America's Blood Centers®
It's About Life.

ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

2024 #8 **March 1, 2024**

INSIDE:

Please Note: The *ABC Newsletter* will not be published on Mar. 8th. We will resume regular publication on Mar. 15th. Thank you for your continued interest.

ABC Comments to FDA Regarding 506J Guidance, Device List, & Additional Notifications

America's Blood Centers (ABC) submitted comments to the U.S. Food and Drug Administration (FDA) in response to the draft guidance titled "Select Updates for the 506J Guidance: 506J Device List and Additional Notifications." In the draft guidance, the agency, "propose[s] select updates to the FDA guidance document 'Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act' (506J guidance) [and] provides a proposed list of devices, by FDA product code, for which a manufacturer of such devices is required to notify FDA in accordance with section 506J of the FD&C Act (506J Device List)." Through the draft guidance, the agency seeks to, "clarify that manufacturers may submit, and FDA may receive, voluntary notifications regarding supply chain issues at any time, unrelated to the declaration or potential declaration of a public health emergency."

In the comments from ABC, the association urges the FDA to include devices used for the collection of blood products on the 506J Device List noting the important role in public health of devices that are used for the collection of blood products, "[as they] ensure life-supporting, life-sustaining, and emergency blood products are available when needed."

Also, ABC explained how supply chain challenges in recent years have, "threatened the availability of a robust blood supply. The limited number of manufacturers of whole blood and apheresis collection sets licensed in the U.S., the limited number of manufacturing sites for blood bags and collection kits they operate, and the location of these sites in geographically vulnerable areas combine to pose significant concerns to the entire blood community. In addition, throughout the pandemic, blood centers experienced supply chain shortages of blood tubes, pipette tips, and personal protective equipment necessary for collecting and manufacturing blood components. Blood collectors took numerous steps to mitigate the impact of these shortages on patient care…These changes ensured continued availability of blood components to serve patients, however, they also resulted in increased costs, staff time, and increased complexity within blood center operations. While the tactics differed, ensuring a safe and adequate blood supply was always paramount."

ABC provided the agency with a listing of devices used to collect products that should be included on the 506J list:

(continued on page 2)

ABC 506J Comments to FDA (continued from page 1)

"Subpart F – Automated and Semi-Automated Hematology Devices:

- 864.5200 Automated Cell Counter {GKL};
- 864.5600 Automated Hematocrit Instrument {GKF}; [and]
- 864.5620 Automated Hemoglobin System {GKR}.

Subpart H – Hematology Kits and Packages:

- 864.7825 Sickle cell test {JBB}.

Subpart J - Products Used in Establishments That Manufacture Blood/Blood Products:

- 864.9050 Blood Bank Supplies (pipettes, blood grouping slides, blood typing tubes and racks, cold packs for antisera reagents) {KSS};
- 864.9100 Empty container for the collection and processing of blood and blood components {KSR};
- 864.9125 Vacuum-assisted blood collection system {KST};
- 864.9145 Processing system for frozen blood (for both freezing and thawing red blood cells) {KSW};
- 864.9175 Manual blood grouping and antibody test systems {PBC};
- 864.9195 Blood mixing devices and blood weighing devices {KSQ};
- 864.9245 Automated blood cell separator (apheresis devices) {GKT};
- 864.9275 Blood bank centrifuge for in vitro diagnostic use {KSO};
- 864.9575 Environmental chamber for storage of platelet concentrate {KSH};
- 864.9700 Blood storage refrigerator and blood storage freezer {KSE};
- 864.9750 Heat-sealing device (also sterile docking devices) {KSD}; [and]
- 864.9875 Transfer set. {KSB}."

ABC will continue to provide updates on its advocacy efforts. Please contact ABC Director of Regulatory Affairs and Public Policy Justine Coffey JD, LLM with questions. An archive of ABC letters and comments is also available.

(Source: ABC Comments, 2/15/24)

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail.

