

A B C N E W S L E T T E R

URRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2024 #7

February 23, 2024

ABC Comments to FDA Regarding Draft Report and Plan on Best Practices Guidance

America's Blood Centers (ABC) has <u>submitted comments</u> to the U.S. Food and Drug Administration (FDA) in response to the "<u>FDA Draft Report and Plan on Best</u> <u>Practices for Guidance</u>." In the comments, ABC recommended that,

- "FDA develop draft guidance documents for implementation under emergency conditions, and provide these documents to blood centers in advance, so blood centers can reconfigure and validate their blood establishment computer systems (BECS), update their standard operating procedures (SOPs), and train their staff in preparation for immediate implementation, should the need arise; [and]
- that FDA provide additional information in the Center for Biologics Evaluation and Research's (CBER) annual <u>Guidance Agenda</u> regarding the specific topics to be addressed in the Level I planned guidance documents."

Additionally, ABC noted that, "in the event FDA decides to release draft guidance documents for immediate implementation that have not already been provided to blood centers, FDA should look to the Level I guidance documents provided during the public health emergency for immediate implementation, which provided less stringent requirements for blood centers to follow. This allowed blood centers to implement the new, less stringent guidance documents, or maintain the more stringent requirements already in place, allowing blood centers flexibility until they developed the necessary SOPs, without compromising the safety of the blood supply."

Regarding CBER's annual guidance agency, ABC explained that, "[w]e recognize that CBER is not bound by the list of planned guidance documents, nor would the Center be bound by any details they provide. However, this additional information would allow blood centers to begin strategizing around the implementation of potential changes to their operations."

FDA is seeking input on "whether there are any additional circumstances, categories of guidance documents, or topics for guidance for which it may be appropriate and consistent with the FD&C Act and FDA's GGP regulation for FDA to consider issuance as a Level I guidance document for immediate implementation without prior public comment," and also, "whether there are additional categories or types of guidance documents that FDA should consider issuing as Level II guidance documents to streamline the guidance process and allow [FDA] to better leverage its resources for the timely development of more guidance documents."

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In the January <u>notice</u> published in the *Federal Register*, the FDA explained that the draft report, "responds to the Consolidated Appropriations Act of 2023, which directs FDA to issue a report identifying best practices for the efficient prioritization, development, issuance, and use of guidance documents and a plan for implementation of such best practices. It also directs FDA to publish a draft report and plan no later than one year after enactment of the Consolidated Appropriations Act and to consult with stakeholders in developing the report and implementation plan."

(Sources: ABC Comments 2/23/24; FDA Draft Report and Plan on Best Practices Guidance, 1/3/24)

FABC Announces Research Grant Awardees

The Foundation for America's Blood Centers (FABC) has chosen the recipients of the fiscal year 2024-25 Louis Katz, MD Research Grants. The grant award recipients are Gulf Coast Regional Blood Center's "Understanding Donor Sentiments and Knowledge Gaps for Deferrals and Alternative Procedure Types" initiative; and Vitalant's/Vitalant Research Institute's "Does Timely Blood Center Outreach to Deferred Donors Improve Return" initiative.

Results from the selected grants will be presented at the 2025 ADRP Annual Conference and shared with the America's Blood Centers (ABC) and ADRP memberships. FABC and ABC thank all blood centers who submitted proposals for their excellent work and creative ideas and recognize the members of the FABC Research Grant Review Committee for their time.

FABC previously <u>announced</u> funding opportunities for members ABC and members of ADRP via a request for proposals (RFPs) for research initiatives with a focus on communications, engagement, and operational strategy to address donor deferrals has been issued. Eligible project areas included effectiveness of donor communications strategies, effectiveness of engagement strategies with deferred donors, and effectiveness of alternative opportunities for deferred donors.



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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.

