients often receive less well-matched blood which, while clinically suitable, can pose a longer-term risk to patients who receive regular transfusions."

(Source: NHSBT News Release, 6/13/22)

The World Health Organization's (WHO) Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) issued an interim statement "on the composition of current COVID-19 vaccines." In the statement, the TAG-CO-VAC explained that "it may be prudent to pursue an additional objective of COVID-19 vaccination to achieve immune responses that both:

- elicit a greater breadth in the immune response against circulating and emerging variants, to enhance protection against these variants; and
- retain protection against hospitalization, severe disease and death, and protecting health systems.

As such, a modified COVID-19 vaccine composition may be warranted to broaden immune protection against divergent SARS-CoV-2 S protein antigens…available data indicate that the inclusion of Omicron in an updated vaccine composition is likely to be beneficial in populations that have already received a COVID-19 vaccination primary series… Importantly, the TAG-CO-VAC considers that the protection offered by an Omicron-specific vaccine product is likely to differ in those who have already received a COVID-19 vaccine primary series (primed), as compared to those who have not (unprimed). Based on the data to date, it is inferred that an Omicron-specific monovalent vaccine product administered as a booster dose for those who have already received a primary vaccine series may elicit greater breadth in the immune response."

(Source: WHO Interim Statement, 6/17/22)

COMPANY NEWS

BioMarin Pharmaceutical Inc. announced that its investigational gene therapy to treat adults with severe hemophilia A has received "a positive opinion recommending [it] for conditional marketing authorization" from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP). According to a company news release, the recommendation was based on data from multiple clinical trials "including two-year outcomes from the global GENEr8-1 Phase III study, supported by five and four years of follow-up from the 6e13 vg/kg and 4e13 vg/kg dose cohorts respectively, in the ongoing Phase I/II dose escalation study." BioMarin expects an approval decision from "the European Commission in [the third quarter of] 2022." The investigational gene therapy is a one-time infusion to be used in adult patients "without a history of factor VIII inhibitors and without detectable antibodies to adeno-associated virus serotype 5 (AAV5)." It is the first gene therapy to be "recommended for approval in Europe for [treating] hemophilia A."

(Source: BioMarin Pharmaceutical Inc. News Release, 6/24/22)

Vertex Pharmaceuticals Inc. and **CRISPR Therapeutics** reported new data from clinical trials of the companies' investigational gene therapy to treat patients with transfusion-dependent beta thalassemia (TDT) or severe sickle cell disease (SCD). According to a joint news release, data was presented on "75 patients (44 with TDT and 31 with SCD) with follow-up ranging from 1.2 to 37.2 months after [dosing]. Of the 44 patients with TDT, 26 had beta-zero/beta-zero or other beta-zero-like severe genotypes. Forty-

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COMPANY NEWS (continued from page 8)

two of 44 patients with TDT were transfusion-free with follow-up ranging from 1.2 to 37.2 months after [infusion]. Two patients who were not yet transfusion-free had 75 percent and 89 percent reductions in transfusion volume. TDT patients had substantial mean increases in fetal hemoglobin (HbF) and corresponding increases in mean total hemoglobin (Hb) with mean total Hb levels increasing to >11 g/dL by month three and maintained thereafter. All 31 patients with severe SCD characterized by recurrent vaso-occlusive crises (VOCs) (mean of 3.9 VOCs per year over the prior two years) were free of VOCs after [infusion] through duration of follow-up, with follow-up ranging from 2.0 to 32.3 months. SCD patients had mean HbF (as a proportion of total Hb) of approximately 40 percent by month 4 and maintained thereafter. The safety was generally consistent with myeloablative conditioning with busulfan and autologous stem cell transplant. All patients engrafted neutrophils and platelets after [infusion.] Among the 44 patients with TDT, two patients had serious adverse events."