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.

Healthcare Data Searches to Detect Unknown Transfusion-Transmitted Diseases

Researchers in *Lancet Digital Health* published their findings of a retrospective cohort study that aimed to explore if searches of both health-data registries and blood center databases could uncover previously undetected transfusion-transmitted diseases that put the blood supply at risk. They explained the development of a, "systematic algorithm for performing a phenome-wide search for transfusion-transmitted disease without consideration of any a-priori suspicion of blood-borne transmissibility." The authors used the algorithm in combination with the Swedish transfusion database (SCANDAT-3S), "to test for possible transmission of 1,155 disease entities based on all relevant diagnostic coding systems in use during the period." Their analysis included 1,720,000 patients who were recipients of 18,970,000 blood products from 1,040,000 donors from January 1968 to December 2017." The researchers noted that study population included, "all patients, irrespective of age, who were recorded to have received at least one red blood cell, plasma, platelet, or whole blood transfusion [and the study's analyses] were based on the premise that transfusion-transmission of a disease-causing agent would result in an increased disease risk among recipients of blood units from any donor who was a carrier of that agent. Transfusion-transmission could be identified using two independent analytical approaches: (a) by studying disease diagnosis concordance between donors and recipients or (b) by finding a shared increased disease risk among all recipients of a given donor, irrespective of whether that donor was diagnosed. "

According the authors of the study, "[t]he median follow-up was 4.5 (interquartile range (IQR) 0.9–11.4) years for recipients and 18.5 (8.3–26.2) years for donors. [They] found evidence of transfusion-transmission for 15 diseases, of which 13 were validated using a second conceptually different approach." The researchers further explained that, "[w]e compared the risk of each disease for patients who received at least one blood unit from a donor who was later affected by the same disease during follow-up with those who did not receive any blood unit from a donor affected by that disease. Patients were followed up from the date of the first transfusion until the date of first diagnosis of each disease, death, emigration, or until the last day of follow-up (Dec 2017). We excluded patients who had been diagnosed with the disease of interest before their first transfusion from the analysis for that disease…Of the 1,155 disease categories investigated, we identified statistically significant associations between the occurrence of disease in donors and an increased risk in recipients for 65 disease categories. After false discovery rate (FDR) adjustment, 15 of these associations remained statistically significant."

Specifically, the study found that, "[t]he strongest associations were observed for HIV (hazard ratio (HR) 6.83 [95 percent CI 2.50–18.62]; FDR-adjusted p value 0.018) and viral hepatitis (e.g., hepatitis B and C viruses), captured both as a diagnosis of chronic viral hepatitis (HR 6.31 [5.76–6.91]; FDR-adjusted p value 1.0×10^{-241}) and other acute viral hepatitis (HR 3.26 [2.31–4.61]; FDR-adjusted p value $1{\cdot}9 \times 10^{-9}$), as well as through downstream complications such as oesophageal varices (HR 1.37 [1.14–1.65]; FDR-adjusted p value 0.047)." Thus, the researchers stated that, "we failed to detect any strong evidence of unknown, widespread transfusion transmission beyond the expected findings of transmission of HIV and viral hepatitis. This reassuring finding indicates that it is unlikely that unknown transmissible agents exist in the Swedish blood donor pool that have a sufficiently high prevalence and clinical penetrance to result in widespread transfusion-transmission."

However, they also explained that the study, "observed some signals of transfusion-transmission for diseases that might warrant additional investigation. These diseases include unspecific outcome categories such as pneumonia (organism unspecified), other sepsis, and other gastroenteritis and colitis of unspecified origin, which all contain multiple different disease entities. Associations for these outcome categories were statistically significant, but with hazard ratios very close to one. Although speculative, it is possible that these associations are driven either by residual confounding factors or that the small excess risks are reflective of there being only a small fraction of events in these categories that were of a transmissible origin."

