

# ABCNEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

2023 #39

October 27, 2023

#### **INSIDE:**

BRIEFLY NOTED2
RESEARCH IN BRIEF 3
PEOPLE3
WORD IN WASHINGTON4
MEMBER NEWS5
Letter to the Editor Regarding PPTA Study in <i>Transfusion</i> 6
Registration Opens for 2024 ABC Annual Meeting7
ABC Advocacy Forum Set for November 1st7
Register for the 2023 ADRP International Showcase on November 15 <sup>th</sup> 7
Save the Date: SMT Journal Club Webinar Set for December15 <sup>th</sup> 8
GLOBAL NEWS8
COMPANY NEWS8
CALENDAR 10
EQUIPMENT AVAILABLE11
POSITIONS11

#### FDA Communication Regarding Directed Blood Donations That Are Not Medically Indicated

The U.S. Food and Drug Administration (FDA) <u>published</u> a communication on October 23<sup>rd</sup> titled "Important Information About Directed Blood Donations that are Not Medically Indicated." The communication comes in the wake of increased requests for directed donations. According to the agency's communication, "FDA is aware that some blood establishments and hospitals have received requests from patients who need a blood transfusion and wish to receive directed donations only from personally chosen relatives, friends, or other individuals with certain characteristics (e.g., specific gender, sexual orientation, vaccination status, or religion). Such directed blood donations lack scientific support. There is no evidence that directed donation provides safer blood and blood components for transfusion."

Furthermore, the FDA cautions against websites that offer memberships in return for providing blood and blood components from individuals who have not been vaccinated for COVID-19. "We advise consumers and health care professionals to exercise caution about websites offering memberships for delivery of blood and blood components from COVID-19 unvaccinated blood donors. Further, FDA reminds all owners or operators of establishments that manufacture blood products that they must register with the FDA, pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act, and must comply with the requirements for registration and blood product listing in FDA regulations (21 CFR Part 607). Blood and blood components must be labeled according to the requirements of 21 CFR Part 606.121 and 606.122. Blood and blood components labeled in a manner that is false or misleading are misbranded and are in violation of section 502(a) of the Federal Food, Drug, and Cosmetic Act."

America's Blood Centers (ABC) recently informed the FDA that there are websites offering to provide, for a paid membership fee, blood and blood components from donors that have not been vaccinated against COVID-19. The rationale for these requests and services may be based on misinformation and is not supported by any medical or scientific findings. ABC, the Association for the Advancement of Blood & Biotherapies, and American Red Cross have previously denounced these practices in a joint statement released January 27th. Furthermore, the sources of these offerings are not licensed with the FDA so how they would obtain and distribute this product is unclear.

(continued on page 2)

FDA Communication Regarding Directed Blood Donations (continued from page 1)

ABC will continue to monitor this issue and update members blood centers as appropriate. For additional information, please see the following ABC Publications:

- ABC Blood Bulletin, March 2023 Issue, Directed Donations and COVID-19 mRNA Vaccinated Blood Donors; and
- ABC Frequently Asked Questions: COVID Vaccines and Blood Donation.

Please feel free to contact <u>Betzy Gonzalez</u>, <u>MS</u>, <u>BB(ASCP)</u>, director of Scientific and Technical Operations at ABC, if you have any questions.

(Sources: FDA Communication, 10/23/23; MCN 23-088, 10/23/23)

#### **BRIEFLY NOTED**

The Prehospital Blood Transfusion Initiative Coalition (PHBTIC) recently announced that a feature story on prehospital blood transfusion has been published in EMS WORLD. The article, titled "Prehospital Blood Transfusion: Paving the Way for Reimbursement and Policy Reform," explains the benefits of prehospital blood transfusion and barriers to its implementation in the form of, "reimbursement of blood products and scope of practice." The story also noted that PHBTIC was formed to "build a multidisciplinary, industry-wide collaborative initiative to establish reimbursement coverage from government and commercial payors for prehospital blood transfusions and ensure prehospital blood transfusion is included appropriately in the prehospital ground and air EMS clinical scope of practice in all U.S. states and jurisdictions. It includes the development of a reimbursement proposal to the Centers for Medicare and Medicaid Services (CMS) and prehospital blood policy recommendations to Congress and the National Association of State EMS Officials addressing the scope of practice inconsistencies. The Coalition also will address U.S. strategic preparedness as it pertains to blood availability in the field for everyday trauma and mass casualty events as well as implement an educational support program for EMS related to prehospital transfusions." America's Blood Centers is a part of PHBTIC Steering Committee.