(Source: Vertex Pharmaceuticals Inc. and CRISPR Therapeutics News Release, 6/11/22)

Emergent BioSolutions Inc. published results in *The Lancet Infectious Diseases* from a phase II clinical trial "valuating the safety and immunogenicity" of its investigational chikungunya virus vaccine candidate. The "two-year persistence data" reveals results from the randomized, double-blind, parallel-group study that took place in three sites within the U.S. and included 415 individuals. "Eligible participants were healthy chikungunya virus -naïve adults aged 18–45 years. The primary endpoint was the geometric mean titer of anti-chikungunya virus neutralizing antibody on day 57 (28 days after the last vaccination). Safety was also assessed. Emergent's vaccine candidate was well tolerated and induced a robust and durable serum neutralizing antibody immune response against the chikungunya virus up to two years. A single dose, 40 µg injection of adjuvanted [vaccine] is being further investigated in phase III clinical trials."

(Source: Emergent BioSolutions Inc. News Release, 6/21/22)

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.)*

2022

June. 29-30. **FDA CTGTAC Meeting (Virtual)**. More information available here.

July 19-20. **U.S. Department of Health and Human Services (HHS) Tick-Borne Disease Working Group Meeting**, **Washington, D.C.** More information available here.

Aug. 2-4. **ABC Summer Summit and Medical Directors Workshop**, **Minneapolis, Minn.** Registration is open. More information available here.

Aug. 29-30. **National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) and the Office of the of the Assistant Secretary of Health (OASH) of the Department of Health and Human Services (HHS) 2022 State of the Science in Transfusion Medicine Workshop (Virtual)**. More information coming soon.

Sept. 19-22. **American Association of Tissue Banks Annual Meeting, San Antonio, Texas.** More information available here.

Sept. 21-22. **28th IPFA/ Paul-Ehrlich-Institut[e] (PEI) International Workshop on Surveillance and Screening of Blood-borne Pathogens, Porto, Portugal.** Registration is open. More information available here.

Sept. 28-29. **2022 ADRP Master Class (Virtual).** More information coming soon.

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Sept. 28-29. **BEST Meeting LXIV, Cocoa Beach, Fla.** More information available here.

Oct. 1-4. **Association for the Advancement of Blood & Biotherapies Annual Meeting, Orlando, Fla.** Registration is open. More information available here.

Nov. 15-16. **The Biomedical Advanced Research and Development Authority (BARDA) Industry Day (Virtual).** More details available here.

2023

Mar. 6-8. **ABC Annual Meeting, Washington, D.C.** More information coming soon.

May 9-11. **2023 ADRP Conference.** More information coming soon.

Upcoming ABC Webinars – Don't Miss Out!

- **ABC Human Resources Forum Webinar** – June 28th from 2-3 PM EDT. More information coming soon.
- **The Clinical Laboratory Workforce: Understanding the Challenges to Meeting Current and Future Need-ASCP Blueprint Webinar** – July 20th from 3-4 PM EDT. More information coming soon.
- **ABC SMT Journal Club Webinar** – August 10th from 3-4 PM EDT. More information coming soon.
- **ABC HIPAA & Privacy in Blood Banking Webinar** – September 13 from 3-4 PM EDT. More information coming soon.
- **ABC Cybersecurity Threats & Mitigation for Blood Centers Webinar** – September 20 from 3-4 PM EDT. 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 institutional 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

EQUIPMENT AVAILABLE:

For Sale. New and Unused CompoMat G5 Units. The Blood Bank of Alaska has three new and unused CompoMat G5 Units for sale. These units have not been validated or used. If interested, please contact Bryan Baynard at bbaynard@bbak.org or (907) 222-5664.

