America's Blood Centers®
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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2024 #9 **March 15, 2024**

INSIDE:

OIRA Reviewing LDT Final Rule

The "Medical Devices; Laboratory Developed Tests" final rule is currently being reviewed by the White House Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB). The draft regulation previously announced by the U.S. Food Drug Administration (FDA) in a proposed rule released in September 2023 explicitly stated that *in vitro* diagnostic products (IVDs) are medical devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory. In addition to this change, the agency proposed a policy under which the FDA intends to provide greater oversight of laboratory developed tests (LDTs), through a phaseout of its general enforcement discretion approach to LDTs, so that IVDs manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs.

America's Blood Centers responded to the proposed rule in comments submitted to the FDA in December 2023 that outlined four areas of concern including:

- "LDTs developed by blood establishments are not associated with the type of safety concerns FDA is addressing with this rule;
- many LDTs developed in a blood center's lab are 1976-Type LDTs and/or are developed with a high level of standardization across institutions;
- blood centers' LDTs are comparable to Human Leukocyte Antigen (HLA) tests. FDA should apply general enforcement discretion to all HLA tests and blood center's LDTs; [and]
- the impact [of the LDT regulation] on patient access; [explaining that] blood centers' LDTs are extremely safe and effective under the current framework and do not have a history of safety issues. Blood centers and hospitals are required to report adverse events to FDA. The safety record of these tests is well-documented in this reporting system, and a mechanism exists to resolve any safety issues that are potentially identified."

Sen. Bill Cassidy, MD (R-LA.), ranking member of the Senate Health, Education, Labor, & Pensions (HELP) Committee, issued a request for information (RFI) on March 13th regarding reforms to diagnostics regulations including LDTs. "In the past, Congress has considered proposals to bring needed reforms to diagnostics regulation. These efforts have been unsuccessful and have resulted in missed opportunities to implement substantive updates to both regulatory frameworks. To further guide ongoing discussion of these matters, I welcome your insights on the following topics, specifically addressing the actions Congress should pursue to meet the challenge of ensuring patient access to timely and advanced diagnostics." Responses are due by April 3rd. Reps. Cathy McMorris Rodgers (R-Wash.), chair of

(continued on page 2)

LDT Final Rule (continued from page 1)

the House Energy and Commerce Committee, and Brett Guthrie (R-Ky.), chair of the Subcommittee on Health, announced that a hearing is scheduled for March 21st to, "discuss the FDA's proposed rule to regulate LDTs and alternative approaches to diagnostic regulation."

ARUP Laboratories, a national reference laboratory, conducted a survey of its customer contacts and announced results of a survey, that included more than 500 responses, in a news release that included a link to preprint (non-peer reviewed) paper. Findings included, "[a] total of 83.9 percent of respondents believe the proposed rule will negatively impact their laboratories; nearly 61 percent of participants said they would likely remove tests from their laboratory menus if the proposed rule is enacted, and an additional one-third of respondents are not yet sure what they would do."

OIRA is, "the U.S. Government's central authority for the review of Executive Branch regulations, approval of Government information collections, establishment of Government statistical practices, and coordination of Federal privacy policy."

(Sources: OIRA Announcement, 3/1/24; Sen. Bill Cassidy RFI, 3/13/24, House Energy & Commerce Subcommittee on Health News Release, 3/14/23)

BPAC Meeting Set to Discuss Mitigation Strategies for Malaria TTIs

The U.S. Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC) will hold its next meeting on May 9th from 9:30 a.m.- 3:10 p.m. (EDT). According to the March 11th announcement, the virtual meeting will be livestreamed as the committee, "discuss[es] strategies to reduce the risk of transfusion-transmitted malaria by testing blood donations from donors at risk of malaria exposure."