(continued on page 4)

Healthcare Data Searches to Detect Unknown Transfusion-Transmitted Diseases (continued from page 3)

Additionally, the authors explained that another association in their findings worth further exploration was, "tular[e]mia, caused by the bacteria *Francisella tularensis*, for which there have been sporadic reports of transmission in solid-organ transplants and evidence that the bacteria can invade erythrocytes, making transfusion-transmission plausible. This finding might warrant replication, especially due to the low number of events in the exposed group."

They concluded that, "[i]n this large-scale agnostic phenome-wide study of transfusion-transmitted disease during five decades, we did not find evidence for any novel transfusion-transmitted illnesses. Our study constitutes a proof-of-concept of an agnostic, data-driven, exploratory surveillance tool for transfusion-transmitted diseases. This approach might incite additional future efforts to improve input data quality, determine appropriate downstream confirmatory look-back and trace-back activities, and evaluate its effectiveness to improve safety of blood transfusions."

Citation: Dahlén, T., Jingcheng Zhao, J., Busch, M.P., Edgren, G. "Using routine health-care data to search for unknown transfusion-transmitted disease: a nationwide, agnostic retrospective cohort study." *Lancet Digital Health*. 2024.

RESEARCH IN BRIEF

A Computer Simulation: Mother and Child Life Years Gained Using Low Titer Group O Whole Blood (LTOWB). A study in *Transfusion* aimed, "to put the risk of future hemolytic disease of the fetus and newborn (HDFN) into the overall context of how to select the types of blood products provided in emergency situations." The authors explained that, "a more detailed understanding of the benefits of administering RhD-positive LTOWB compared with RhD-negative conventional component therapy (CCTs) to females of childbearing potential (FCPs) during their trauma resuscitation in terms of the number of FCP life years gained and the opportunity to have future pregnancies is required." They noted that, "[a] HDFN risk prediction model was modified to estimate the potential gain of life years following the administration of RhD-positive LTOWB compared with the administration of only RhD-negative CCT to FCPs during trauma resuscitation…[The] three factors to determine the effect on life years gained or lost by administering RhD-positive LTOWB [were]: number of FCP life years lost due to trauma assuming LTOWB provided a survival benefit over CCT, number of future child life years lost due to death of the FCP in trauma, and the number of life years lost due to future pregnancies affected by severe HDFN." For this study, "[t]he model simulated 500,000 FCPs of unknown RhD-status from 0 to 49 years who were resuscitated using RhD-negative conventional components…To simulate the survival benefits of transfusing RhD-positive LTOWB during trauma resuscitation, groups of patients, each with a different mortality relative reduction (MRR) of 0.1 through 25.0 percent compared with the absolute trauma mortality rates associated with CCT, were created…When the MRR for LTOWB was 25 percent, the largest increase in the average number of life years gained was when the patient received transfusion at age 0; this is because the surviving patients were gaining the maximum life years, as well as being able to have the expected number of pregnancies in the future." The researchers explained that, "[a]t an LTOWB MRR of >0.1 percent, the life years gained for the FCP and for her future children due LTOWB's survival benefit is >0, that is, greater than CCT; this indicates that even a small survival benefit from RhD-positive LTOWB compared to CCT results in a scenario where the life years gained from LTOWB transfusion outweigh the life years lost due to HDFN in future pregnancies." The authors emphasized that, "[w]hen RhD-negative LTOWB is not available, a life-saving transfusion should not be withheld from an injured FCP out of concern for causing HDFN in a future pregnancy."