POSITIONS

Manager, Component Manufacturing. The Manager, Component Manufacturing is responsible for the daily leadership and oversight of all manufacturing, labeling storage, and release of blood components, derivatives, and resale products. Establishes proper weekly production schedules to best meet local demand based on current inventory levels and hospital usage. Ensures operations in manufacturing are in compliance with all applicable Federal, State, AABB, OSHA and CLIA guidelines. Oversees the daily and monthly quality control program to ensure products and components are in compliance with established requirements. Responsible for the proper

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POSITIONS (continued from page 10)

labeling and release of all components based on established Standard Operating Procedures. Ensures team members provide the highest level of customer service to internal and external customers. **Education:** Four-year bachelor's degree (BA or BS) or equivalent. **Experience:** Three years laboratory experience in either Blood Banking or a Hospital. Management and/or Supervisory experience preferred. Please click here to view the full job description and apply.

Chief Administrative Officer (Shreveport, LA). LifeShare Blood Center is seeking an experienced human resources, risk management, or business administration professional as our Chief Administrative Officer (CAO). Reporting to the President & CEO, the CAO develops and administers Company-wide policies and practices to facilitate business operations and manage risk exposures; ensures compliance with applicable laws, standards and regulations governing various areas of responsibility; and provides executive leadership of human resources, safety, quality assurance, and information systems and technology functions. Please join us in our important mission to connect blood donors and the lives they impact! LifeShare offers a competitive beginning salary, commensurate with experience and a generous benefits package, including employer-paid medical, life and disability insurance; employer base retirement and matching contributions (6%) to the 401(k) savings plan, paid time off bank, and employee wellness program. Visit our Careers Page to apply.

Regional Operations Director (Baton Rouge, LA). LifeShare Blood Center is seeking an Operations Director to oversee blood collection and donor recruitment operations in the Baton Rouge, LA region. Relocation assistance may be available for the right candidate. The Operations Director will develop and implement strategic and tactical plans for donor recruitment and collections within the donor center and community-based activities; direct, develop and coach teams for achievement of established goals and KPI's; develop relationships with community leaders and groups to promote our mission and business needs; ensure operations adhere to standards and regulations governing the blood banking industry; and model LifeShare's mission and values, integrating them into daily decisions, behaviors and actions. **Join us in our important mission to connect blood donors and the lives they impact!** LifeShare offers a competitive salary, commensurate with experience plus incentive bonus opportunities, as well as a generous benefits package, including employer-paid medical, life and disability insurance; 401k with employer contributions (6%), paid time off bank, and employee wellness program. Visit our Careers Page to apply.

Clinical Laboratory Scientist Specialist. Ranked No. 5 in the nation by U.S. News & World Report, Children's Hospital Los Angeles (CHLA) provides the best care in California. Here world-class experts in medicine, education, and research work together to deliver family-centered care half a million times each year. Position Summary: The CLS Specialist functions as a licensed staff member performing duties approved by California Business and Professions Code, CLIA, and other regulatory agencies. Plan, coordinate, and lead all areas of Transfusion Medicine (TM) in activities related to quality and regulatory affairs. Review of all SOPs. Review of all validation plans. Review of all quality audits and other required assessments. Management of the overall deviation management program. Oversee the implementation and the interpretation of the effects of all new and revised standards and guidelines from regulatory and accrediting agencies on TM operations. Serve as the primary contact and liaison with all external regulatory and accrediting agencies. Maintain all licenses, registrations, and certifications required for TM. Education/Licensure: Bachelor's degree in Biology or related science required. Valid California CLS license required. SBB preferred. **Minimum Qualifications:** Five plus years of relevant experience. Prior experience performing quality functions and working with regulatory and accrediting agencies preferred. AABB assessor preferred. Please click here to view the full job description and apply.