Meeting materials will be made available by the FDA, "no later than 2 business days before the meeting." The agency also noted that, "[i]nterested persons may present data, information, or views, orally or in writing, on issues pending before the committee. FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2024-N-0948, [and it] will close on May 8th. Comments received on or before May 2 will be provided to the committee. Comments received after May 2nd and before the May 8th deadline will be taken into consideration by the FDA." Please provide feedback to ABC Director of Regulatory Affairs and Public Policy Justine Coffey, JD, LLM by March 25th.

(Source: FDA Announcement, 3/11/24)

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

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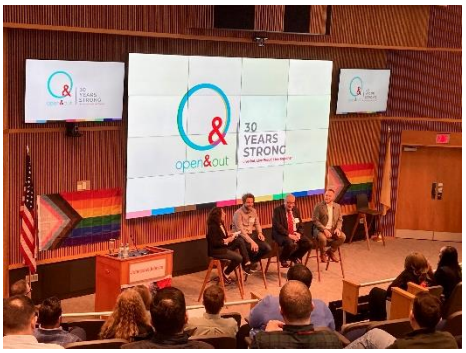
ABC Takes Part in Johnson & Johson Summit



Representatives from America's Blood Centers (ABC) and New York Blood Center Enterprises (NYBCe) participated in Johnson & Johnson's Open&Out Summit this week. The event, organized by Open&Out, Johnson & Johnson's Employee Resource Group, brings together Lesbian, Gay, Bisexual, & Transgender+ professionals and allies who are committed to making a positive impact in both the workplace and the community.

During the summit, Jeff Gohringer, director of Strategic Communications and National Partnerships at ABC, and Eric Senaldi, MD, Deputy Chief Medical Officer at NYBCe, took part in a panel discussion on the U.S. Food and Drug Administration's (FDA) groundbreaking shift toward individual donor assessments. Additionally, Nate Frueh, Information Technology Lead at Johnson & Johnson, shared his experience of donating blood for the first time in many years following the implementation of the new eligibility guidelines. The panel also took questions from a global audience and encouraged those in attendance to contact their local blood center and make an appointment to give blood.

Throughout the event, members of Johnson & Johnson's blood program, in collaboration with ABC and NYBCe, hosted a booth to further educate attendees about the recent changes and address common donor questions. Attendees expressed their support for these new guidelines by signing a postcard to the FDA, thanking the agency for taking this proactive step while also advocating for additional science-backed changes to further promote equity in the blood donation process. Since ABC began its partnership with Johnson & Johnson in 2021, ABC members have organized blood drives at various company facilities nationwide, resulting in over 2,000 blood donations and saving up to 6,000 lives. Johnson & Johnson also sponsored the development of ABC's and ADRP, the Association for Blood Donor Professionals' Vein-to-Vein education program, which is being used in classrooms across the country to raise awareness about the significance of blood donation and inspire high school students to help build the next generation of lifelong blood donors.

Contributed by Jeff Gohringer, Director of Strategic Communications and National Partnerships at ABC

PEOPLE

Derek Tyus, MBA has been named executive vice president (EVP) and chief financial officer (CFO) at Versiti, Inc. According to an announcement from the organization, he will, "provide leadership of the finance, information services, continuous improvement, facilities, supply chain, and corporate business development functions for Versiti. He succeeds current EVP and CFO, Tony Watkins, who is retiring after 10 years with the organization." Mr. Tyus has a degree in Accounting from Marquette University and completed his MBA at the University of Michigan Ross School of Business. He most recently, "served as the senior vice president and chief investment officer for West Bend Mutual Insurance from 2016 to 2024 and worked for Northwestern Mutual Insurance in several leadership positions from 2005 to 2016." Versiti President and Chief Executive Officer Chris Miskel, MBA, added in the news release, "Derek's extensive experience providing financial and strategic leadership in a variety of settings will be a significant asset to Versiti and the communities we serve. He is a proven leader and as a member of our Executive Leadership Team, Derek's combination of emotional intelligence (EQ), IQ, and strong cultural fit will help fuel our continued growth." Mr. Tyus stated in the news release, "I am thrilled to be joining this outstanding and dynamic team at Versiti. I am very much looking forward to contributing my expertise and collaborating with everyone to drive success of the organization's mission."