Citation: Yazer, M.H., Leeper, C., Spinella, P.C., Emery, S.P., Horvath, S., Seheult, J.N. "Maternal and child life years gained by transfusing low titer group O whole blood in trauma: A computer simulation." *Transfusion*. 2024.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

PEOPLE

Don Campbell, MBA has been named chief operating officer (COO) of SunCoast Blood Centers. According to a blood center news release, Mr. Campbell has an, "extensive career in healthcare administration [and] brings a wealth of expertise and qualifications to his new role as COO. [He has] a master's degree in business administration, a master's in exercise science, and a bachelor's in biology. [H]is educational background equips him with a diverse skillset crucial to driving operational excellence. Additionally, his proven track record in healthcare leadership, most recently as Chief Executive Officer (CEO) of March Regional Blood Center in Kingsport, Tenn., highlights his ability to improve service delivery and achieve operational efficiency." SunCoast CEO Scott Bush added in the news release, "[a]s a firm believer in the power of unified purpose and understanding, Don is enthusiastic about contributing to SunCoast Blood Centers' legacy. [H]is commitment to cultivating strong relationships within the team aligns seamlessly with the organization's ethos of compassion, innovation, and service to the community, positioning us to thrive as our region grows." Mr. Campbell stated in the news release, "I am honored and excited to join the incredible team at SunCoast Blood Centers. I am committed to embracing the organization's values and working closely with the dedicated staff, donors, and partners to further advance our mission of saving lives. Together, we will continue to make a lasting impact on the Suncoast community."

(Source: SunCoast Blood Centers News Release, 3/1/24)

BRIEFLY NOTED

The Center for Infectious Disease Research and Policy (CIDRAP) at the University of Minnesota reported that the Center for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) voted in favor or recommending that adults 18 years of age and older receive the chikungunya vaccine if they are, "traveling to a country or territory experiencing an outbreak of the disease." The ACIP also added in their recommendation that, "use of the vaccine may be considered for certain people traveling to a country or territory where chikungunya has been known to circulate in the past five years. They include people older than 65, especially those with underlying health conditions who are likely to have at least moderate exposure to mosquitoes, and people who will be staying in affected areas for six months or more…[T]he group recommended chikungunya vaccination for lab workers who are potentially exposed to the virus." The U.S. Food and Drug Administration (FDA) approved Valneva's chikungunya vaccine, Ixchiq®, in November 2023.

(Source: *CIDRAP*, "Chikungunya vaccine recommended for U.S. travelers in outbreak settings," 2/28/24)

The CDC ACIP also has recommended that adults 65 years of age and older receive an additional dose of the updated 2023-24 COVID-19 vaccines. An agency news release stated, "[t]he recommendation acknowledges the increased risk of severe disease from COVID-19 in older adults, along with the currently available data on vaccine effectiveness…Data continues to show the importance of vaccination to protect those most at risk for severe outcomes of COVID-19. An additional dose of the updated COVID-19 vaccine may restore protection that has waned since a fall vaccine dose, providing increased protection to adults ages 65 years and older. Adults 65 years and older are disproportionately impacted by COVID-19, with more than half of COVID-19 hospitalizations during October 2023 to December 2023 occurring in this age group."

(Source: CDC News Release, 2/28/24)

America's Blood Centers®
It's About *Life.*

INSIDE ABC

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

2024 ABC National Partnerships User Guide Available

The 2024 National Partnerships User Guide is available. Designed to serve as a comprehensive resource to foster stronger collaboration between ABC's national partners and member blood centers, the guide outlines the exclusive member benefits offered by each national partnership and how these collaborations can help blood centers build on their important work. It also provides detailed contact information and a roadmap for initiating partnerships with organizations like HOSA Future Health Professionals, ValPak, iHeart Media, Johnson & Johnson, the Department of Veterans Affairs, and more. Please contact ABC Director of Strategic Communications and National Partnerships Jeff Gohringer for more information.

(Source: MCN 24-013, 2/21/24)

ABC SMT Spring Journal Club Webinar Articles Announced

The next ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar will take place on March 29th from 12-1 p.m. EST. The webinar is free to all ABC members. The articles to be discussed during the webinar include:

- Reevaluation of the medical necessity of washed red blood cell transfusion in chronically transfused adults (*Transfusion*);
- Restrictive or liberal transfusion strategy in myocardial infarction and anemia (*NEJM*); and
- Patient and caregiver perceptions of the possibility of home transfusions (*Transfusion*).