Director of Quality. National Blood Testing Cooperative is now interviewing for a Director of Quality who through direct or delegated oversight, ensures financial feasibility, customer, and employee desirability of business decisions, strategic planning, development and execution of all quality systems for the Donor Testing Lab. Creates and fosters a collaborative environment in the organization that allows all employees to work together to further the mission and vision of the organization to ensure that the organization is increasing customer value, growing in a smart and efficient manner driving operational efficiency, inspiring the talent base, and continually reinventing the business. A BA in Life Science, nursing, or allied science discipline. Medical Technology (MT), Medical Laboratory Specialist (MLS), or at a minimum, Medical Lab Technology (MLT) certification preferred. Valid driver's license required. A minimum of two to four years Management/Supervisory experience with emphasis on employee development, performance evaluations, coaching and counseling and daily work management. Experience/involvement in strategic planning and execution. Minimum four to six years of Quality Assurance/Quality Management experience with emphasis on quality assurance, process design, error management, document control, auditing, licensure, and ensuring compliance. If you meet the above qualifications, please apply by sending your resume to: wendy@nationalbloodcollaborative.org. **EOE/AAE**

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POSITIONS (continued from page 11)

QRA Supervisor. Responsibilities: Quality Assurance/Training/ GMP/GTP/GLP: Lead the department's quality activities, initiatives, and process improvement activities. Perform training on QRA core functions and activities, Good Manufacturing Practice/Good Tissue Practice/Good Laboratory Practice, and safety. Compliance: Ensure compliance to current regulations and accreditation requirements by federal, state, county, and accreditation agencies. Team Leadership: Manage the performance of direct reports. Set team objectives, priorities, and resources to align staff with Blood Center objectives. Safety: Lead the safety, emergency, and disaster management of the organization. Quality Management System: Provide oversight on the appropriate use of the quality management tools in handling the various documents, records, and activities of the blood center. Registration and Licensure: Ensure all licenses, permits and certificates are current and regulatory requirements are met. Qualifications: Bachelor's degree required. One to two plus years supervisory experience in a regulated or GMP (Good Manufacturing Practice) required. Please click here to view the full job description and apply.

Medical Technologist – Overnight/Shift Differential. LifeSouth Community Blood Centers is currently seeking a skilled individual for a **Medical Technologist** position in our Immunohematology Reference Laboratory (IRL) in **Jacksonville, FL**. This position is responsible for performing and interpreting clinical laboratory tests that require the exercise of independent judgment. **We are looking to fill an overnight/third shift.** Starting salary range is $27.00 - $32.40 an hour. Shift differential of 15 percent – 20 percent may apply for working overnight hours. Applicants should apply here.

Director of Finance. LifeSouth Community Blood Centers is currently seeking an individual to join our team as the Director of Finance in Gainesville, FL. This position is charged with ensuring the stability of LifeSouth's finances through planning, directing, and controlling financial functions, including establishing appropriate control environments, financial reports for management on the company's financial status, preparing financial reports and analysis, and overseeing the development and implementation of effective financial and accounting systems. The selected candidate will also manage the Purchasing and Accounting departments. Applicants should apply here.

QA Specialist (R2216359) (Stanford Blood Center). Responsibilities: Cover the quality essentials and perform regulated tasks addressing organization, resources, equipment, supplier & customer issues, process control, document and records, deviations and adverse events, assessments, process improvement, and facility & safety. Assist in training appropriate personnel pertaining to QRA and safety activities. Ensure compliance to current regulations, accreditation standards, guidance documents and policies and procedures consistent with the latest releases of Code of Federal Regulations, California Code of Regulations, Health & Safety Codes, Business and Professions Code, AABB Blood Bank and Transfusion Services and College of American Pathologist accreditation standards including local Bills (Assembly and Senate Bills) and applicable County Directives. Perform regulated document reviews of standard operating procedures, forms, training plans, other pertinent documents, change controls, and validations. Also, review and monitor incident and deviation management through the different Quality Management System applications. Act as member of the safety committee member and perform designated roles as Emergency Response Team (ERT), Assembly Point Coordinator (APC). Facilitate external inspection conducted by inspectors. Qualifications: Bachelor's degree required. Three plus years to five years in blood banking, laboratory, or manufacturing with solid familiarity of GMP, safety in a manufacturing setup, and CAL-OSHA regulations required. Please click here to view the full job description and apply.