(Source: *EMS World*, "Prehospital Blood Transfusion: Paving the Way for Reimbursement and Policy Reform," 10/18/23) ♦



The ABC Newsletter (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail. Contents and views expressed are not official statements of ABC or its Board of Directors. Copyright 2023 by America's Blood Centers. Reproduction of the ABC Newsletter is forbidden unless permission is granted by the publisher (ABC members need not obtain prior permission if proper credit is given).

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

#### **America's Blood Centers**

Chief Executive Officer: Kate Fry Chief Medical Officer: Jed Gorlin

Editor: Mack Benton

Subscriptions Manager: Leslie Maundy Annual Subscription Rate: \$390

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 <a href="mailto:newsletter@americasblood.org">newsletter@americasblood.org</a>.

#### **RESEARCH IN BRIEF**

Blood Safety of Volunteer vs. Replacement Donors in Pakistan. The aim of a study in Vox Sanguinis, "was to identify trends of voluntary donations and provide a detailed comparative analysis of transfusion transmissible infections (TTIs) in replacement donors (RD) versus voluntary non-remunerated blood donors (VNRBD) across two large provinces of Pakistan." The authors explained that, "[d]ata were collected from October 2017 to May 2021. A total of 591,820 healthy blood donors were thus included...All blood donors were screened using serological testing performed by chemiluminescent immunoassay (CLIA) method...A total of 591,820 healthy blood donors (RD = 477,938 [80.7 percent], VNRBD = 113,882 [19.3 percent]) were screened at eight sites." The study found that, "[i]n screening assays, 53,590 (9.06 percent) donors were reactive for various TTIs. Among donors positive for TTIs, 5,018 (4.4 percent) were VNRBDs, while 48,572 (10.2 percent) RDs were positive for any TTI (p value <0.05)." The authors noted that, "[t]he prevalence of TTIs was highest in semi-urban Sindh, with Thatta showing the highest incidence...Further, the urban cities, Karachi and Lahore, showed lower seroprevalence for TTIs...In semi-urban cities, Thatta from Sindh and Multan from Punjab revealed the highest burden of TTIs...Among all TTIs, hepatitis C virus (HCV) and malarial parasite (MP) were found to be the most and the least frequent in both types of donors, respectively." The researchers explained that, "[t]he highest rate of HCV, hepatitis B virus (HBV) and syphilis was observed in RDs of Thatta followed by Jamshoro, Multan, and Bahawalpur...In RDs, coinfection was observed in 2,367 (0.5 percent), while in VNRBD, only 159 (0.1 percent) revealed co-infection for more than one TTI. Among these co-infections, co-existing HBV and HCV was observed in highest frequency [at] 990 (42 percent) followed by HBV and syphilis co-infection in 436 (18 percent) donors." The authors concluded that, "the study showed higher prevalence of TTIs among RDs in comparison with VNRBDs. The highest prevalence was observed for HCV in both types of donors. The difference between urban and semi-urban areas is significant with higher rates of overall TTIs in semi-urban areas." There was also a call for a, "substantial increase in voluntary blood donations in order to maintain a safe and sustainable blood supply [in Pakistan]."

Citation: Jamal, S., Mansoor, N., Ali, A., et al. "Degree of blood safety of voluntary nonremunerated versus replacement blood donations: A multicentre study of the large cohort of blood donors from two provinces of Pakistan." Vox Sanguinis. 2023

Contributed by Richard Gammon, MD, Medical Director at OneBlood

#### **PEOPLE**



Kris Fraizer, regulatory compliance manager, has announced her retirement from Vitalant after 45 years with the organization. Ms. Fraizer began her career as a donor interviewer and phlebotomist in 1978. She later served in the reference lab before moving to the quality management department, where she held both regional and national roles for the last 27 years of her career. Through her 45 years, she experienced many impactful blood industry events such as the AIDS epidemic, consent decrees, and the COVID-19 pandemic as well as the expansion of the donor history questionnaire and significant advancements in technology to enhance the safety of the blood supply. "I am grateful to have had such a knowledgeable and dedicated employee in Kris," said Mary Beth Bassett, executive vice president and chief quality officer at Vitalant, in the announcement. "Vitalant is thankful to Kris for her

numerous contributions and congratulates her on her long and impressive career. We wish Kris a wonderful retirement journey!"