A registration link is available to ABC members in MCN 24-016. A Continuing Medical Education (CME) credit (1.0) is now offered for all ABC SMT Journal Club webinars.

Webinar Recording Available: Developing Leaders for Tomorrow & Employee Conflict Resolution!

A recording of the February 20th "Developing Leaders for Tomorrow & Employee Conflict Resolution!" webinar is available to ABC members. Featured speakers included Maria Brcka of LifeServe Blood Center and Stephanie Rue of SunCoast Blood Centers. The webinar aimed to be a useful resource for developing staff and strengthening professional interpersonal skills. Please contact ABC Director of Scientific and Technical Operations Betzy Gonzalez, MS, BB(ASCP) with questions.

(Source: MCN 24-014, 2/26/24)

Still Time to Register for 2024 ABC Annual Meeting

Registration remains open for the ABC 2024 Annual Meeting. The meeting will take place March 4th-6th in Arlington, Va. at the Ritz-Carlton in Pentagon City and the program features several exciting changes, including expanded content offerings and a new format. With a focus on advocacy, leadership, operations,

(continued on page 7)

INSIDE ABC (continued from page 6)

and science and medicine, the program will feature a mix of general and breakout sessions, external speakers, blood center-led case studies, committee and council meetings, networking events, and more. *Awards of Excellence* (AoE) winners will be recognized throughout the Annual Meeting and at a reception on Capitol Hill, where we can celebrate their achievements with fellow meeting attendees, members of Congress and their staff, our federal agency partners, Blood Advocacy Week partners, and more. Contact us with any questions.

Schedule Available 2024 ADRP Annual Conference

The schedule is now available for the 2024 ADRP Annual Conference. Register today! Join more than 400 blood center professionals in St. Louis, Mo. May 14th-16th at The St. Louis Union Station Hotel. This year's conference will feature keynotes Jason Kotecki, an expert at helping people "Escape Adulthood" in order to beat burnout and become more innovative and creative by breaking rules that do not exist, and Candy Whirley, a recognized motivational speaker, leadership, and team building expert. The 2024 ADRP Annual Conference is your opportunity to gain insights into industry trends, exchange ideas, and share information with your peers, while taking advantage of networking opportunities. Attendees will be able to participate in pre-conference workshops, educational sessions, roundtables, and have access to an expansive exhibit hall. Learn more about available exhibitor and sponsorship opportunities. Remember to book your hotel room by April 19th for the discounted rate. Please contact us with questions.

GLOBAL NEWS

The New Zealand Blood Service (NZBS) has **announced** **that the blood donor deferral for variant Creutzfeldt Jakob disease (vCJD) has been lifted officially as of February 29th.** An announcement on the NZBS website stated, "lived in the United Kingdom (UK), France or [Ireland] between 1980 and 1996, for six months or more? Well, the madness is over! As of [Thursday], the 'mad cow' (vCJD) blood donation criteria restriction in New Zealand has been lifted. You can now book an appointment to donate blood or plasma and start your lifesaving journey. We'd like to thank you for your patience and understanding while we prepared ourselves for this significant change." NZBS previously announced in November 2023 that the deferral change was coming in 2024.