America's Blood Centers

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ABC Body Interact Announce Multiyear Partnership

America's Blood Centers and Body Interact officially <u>announced</u> a multiyear partnership, aimed at helping innovate the way students and potential blood donors learn about the critical importance of blood donation. The partnership will provide, "cutting-edge virtual patient scenarios illustrating the lifesaving impact of blood donation as part of an expanded <u>Vein to Vein: The Science of Blood Donation</u> high school education program, to be released in the coming weeks...[Additionally this collaboration] recognizes the increasing demand for digital healthcare education...As part of this [partnership], Body Interact will develop 10 cutting-edge digital scenarios covering essential topics such as blood and trauma, pre-hospital blood use, and the vital need for a diverse blood supply...Over the five-year duration of this partnership, ABC members will [use] these scenarios in schools nationwide, enhancing their ability to provide immersive and impactful education in classrooms across the country.

(Source: ABC <u>News Release</u>, 2/20/24) •

WORD IN WASHINGTON

The Department of Health and Human Services (HHS) has stated that it <u>intends</u> to, "propose new standards for HIV-positive kidney and liver transplants to help increase access and reduce administrative burden. A notice of proposed rulemaking (NPRM) is expected to be developed later this year, and it will solicit public comment." A blog post titled, "HHS Intends to Propose Rulemaking on HIV-positive Organ Transplantation," further explained that, "[the agency's] action will be informed by recommendations from the Advisory Committee on Blood and Tissue Safety and Availability and the Blood, Organ, and Tissue Senior Executive Council, which considered evidence accumulated from years of research authorized by the HIV Organ Policy Equity Act (HOPE Act). Enacted in 2013 and implemented beginning in 2015, the HOPE Act made possible previously prohibited research related to the transplantation of organs in which both the donor and recipient have HIV. Since its implementation, more than 440 organs have been transplanted from donors with HIV to recipients with HIV...HHS intends to move forward with an NPRM, and once public comments are received and considered, HHS will decide whether to modify or implement the proposed policy change."

(Source: HHS <u>Announcement</u>, 2/15/24)

The U.S. Food and Drug Administration (FDA) <u>published</u> a letter on February 20th that is meant to, "[remind] sponsors of device studies and manufacturers of devices ('device firms') to carefully evaluate the third parties they engage to conduct performance testing and to independently verify all testing results before submitting to the FDA." The agency explained that, "[i]n recent years, the FDA has observed that an increasing number of entities that contract with device firms to conduct testing on medical devices ('third-party test labs') are generating testing data that are fabricated, duplicated from other device submissions, or otherwise unreliable. When such data are submitted to the FDA, the agency is unable to rely on them to grant marketing authorization and it calls into question the data integrity of the entire file. The FDA has identified an increase in submissions containing unreliable data generated by third-party test labs, including from numerous such facilities based in China and India. This alarming trend has resulted in the FDA being unable to reach a substantial equivalence determination or otherwise authorize marketing for medical devices whose submissions include such data...To reverse the trend of unreliable data being submitted to the FDA, it is incumbent on device firms to take proactive steps to qualify third-party test labs and to closely scrutinize all testing data that a firm does not perform itself, especially relating to biocompatibility and other performance testing, that are included in a submission to the FDA."

(Source: FDA Letter, 2/20/24) \blacklozenge



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

February Blood Bulletin Available

America's Blood Centers (ABC) has published the February 2024 edition of the *Blood Bulletin*. The issue, titled "Consignee Notification," is available in PDF or MS Word formats. The article was written by Daniela Hermelin, MD, Chief Medical Officer at ImpactLife; Louis Katz, MD, Chief Medical Officer Emeritus at ImpactLife; Richard Gammon, MD, Medical Director at OneBlood; Kip Kuttner, DO, Vice President and Medical Director at Miller-Keystone Blood Center; Kirsten Alcorn, MD, Co- Chief Medical Officer at Bloodworks Northwest; Ruchika Goel, MD, Senior Medical Officer at Vitalant; Courtney Hopkins, DO, Senior Medical Officer at Vitalant; Alcinda Flowers, MD, Medical Director at Versiti; Timothy Pancioli, DO, Associate Medical Director at Versiti, Kevin Ha, MD, Associate Medical Director at Versiti. Jed Gorlin, MD, MBA, Chief Medical Officer at ABC, was a contributor on this issue. *Blood Bulletin* is a quarterly publication reviewed and edited by ABC's Scientific, Medical, and Technical (SMT) Publications Committee. An archive of Blood Bulletin issues prior to 2022 are available exclusively to ABC members here.