(Source: Versiti News Release, 3/14/24)

STATE ADVOCACY BRIEFS

On March 5th, the Connecticut General Assembly introduced a bill in the Senate (SB 368) that would, "require the Commissioner of Public Health to (1) adopt regulations allowing source plasma donation centers to (A) designate physicians as directors of such centers, and (B) collect source plasma through plasmapheresis, provided such centers comply with federal laws and regulations governing source plasma collection; and (2) update the department's policies and procedures concerning source plasma donation centers." A public hearing on the bill took place on March 13th.

On March 4th, the State of Rhode Island General Assembly introduced House Bill H7881. The legislation, titled "An Act Relating to Health and Safety — Blood Donations and Vaccinations Act," would require that the person collecting blood for transfusion make blood donors disclose "whether [they have] received a COVID-19 vaccine or messenger ribonucleic acid vaccine during the donor's lifetime. Blood originating from a donor who has received a COVID-19 vaccine or messenger ribonucleic acid (mRNA) vaccine shall be conspicuously marked and/or labeled. [Additionally,] a person receiving a blood transfusion shall have the right to request blood based on whether or not the blood originated from a person who has received a COVID-19 vaccine or a mRNA vaccine and to refuse any such transfusion if the blood originates from any person who has, or has not, received a COVID-19 vaccine or messenger ribonucleic acid vaccine, provided that the patient's preferred choice is available."

The Missouri General Assembly introduced companion bills in the House (HB 2759) and Senate (SB 1429) that would require a blood bank to, "test or have tested donated blood for evidence of any COVID-19 vaccine or any other mRNA vaccine components, including evidence of lipid nanoparticles and spike protein from a vaccine. If blood tests positive for evidence of a COVID-19 vaccine or any other mRNA vaccine components," the container of blood or blood components must be labeled to include "a designation of such positive status" and the person receiving the transfusion has the right to refuse the blood.

On February 22, the Iowa House of Representatives introduced a bill (H.F. 2628) that would expand the sales and use tax exemption allowed for nonprofit blood centers. "The bill provides that tangible personal property or specified digital products sold or any services furnished are exempt from sales and use tax if sold or furnished to a blood collection and processing establishment."

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)

ABC members are encouraged to login and join the conversations today!

RESEARCH IN BRIEF

Estimated Median Density Identifies Donor Age and Sex Differences in Red Blood Cells. A study in *Transfusion*, "aimed to establish an approach for assessing the median biological age of red blood cells (RBCs) in blood products using density analysis and to use this approach to understand RBC biological aging with respect to donor age and sex." The authors noted that, "[s]ixty red cell concentrates (RCCs) were produced." For this study, "[t]eenage (17–19 years old, n = 30) and senior (75+ years old, n = 30) donors were separated by sex" with 15 in each group. The researchers explained that, "Percoll density gradient centrifugation was performed (Days 5, 14, 28, and 42)…A panel of eight solutions ranging in Percoll density from 1.083 to 1.107 g/mL and based on initial mean corpuscular hemoglobin (MCHC) values was utilized, allowing [the study] to isolate portions of young, less-dense RBCs from old more, dense RBCs…Notably, no donors within the female groups fell within the range designated high estimated median densities (EMD)." The study found that, "[d]onors within the teenage male group were consistently within the high EMD range…A sex-stratified analysis of EMD, on the other hand, established there were significant differences between males and females, with the median EMDs of male donors post-donation being significantly elevated at Day 5 ($p = .0005$), 14 ($p = .0324$), and 28…In an age-combined analysis, a strong positive correlation between MCHC and EMD was only observed with senior donors ($R2 = 0.78$)." The authors stated that, "[t]his study introduced further evidence for age and sex specific differences in RBC density throughout storage…Subsequent estimation of the EMD of RCCs, a surrogate for biological age, was found to not only vary among individual blood donors but shift over time with storage." They also added that, "[t]he interconnectedness of donor characteristics and their influence on hematological parameters is systematically unraveling, with MCHC being an example of a measurement highly influenced by donor factors such as age due to hormonal fluctuations decreasing." The researchers concluded that, "this study demonstrates the growing necessity to understand the transferability of these findings by labeling RBCs in vivo based on their biological age to determine the 24-h survival in circulation."