(Source: NZBS Announcement, 2/29/24)

The Chief Executive Officer of the Australian Red Cross Lifeblood, Adj. Prof. Stephen Cornelissen AM, has published a statement identifying two new approaches that the blood provider has proposed to the Australian regulatory authority regarding individual donor assessments. In the statement, Prof. Cornelissen explains that, "[w]e want to propose donation options that allow as many people as possible to donate, including those with new or multiple partners and the tens of thousands taking PrEP, an antiretroviral medication to prevent HIV. To this end, we have been working towards two approaches. One would allow everyone, regardless of their sexual activity, including gay and bisexual men, and anyone taking PrEP, to donate plasma without any wait period at all through the 'plasma pathway.' The other sees people donating blood using what's called an individual risk assessment (IRA) or a gender-neutral approach, where all donors are asked the same questions regardless of their gender. Why two approaches and not just a gender-neutral approach as introduced in the [UK], Canada, and U.S.? Because under this approach, many people who can't donate under current rules in Australia would remain ineligible to donate blood and plasma. In the U.S., it is estimated that three quarters of the gay and bisexual population remain ineligible. We know we can do better in Australia by having a way forward that allows for both plasma and blood donations, and we can do it without [impacting] patient safety. It doesn't have to be an 'either/or' approach." Lifeblood also noted that, "[b]eing able to have these two approaches working side by side means

(continued on page 8)

GLOBAL NEWS (continued from page 7)

Australia would be the first country in the world to remove wait times for plasma donation for gay and bisexual men taking PrEP or having anal sex with new or multiple sexual partners, and have individual risk assessments for blood donation, under which gay and bisexual men having sex with only one partner in the three months prior would become eligible to donate blood. We acknowledge that gender-based sexual activity rules, whilst necessary to ensure a safe blood supply in the past, have contributed to the stigma faced by gay and bisexual men in Australia. This dual approach to blood and plasma donation offers the greatest opportunity for people to save lives — a common goal for both Lifeblood and advocacy groups — and is a world-first opportunity to change donation options for gay men without compromising the safety and quality of Australia's blood supply."

(Source: Lifeblood Statement, 12/27/23)

COMPANY NEWS

The U.S. Food and Drug Administration (FDA) has approved the biologics license application for **Roche Diagnostics**' Elecsys Anti-HBc II. According to the February 27th approval letter from the agency, "[the] Elecsys Anti-HBc II is an *in vitro* immunoassay for the qualitative detection of antibodies to hepatitis B core antigen (anti-HBc) in human serum and plasma. Elecsys Anti-HBc II is intended to screen individual human donors, including volunteer donors of whole blood and blood components. The assay is also intended to be used to screen organ, tissue, and cell donors, when donor samples are obtained while the donor's heart is still beating…The electrochemiluminescence immunoassay 'ECLIA' is intended for use with cobas pro serology solution equipped with cobas e 801 analytical unit."

(Source: FDA Letter, 2/75/24)

NEW on Coll*ABO*rate

COLLABORATE

SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

Recent discussion topics on the ABC Coll*ABO*rate Online Member Community include:

- Electronic Young Donor Parental Consent (MEMBER RESOURCES)
- Error Management and Error Tracking (MEMBER RESOURCES)
- FK Recent Voluntary Recall (COLLECTIONS & DONOR SERVICES)
- Equipment Software (QUALITY BYTES)
- Hepatitis A Outbreaks and the Hepatitis A Vaccination (QUALITY BYTES)
- BBCS and Hemoflows (QUALITY BYTES)
- Collecting Blood in a New State (QUALTIY BYTES)
- PPE for Distribution/Hospital Services (QUALITY BYTES)
- Topical Finasteride (MEDICAL ISSUES)
- One Dad Can — Sickle Cell Awareness (ALL MEMBER FORUM)
- LTOWB in Pre-hospital Transfusion (ALL MEMBER FORUM)
- Hospital Satisfaction Survey (ALL MEMBER FORUM)
- Hematology Proficiency Testing Program (TECHNICAL DIRECTORS)

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

- **ABC Scientific, Medical, and Technical (SMT) Spring Journal Club Webinar** – Mar. 29th. More information available to ABC members in MCN 24-016 including a link to registration..
- **ADRP Master Class** – Sept.18th-19th. More information is coming soon.

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

Mar. 4-6. **ABC Annual Meeting. Arlington, Va.** Registration is open. More information available here.