(Source: MCN 24-012, 2/13/24)

Save the Date: SMT Journal Club on March 29th

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. An email announcement with a registration link and the articles to be reviewed on the webinar will be available soon. A Continuing Medical Education (CME) credit (1.0) is now offered for all ABC SMT Journal Club webinars.

Program Available for 2024 ABC Annual Meeting

Registration is open for the ABC 2024 Annual Meeting and the program is available. The meeting will take place March 4th-6th in Arlington, Va. at the Ritz-Carlton in Pentagon City and features several exciting changes, including expanded content offerings and a new format. With a focus on advocacy, leadership, operations, 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. Sponsorship opportunities are also available. <u>Contact us</u> with any questions.

Registration Is Open for 2024 ADRP Annual Conference

Register today for the 2024 ADRP Annual Conference! 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

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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 <u>us</u> with questions.

RESEARCH IN BRIEF

Platelet Transfusion in Cardiac Surgery and Association with Morbidity and Mortality. A study in Anesthesia & Analgesia, "investigated the association of platelet transfusion with key outcomes in cardiac surgery patients." The authors explained that, "[the] primary objective was to assess the association between platelet transfusion in cardiac surgery practice [in addition to] two independent primary outcomes: operative mortality (composite of both 30-day and in-hospital mortality) and 90-day mortality." The study's secondary objective was to, "assess the morbidity associated with platelet transfusion in cardiac surgery. [It was] hypothesized that after adjustment for concurrent blood product transfusion via entropy balancing, platelet transfusion would be associated with reduced operative mortality and reduced morbidity when compared to controls." The researchers noted that, "[t]his study was a retrospective, multicenter, inverse probability of treatment weighting via entropy balancing study using the Australian Society of Cardiac and Thoracic Surgeons (ANZSCTS) Cardiac Surgery Database. [This included] data on adults who underwent cardiac surgery from 2005 to 2018 across 40 centers in Australia...A total of 119,132 adults met study inclusion criteria. Of these, 25,373 (21.3 percent) received platelets with a median of two units transfused (interquartile range, 1-4)...After entropy balancing and when comparing patients who received platelets to controls, the odds ratio (OR) of operative mortality was 0.63 (99 percent CI, 0.47-0.84; P<.0001)...Additionally, the OR of 90-day mortality was 0.66 (99 percent CI, 0.51-0.85; P<.0001)...[I]t was associated with reduced odds of deep sternal wound infection (OR, 0.57; 99 percent CI, 0.36-0.89; P=0012), acute kidney injury (OR, 0.84; 99 percent CI, 0.71–0.99; P=.0055), and postoperative renal replacement therapy (OR, 0.71; 99 percent CI, 0.54–0.93; P=.0013)." However, the authors of the study found that there was, "an association with increased odds of return to theatre for bleeding (OR, 1.55; 99 percent CI, 1.16–2.09; P<.0001), pneumonia (OR, 1.26; 99 percent CI, 1.11–1.44; P<.0001), intubation for longer than 24 hours postoperatively (OR, 1.13; 99 percent CI, 1.03–1.24; P=.0012), inotrope use for >4 hours postoperatively (OR, 1.14; 99 percent CI, 1.11–1.17; P<.0001), readmission to hospital within 30 days of surgery (OR, 1.22; 99 percent CI, 1.11–1.34; P < .0001), as well as increased drain tube output (adjusted mean difference, 89.2 mL; 99 percent CI, 77.0 mL-101.4 mL; P < .0001)." Additionally, the researchers noted that the study, "found that platelet transfusion was independently associated with decreased operative and 90-day mortality in adults undergoing cardiac surgery."