Citation: Mykhailova, O., Brandon-Coatham, M., Durand. K., Olafson, C., Xu, A., Yi, Q.L., Kanias, T., and Acker, J.P. "Estimated median density identifies donor age and sex differences in red blood cell biological age." *Transfusion*. 2024.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

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.

America's Blood Centers®
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INSIDE ABC

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

Meet Us in St. Louis for the ABC 2024 Quality and Technical Workshop!

Registration remains open and time is running out to book your room in the Live! by Loews Hotel for the 2024 America's Blood Centers (ABC) Quality and Technical Workshop. Check out our program as this year's workshop is centered around highlighting collaboration amongst blood banking professionals to allow for an exchange of innovative ideas and best practices. Sessions have been developed to emphasize the important topics that are affecting you and your blood center. The workshop will feature experts in their field presenting topics that include implementation of new devices and blood products, regulatory and licensure round tables, and peer to peer strategic discussions to name a few. Don't miss out on the opportunity to network with your peers and gain greater insights into the challenges that the blood industry is facing now.

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)

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

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INSIDE ABC (continued from page 6)

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.

MEMBER NEWS

Winter Haven Hospital Community Blood Center (WHHCBC) is transitioning its operations to **OneBlood**, according to a news release. The announcement explained that, "[a] complete rebranding of WHHCBC will begin immediately." Tom Garthwaite, president of Winter Haven Hospital and Winter Haven Women's Hospital, added in the news release, "the time is right for the blood center to take this step and OneBlood is the right partner. When we considered all factors, we decided OneBlood is better positioned to collect and distribute blood products for our hospitals. Having a unified approach to the blood supply for the entire BayCare Health System will allow us to provide safe, available, and affordable blood even more effectively and efficiently for the patients we serve." George "Bud" Scholl, president and chief executive officer of OneBlood, stated in the news release, "OneBlood has a long-standing partnership with BayCare Health System. We welcome the opportunity to increase donor outreach in the Winter Haven area and further ensure a safe and available blood supply for the entire BayCare Health System and their patients."

(Source: BayCare News Release, 2/27/24)

To celebrate Women's History Month, **Bloodworks Northwest** published a blog post recognizing, "10 pioneering women in transfusion medicine." Written by Helen Pitlick, manager of communications at Bloodworks Northwest, the female physicians and researchers whose impact on blood banking are described include:

- Winifred Mayer Ashby, PhD;
- Jane F. Desforges, MD;
- Marilyn Hughes Gaston, MD;
- Eloise 'Elo' Giblett, MD;
- Judith Graham Pool, PhD;
- Helen Ranney, MD;
- Clarice Reid, MD;
- Lucy Wills, LRCP;
- Rosalyn Yalow, PhD; and
- Dorothea Zucker-Franklin, MD.

(Source: Bloodworks Northwest, "10 women hematology pioneers, 3/4/24)

GLOBAL NEWS

The Hungarian National Blood Transfusion Service (HNBTS) has replaced its last "high-activity cesium-137 (Cs-137) blood irradiators with X-ray technology." The U.S. Department of Energy's National Nuclear Security Administration's (NNSA) Office of Radiological Security (ORS) funded, "four new X-ray blood irradiators and facility modifications for operating the new devices. HNBTS paid for removal of the disused cesium source and device and their transport to a secure facility," explained a NNSA news release. "The partnership began in 2020 when ORS initiated discussions with the Hungarian Atomic Energy Authority (HAEA) about the replacement of its Cs-137-based blood irradiators with X-ray technology. Subsequent discussions led to an agreement to replace all the Cs-137 blood irradiators with X-ray devices…In addition to eliminating radiological risks posed by Cs-137, these X-ray irradiators offer increased capacity to irradiate blood products in a shorter amount of time." NNSA added in the news release that, "ORS's work in Hungary and across the globe directly supports the U.S. National Security Strategy, which calls for the United States to lead the world in coordinated efforts to lock down nuclear and radiological materials and prevent terrorist acquisition."