Mar. 7. **U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) Webinar: "Considerations for the Development of CAR T Cell Products."** Registration is open. More information available here.

Mar. 29. **ABC Scientific, Medical, and Technical Journal Club Webinar.** More information available to ABC members in MCN 24-016 including a link to registration.

April 11-12. **International Haemoviglance Network Symposium. Athens, Greece.** Registration is open. More information available here.

April 12-13. **BEST Meeting. Amsterdam, Netherlands.** More information is coming soon.

April 16-17. **International Plasma Protein Congress. Athens, Greece.** Registration is open. More information available here.

April 17-18. **ABC Quality and Technical Workshop. St. Louis, Mo.** Registration is open. More information available here.

May 3-4. **California Blood Bank Society (CBBS) Annual Meeting.** More information is coming soon.

May 14-16. **2024 ADRP Annual Conference. St. Louis, Mo.** Registration is open. More information available here.

May 15-16. **International Plasma and Fractionation Association/Paul-Ehrlich Institut[e] 30th International Workshop on Surveillance and Screening of Blood-borne Pathogens. Aarhus, Denmark.** Registration is open. More information available here.

June 7-8. **2024 South Central Association of Blood Banks (SCABB) Annual Meeting and Exhibit Show. Orlando, Fla.** More information is coming soon.

(continued on page 10)

CALENDAR (continued from page 9)

June 23-27. **38th International Society of Blood Transfusion (ISBT) Congress. Barcelona, Spain.** Registration is open. More information available here.

Sept. 4-6. **American Society for Clinical Pathology (ASCP) Annual Metting. Chicago, Ill.** Registration is open. More information is available here.

Sept. 18-19. **2024 ADRP Master Class.** More information is coming soon.

Sept. 30- Oct. 3. **American Association of Tissue Banks (AATB) Annual Meeting. Denver, Colo.** More information is coming soon.

Oct. 19-22. **Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting. Houston, Texas.** More information is coming soon.

2025

May 20-21. **International Plasma Protein Congress. Warsaw, Poland.** More information is coming soon.

Oct. 12-15. **AATB Annual Meeting. Atlanta, Ga.** More information is coming soon.

Oct. 25-28. **AABB Annual Meeting. San Diego, Calif.** 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

Manager of Donor Resources. The Blood Connection is seeking a Manager of Donor Resources for our operations based out of Roanoke, Va. and Augusta, Ga. These positions will be responsible for monitoring progress to goal proactively, and effectively coaching and managing their team to success. The ideal candidate for these positions possesses strong leadership and organizational skills with a proven ability to meet organizational goals. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community! *Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Donor Resources – Roanoke, VA. Manager of Donor Resources – Augusta, GA.

Manager of Donor Services. The Blood Connection is seeking a Manager of Donor Services for our operations based out of Raleigh, NC. This position will oversee donor collection operations within their assigned divisional territory. This position will provide leadership and discipline to direct reports, interviews, and hires staff, and ensures staff are appropriately trained. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community! *Prospective*

(continued on page 11)

POSITIONS (continued from page 10)

candidates may be eligible for relocation assistance. How to apply: Manager of Donor Services – Raleigh, NC.

Director, Quality Assurance & Regulatory Affairs (Hoxworth Blood Center). The University of Cincinnati College of Medicine (COM) has a reputation for training best-in-class health care professionals and developing cutting-edge procedures and research that improves the health and clinical care of patients. Hoxworth Blood Center (HBC) is located within the College of Medicine and is the only Regional Blood Center owned and operated by a University in United States. The HBC is seeking a Director of Quality Assurance & Regulatory Affairs. This position will oversee and direct the coordination of quality assurance and regulatory compliance for the Cellular Therapy, Therapeutic Apheresis, and Transplantation Immunology divisions. Required Education & Experience: Bachelor's degree in Medical Technology, Biology, Chemistry, or related field. Seven (7) years of experience in a clinical laboratory, blood banking or other related experience. Additional Qualifications Considered: Previous experience in a FACT, AABB and HCT/P (21 CFR 1271) and GMP (21 CFR 211) for Phase I/II clinical manufacturing, Regenerative Medicines, Cleanrooms, and Aseptic Processing is ideal. Understanding of CAP requirements for histocompatibility (HLA) laboratories which includes disciplines of sequencing, molecular, serological, immunology, flow cytometry, and cellular analysis is preferred. For full description and to apply, visit https://bit.ly/489l7Gl. The University of Cincinnati is an Equal Opportunity Employer.