Citation: Fletcher, C.M., Hinton J.V., Xing, Z., *et al.* <u>Platelet Transfusion in Cardiac Surgery: An Entropy-</u> <u>Balanced, Weighted, Multicenter Analysis</u>. *Anesthesia & Analgesia*. 2024.

Contributed by Richard Gammon, MD, Medical Director at OneBlood 🌢



MEMBER NEWS

Avera Health (Sioux Falls, S.D.) has officially joined America's Blood Centers (ABC). The organization has been approved for hospital-based blood center associate membership. The **National Blood Testing Cooperative** (Stone Mountain, Ga.) has also been approved for ABC membership as an organizational affiliate member. Contact ABC's <u>member services</u> for additional information about joining ABC and to learn more about the available <u>membership categories</u>.

Vitalant has partnered with Excellos Inc. According to a news release, "[the] strategic partnership includes an investment by Vitalant, and cell sourcing, testing and laboratory services. It also includes collaboration with the Vitalant Innovation Center, which provides scientific research and translational development expertise to bring new products and services to patients across the country. The strategic partnership is focused on supporting organizations to develop and deliver new cell therapies and addresses major challenges in bringing therapies to patients. Cell therapy development teams will now have access to larger and better geographically distributed donors that are well-characterized for aspects including metabolic and effector function profiles." Becky Cap, MBA, senior vice president of Biotherapies at Vitalant, added in the news release, "through our partnership with Excellos and other innovators, Vitalant can leverage our unique capabilities and expertise to transform healthcare. We look forward to working with Excellos to help develop new technologies and therapies that improve patient access and outcomes." Excellos Chief Executive Officer David Wellis, PhD stated in the news release, "[t]his is a great opportunity for Excellos to extend its collection network across the country and to collaborate with Vitalant in several areas, including testing services and research and development at their state-of-the-art Innovation Center. Additionally, Vitalant's investment brings financial capital to accelerate the launch of new Excellos products and services, including donor characterization through our Excellos 360 platform."

(Source: Excellos Inc. <u>News Release</u>, 1/17/24) •

GLOBAL NEWS

Researchers at Brigham and Women's Hospital and Havard Medical School have formed a new global coalition, "to address the pressing issue of extreme blood unavailability in rural settings and propose short-term strategies to address the urgent need for blood." According to a Brigham and Women's Hospital news release, the collaborative, called the Blood D.E.S.E.R.T. (Delivery via Emerging Strategies for Emergency Remote Transfusion) Coalition, has published a paper in Lancet Global Health that outlines recommendations of the coalition and provides, "ways health care professionals and governments can significantly increase global access to blood transfusion with several interventions, suitable for implementation in the short term...The solutions they proposed include civilian walking blood banks, a military strategy being adapted to civilian contexts in which volunteers within communities are ready and able to give blood at short notice so rural areas don't have to rely solely on central storage, and intraoperative auto-transfusion, in which a patient's own blood is recirculated during medical procedures." The paper is the result of the Blood D.E.S.E.R.T. Coalition, "conduct[ing] a three-month series of video conference and live workshops with participants in 11 countries in which they identified urgent research, policy, and implementation priorities for health systems to improve access to blood in the interim." The coalition's stated mission is, "to establish the research, education, implementation agenda needed to eliminate the world's blood deserts."

(Source: Brigham and Women's Hospital News Release, 2/14/24)

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GLOBAL NEWS (continued from page 6)