(Source: NNSA News Release, 3/6/24)

NHS Blood and Transplant (NHSBT), the national blood provider for England and transplant services for the United Kingdom (UK), recently debuted its initial virtual reality (VR) training app. According to a news release from NHSBT, the VR training app named NHSBT Blood Identification, "realistically simulates the process of testing blood for lifesaving blood transfusions." The app, created by Make Real, is available in the Meta Quest App Lab store and is being used at NHSBT facilities. The news release explained that, "During this immersive training progra[m], users meet a patient and enter a virtual transfusion laboratory. Just as in real life they will be guided through the process required to test the blood group of a sample and select the correct unit of blood for a blood transfusion. The user then gets feedback on the outcome of the transfusion. If the wrong blood is given in error, the trainee sees the red cells bursting and the heart monitor goes flat. The app aims to give training an engaging, hands-on environment. It also aims to increase awareness of the transfusion science specialism and boost the recruitment of scientists to the profession. NHSBT also recommends the app to secondary schools, colleges and universities to help inspire young people to take up careers in transfusion science…Over the course of 14 minutes, users meet a patient, then enter a virtual laboratory where they test a sample of their blood by selecting reagents, mixing them and checking to see if the cells clump together. They then select a unit of blood and hang it by the patient bedside for transfusion. The handset realistically recreates the sense of holding items such as the pipettes."

(Source: NHSBT News Release, 2/27/24)

Estonia has announced a shift to individual donor assessments. As of January 2024, "the donor questionnaire and selection criteria [is now] the same for all donors, regardless of gender or [sexual] orientation, according to a report from *Eesti Rahvusringhääling* (*ERR*), Estonian Public Broadcasting. "[T]he Estonian Society of Transfusion Medicine (ETMS) in collaboration with Estonian blood banks, conducted a risk assessment based on European Medicines Agency (EMA) methodology, taking into account the prevalence of blood-borne infections in the target population and the sensitivity and specificity of the testing methods used by the blood banks to screen donors. The results of the risk analysis showed that the addition of men who have had sexual contact with another man to the blood donor population increases the residual risk to some extent, but does not change the overall risk estimate for blood-borne viruses (HIV, hepatitis B virus

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GLOBAL NEWS (continued from page 7)

(HBV) and hepatitis C virus (HCV))…Sex work, casual sex and a new sexual partner will continue to be classified as sexual risk behaviors, disqualifying a potential donor from donating blood for a period of four months."

(Source: *ERR*, Estonia drops final extra restrictions on men's blood donations, 1/3/24)

COMPANY NEWS

InVita Healthcare Technologies recently announced that it will partner with three blood centers to develop a solution for "managing advanced therapies, including cell and gene therapy." According to the company news release regarding the new offering, [it] will focus on receipt, processing, preservation, and infusion. Over time the offering is expected to expand to mirror InVita's Blood & Plasma Management offerings that support donor management, collections, scheduling, inventory management, billing, IRL workflow automation, and more."

(Source: InVita Healthcare Technologies News Release, 3/4/24)

HemoClear B.V. and Nigeria's National Blood Service Commission are collaborating as part of an initiative, "to introduce autologous blood transfusion services, addressing the critical issue of blood shortages." Vincent Franssen, chief executive officer of HemoClear, stated in a news release, "[p]artnering with the NBSC, a regional leader in blood service expertise, guarantees streamlined implementation support, offers premier clinical training and logistics know-how, and sets the stage for future local production." Financial support for the alliance is being provided by the French Fund for Innovation in Development.