Division Director, Core Operations (Hoxworth Blood Center). Hoxworth Blood Center is recruiting for Division Director, Core Operations, to provide leadership, vision, and oversight of programs related to donor center core operations, including Biomedical Engineering, Materials Management, Physical Operations, and computer software informational systems. Experience in daily production of cleanroom environments, as well as recruitment and training of new employees with knowledge in cleanroom environment and regulatory framework in accordance with cGMP, FDA, and ISO regulations pertinent to the environmental control in ISO7/8 facilities is crucial. Enforce current strategic planning initiatives; develop new activities and establish goals in support of blood center strategic plans. Direct and facilitate cross functional activities that support the interdepartmental communications, productivity, and quality between various operating units. Develop innovative processes for monitoring operations to ensure high quality customer service and successful delivery of outputs. Required Education and Experience: Bachelor's Degree in related field of healthcare, biological or computer sciences. Seven (7) years of relevant experience in equipment management, computer and software information systems, blood banking, biotherapies, transfusion medicine, or scientific research. Three (3) years of direct supervisory experience managing employees, teams, and assets. For full description and to apply, visit: https://bit.ly/3OHlZet. The University of Cincinnati is an Equal Opportunity Employer.

Quality and Regulatory Services Manager. The Quality and Regulatory Services Manager reports to the Director of QRS and is responsible for the quality and regulatory affairs, duties, and responsibilities by reviewing department procedures, forms, training documents, product and equipment quality control (QC), change control processes, and validations, and assist with the development, as necessary. Reviews applicable regulations and standards from FDA, AABB, CLIA, OSHA, NRC, State of Tennessee, and manufacturers to ensure compliance. Personnel Training: Perform Good Manufacturing Practice (cGMP) and safety training and assist in inter-departmental training and competency evaluation. Maintain compliance by enforcing applicable regulations and standards set by regulatory agencies and submit appropriate reports when required. Document Control: Maintain proficiency in Document Control within MediaLab. Able to revise and create SOPs, Forms, and Job Aids. Create, perform, and review validations. Manage the overall deviation management program to include investigation, root cause, analysis, corrective and preventative actions, and documentation. Responsible for developing, tracking, monitoring, and reporting quality indicators. Monitor and conduct trend analysis of quality indicators. Process improvement, including change control and corrective/preventative actions. Please click here to view the full job description and apply.

Medical Laboratory Technologist. The Medical Laboratory Technologist will report to the Manager of Technical Services and is responsible for performing lab procedures such as compatibility testing, reference lab work, specimen processing, test performance, and reporting test results. They also may perform computer aided labeling, component production, and distribution. They will be responsible for the maintenance and storage of blood components including temperature monitoring, labeling of blood, biohazard disposal, component preparation, daily orders, blood shipments and returns. The laboratory duties will include qualifications of Apheresis Platelets and Plasma, lot release, blood grouping, compatibility testing, antibody detection and emergency release of products. The distribution duties will include daily orders, blood shipments and returns, shipping recovered plasma, resource management, irradiation of blood products. Please click here to view the full job description and apply.

(continued on page 12)

POSITIONS (continued from page 11)

Donor Recruitment Manager. Blood Assurance is seeking a Donor Recruitment Manager to lead field recruitment efforts that build new and existing business in our Chattanooga and North Georgia 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 five 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, 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 Environment.