ABC Newsletter

The Ontario Public Service Employees Union (OPSEU/SEFPO) issued a news release this week opposing privatizing plasma collection in Canada. In the news release, the organization, "condemn[ed] the announcement by Canadian Blood Services that [Grifols] will open paid plasma collection sites in Whitby, Cambridge, and Hamilton in late 2024 and 2025. Grifols will be operating under an undisclosed 15-year deal with Canadian Blood Services." OPSEU/SEFPO Executive Board Member Geoff Cain, chair of the Blood Services and Diagnostics sector, stated in the news release that, "Canadian Blood Services already collects plasma. There's no reason why we can't invest in our own plasma cent[ers], and upgrade more of our blood donation cent[ers] so they can collect plasma as well from voluntary donors. We don't need a blood-for-money system in Ontario." Canadian Blood Services previously addressed such concerns in a statement in August 2022. "In Canada, Canadian Blood Services operates the national blood system where donors are not paid. This is not changing...Currently, we collect 15 [percent] of the plasma required to meet Canada's demand. The balance (approximately 85 [percent]) is purchased through the biologics industry as finished medications, which were made from plasma they collected themselves from donors who were likely paid. This is the model we have now in Canada. To be clear, we are not selling off or privatizing any part of our business. Globally, demand for immunoglobulins is outpacing plasma collection needed to manufacture them. This is putting Canada's supply at risk...To ensure patients' needs keep being met, we must increase domestic plasma collection so that at least half (50-60 [percent]) of immunoglobulins are made from plasma collected in Canada. In response to escalating risks to Canada's supply, we have opened five new dedicated plasma donor cent[ers], with six more to follow by 2024, and we are optimizing plasma collection programs at our blood donor cent[ers] to collect more plasma. These efforts are on track to improve plasma sufficiency to 25 [percent]. But this only gets us halfway there. More needs to be done....Any options considered must necessarily include controls to ensure plasma collected in Canada is used exclusively to manufacture immunoglobulins for patients in Canada, while also ensuring no negative impacts on Canadian Blood Services' current and future blood and plasma collections network. Canadian Blood Services will not consider any option that fails to achieve these controls, at a minimum."

(Sources: OPSEU/SEFPO News Release, 2/20/24; Canadian Blood Services Statement, 8/12/22)

COMPANY NEWS

Terumo Blood and Cell Technologies (Terumo BCT) has <u>announced</u> the publication of a study in <u>Blood</u> <u>Advances</u> that provides, "new consensus recommendations from an international panel of multidisciplinary experts for sickle cell disease (SCD) management during pregnancy." According to the company news release, the study includes, "recommendations for prenatal care, including guidance for when to administer prophylactic medicines and conditions under which healthcare professionals should consider simple blood transfusions or automated red blood cell exchanges (aRBCx)...[The expert panel, which included 12 hematologists, physiologists, obstetricians, maternal-fetal medicine specialists, and transfusion medicine physicians,] clarified the situations when patients are most likely to benefit from prophylactic blood transfusions or aRBCx, a process through which sickled red blood cells are removed using apheresis and replaced with donor cells. This includes aRBCx for patients with iron overload due to multiple blood transfusions or severe acute chest syndrome."

(Source: Terumo BCT News Release, 2/19/24)

The Alliance for Regenerative Medicine and Catalyst Healthcare Consulting recently <u>published</u> a white paper that aims to serve as a horizon scan of the cell and gene therapy industry. Specifically, the document, titled "Preparing for the Future: Emerging Technologies Shaping the Cell & Gene Therapy Landscape," is designed to, "identify emerging technologies in the for-profit cell and gene therapy sector that are most

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<u>COMPANY NEWS</u> (continued from page 7)

likely to require novel solutions for agency review and regulation over the next 3-10 year[s]. The findings reported herein are intended to spur conversations around the state of the cell and gene therapy landscape and to increase awareness of technologies in development, especially those that are likely to challenge regulatory paradigms currently in place."

(Source: Alliance for Regenerative Medicine White Paper, 1/31/24)

NMDP Biotherapies has <u>named</u> Tom Hochuli, MBA as president. Mr. Hochuli previously served as, "chief executive officer (CEO) of Current Biologics, a startup company focused on providing cell and gene therapy manufacturing and development services, as well as CEO of Vibalogics, a virotherapy process development and manufacturing organization. He has also served several biotherapies organizations as principal consultant, advisor, and board member. He holds an MBA from Rutgers University and a bachelor's degree in electrical and computer engineering from Clarkson University. He is a veteran of the U.S. Army and served as a first lieutenant and platoon leader in Bremerhaven, Germany. Hochuli will report to NMDP's CEO, Amy Ronneberg.