(Source: HemoClear News Release, 2/29/24)

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. 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.

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CALENDAR (continued from page 9)

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.

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

Marketing Manager (Blood Centers of America). This position develops and executes a marketing strategy for BCA and for individual business units including budget planning and measurement of success. The position manages the social media accounts and website content and supports the needs of the Advanced Therapy Network including newsletter, search engine optimization, and maintaining a record of member capabilities. Other responsibilities include press releases, presentations with input from internal stakeholders and trade show participation. A bachelor's degree in business is required; major in marketing preferred. Requires three (3) or more years of marketing experience with a proven track record of success. Social media management experience required. Blood center or related industry experience preferred. Remote work is available for a candidate who does not reside within a reasonable commuting distance of BCA's headquarters in West Warwick, RI; 10%-20% of overnight travel required. Apply at hrjobs@bca.coop.

Supply Chain Contract Manager (Blood Centers of America). This position is responsible for the day-to-day activities specific to BCA and national GPO supplier contract relationships. Position will identify, develop, coordinate and implement supplier contracts working with blood center Materials Directors and Purchasing Managers driving contract savings and increased revenue. A primary responsibility will be to oversee and manage the Third Party Logistics (3PL) operations, adding new product categories to be distributed in this

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POSITIONS (continued from page 10)

program to increase overall program value and efficiency. A bachelor's degree in a related field is preferred. Requires 3-5 years of supply chain experience in a related industry. Ability to travel regularly throughout the year to meet member needs. Remote work is available for a candidate who does not reside within a reasonable commuting distance of BCA's headquarters in West Warwick, RI; 20%-30% of overnight travel required. Apply at hrjobs@bca.coop.

Regulatory and Audit Compliance Specialist. The Regulatory and Audit Compliance Specialist ("Specialist") is responsible for developing and maintaining a risk-based quality auditing program for the New York Blood Center Enterprise division. The Specialist monitors and evaluates divisional compliance with regulatory requirements, professional accreditation standards and internal policies and procedures to ensure the ongoing quality and safety of products and services. Manages Audits: The Specialist manages the quality audit program for the division, including planning, risk assessment, scheduling, executing, and reporting on audits of the organization's facilities and operations. The auditor makes recommendations on areas of improvement based on audit observations and findings. Advises on Compliance: The Specialist represents the division as a direct liaison to regulators, managing communications, Biologics License Applications (BLA) submissions, regulatory reporting, and ongoing compliance matters, including the filing of Biological Product Deviation Reports (BPDRs). The incumbent serves as a subject matter expert, advising divisional leadership of new or changed regulations and standards, and providing interpretation for successful implementation. Please click here to view the full job description and apply.

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

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.

Cord Blood Operations Supervisor. LifeSouth Community Blood Centers is looking for a leader with a passion for making a difference to join our Cellular Therapies team at our headquarters in Gainesville, FL. This position is responsible for supporting and supervising the Cord Blood (CB) program's supply, records, logistics and communication activities. This position is also responsible for supervision and training of the cord blood logistics staff and for coordinating and managing all activities related to orders and shipments of biological products. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Cellular Therapy Scientist. LifeSouth Community Blood Centers is looking for an experienced laboratory scientist, with a passion for making a difference, to join our Cellular Therapies team at our headquarters in Gainesville, FL. The Cellular Therapy Scientist is responsible for performing and developing testing, processes, troubleshooting, and investigation related to cellular therapy and manufactured biologics. Duties and projects may relate to products intended for research, commercial, and clinical use. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

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POSITIONS (continued from page 11)

District Director. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The District Director at our Jacksonville, FL location is responsible for managing and directing the operations within the assigned district to ensure blood donation goals are achieved. They will work closely with local hospitals to ensure blood products are available as needed and all service needs are met appropriately. The District Director also ensures local operations are managed appropriately, in accordance with all procedural requirements and are in line with organizational values. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

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 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.