(Source: NMDP Biotherapies News Release, 1/30/24)

Grifols has announced that Nacho Abia has been <u>named</u> CEO effective April 1st. According to the company news release, Mr. Abia is, "[a] senior executive with 25 years of international management experience at publicly traded life-science and medical-technology companies. He was most recently executive officer and global chief strategy officer of Tokyo-based Olympus Corporation, a Nikkei-listed company with 33,000 employees that specializes in medical technology and is a global leader in diagnostics and minimally invasive treatments."

(Source: Grifols <u>News Release</u>, 2/5/24)

SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

NEW on CollABOrate

Recent discussion topics on the ABC CollABO rate Online Member Community include:

- Error Management and Error Tracking (MEMBER RESOURCES)
- Collecting Blood in a New State (QUALTIY BYTES)
- <u>PPE for Distribution/Hospital Services</u> (QUALITY BYTES)
- <u>Topical Finasteride</u> (MEDICAL ISSUES)
- <u>One Dad Can Sickle Cell Awareness</u> (ALL MEMBER FORUM)
- <u>LTOWB in Pre-hospital Transfusion</u> (ALL MEMBER FORUM)
- Hospital Satisfaction Survey (ALL MEMBER FORUM)
- <u>Illinois Colleagues: House Bill 4250</u> (COUNCIL OF STATES)
- <u>Hematology Proficiency Testing Program</u> (TECHNICAL DIRECTORS)

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



CALENDAR

Note to subscribers: Submissions for a free listing in this calendar (published weekly) are welcome. Send information to <u>newsletter@americasblood.org</u>. (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." <u>Registration</u> is open. More information available <u>here</u>.

Mar. 29. ABC Scientific, Medical, and Technical Journal Club Webinar. More information is coming soon.

April 11-12. International Haemoviglance Network Symposium. Athens, Greece. <u>Registration</u> is open. More information available <u>here</u>.

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

April 16-17. International Plasma Protein Congress. Athens, Greece. <u>Registration</u> is open. More information available <u>here</u>.

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

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. <u>Registration</u> is open. More information available <u>here</u>.

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.** <u>Registration</u> is open. More information available <u>here</u>.

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Sept. 4-6. American Society for Clinical Pathology (ASCP) Annual Metting. Chicago, Ill. 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 and Augusta, GA. These positions will oversee donor collection operations within their assigned divisional territory. These positions provide leadership and discipline to direct reports, interviews, and hire staff, and ensure 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: <u>Manager of Donor Services –</u> <u>Raleigh, NC. Manager of Donor Services – Augusta, GA</u>.

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

POSITIONS (continued from page 10)

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/48917Gl. 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/3OHIZet. The University of Cincinnati is an Equal Opportunity Employer.

Chief Operating Officer. As we enter our 50th year of service, ImpactLife is seeking a talented and passionate individual to join our executive leadership team as the Chief Operating Officer (COO). As a member of the Executive Leadership Team, the COO will oversee and lead



the operational aspects of the organization to include all marketing and public relations activities as well as blood recruitment, collection, patient services, manufacturing, and distribution activities. Additional responsibilities include departmental budgeting and development of control systems to ensure that organization objectives are met. Qualifications include bachelor's degree with preference given to candidates with a graduate degree and blood center and/or hospital executive leadership experience. This position can be located anywhere within the ImpactLife service territory extending into four states: Illinois, Iowa, Missouri, and Wisconsin. At ImpactLife we keep our mission, vision, and values at the forefront as we lead our teams. As a leader you will lead, inspire, and mentor with clear communication leading to collaboration within your team and across the organization remaining focused on achieving our tactical goals and fulfilling our strategic initiatives. Click here to apply. EOE: M/W/V/D

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 <u>here</u> to view the full job description and apply.



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.