(Source: Vitalant Announcement, 10/23/23)

Contributed by Roxanne Tata, Vice President of Regulatory Affairs, Corporate Quality Services and Privacy Officer at Vitalant ▶

ABC Newsletter

#### WORD IN WASHINGTON

The U.S. Food and Drug Administration (FDA) has published a guidance on October 19th titled "Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies." According to the announcement, "[the] guidance describes a standards recognition program for regenerative medicine therapies (SRP-RMT) at FDA's Center for Biologics Evaluation and Research (CBER) designed to identify and recognize Voluntary Consensus Standards (VCS) to facilitate the development and assessment of regenerative medicine therapy (RMT) products regulated by CBER when such standards are appropriate." The guidance also explained that, "[t]he SRP-RMT is expected to promote the visibility and use of standards applicable to FDA's public health mission by: Using Agency expertise to evaluate and recognize voluntary consensus standards related to RMT products that are potentially useful to industry and CBER staff. Specifically, this process will allow CBER to: Receive a candidate VCS, with relevant information (e.g., the scope of the standard and the purpose), from FDA staff or external stakeholders for informal recognition. Determine whether to recognize a standard in whole or in part following an internal scientific evaluation. List the recognized standards in a publicly searchable database on CBER's website, accompanied by an information sheet describing the scope and the extent of CBER's recognition of that standard and any other relevant information about the standard. Provid[e] transparency to industry and other stakeholders regarding CBER's thinking about a particular method or approach, thereby increasing regulatory predictability."

(Source: FDA Guidance, 10/19/23)

The U.S. Department of Health and Human Services (HHS), through the Administration for Strategic Preparedness and Response (ASPR), has "announc[ed] the selection of initial next-generation vaccine candidates and more than \$500 million in awards for Project NextGen - kick-starting planning for Phase 2b clinical trials and technologies that advance innovative next-generation vaccine and therapeutics platforms [for COVID-19]." According to the agency announcement, "[a]ll three nextgeneration vaccine selections announced today are distinct from each other, targeting stronger, broader, or longer-lasting immune responses [against COVID-19]. Intranasal vaccines have the potential to stop viruses at the site of infection and self-amplifying mRNA and additional antigens may generate a stronger immune response than current vaccine technologies."

(Source: HHS Announcement, 10/13/23)

## NEW on Coll ABO rate OLLABORA

SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

Recent discussion topics on the ABC CollABOrate Online Member Community include:

- **Donor Physical Exam Criteria** (TECHNICAL DIRECTORS)
- Proficiency Testing for Sysmex XN with Blood Bank Module (TECHNICAL DIRECTORS)
- Unlicensed Products (QUALITY BYTES)
- <u>Ultracrit Verification after Repair</u> (COLLECTIONS & DONOR SERVICES)
- Procedure Change Process (COLLECTIONS & DONOR SERVICES)
- Reentry SOPs (TECHNICAL DIRECTORS)
- Donor Collections Training-completed Phlebotomies for Training (MEMBER EMPLOYEE TRAINING AND DEVELOPMENT)

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

#### **MEMBER NEWS**

South Texas Blood & Tissue (STB&T) and Velico Medical have collaborated to "launch" Velico's Blood Center Education Program (BCEP). Adrienne Mendoza, chief operating officer of STB&T, added in the news release, "South Texas Blood & Tissue is pleased to collaborate with Velico as a BCEP partner. We take great pride in our history of firsts, leading change and innovation in blood transfusion products and services." According to the announcement, "Velico's BCEP is designed to generate deep customer feedback on the commissioning and operational aspects of the FrontlineODP<sup>TM</sup> system for spray drying plasma. FrontlineODP is expected to be an easy to produce, easy to use, point-of-care plasma product for transfusion in settings where current plasma products (most often frozen) are unavailable or inconvenient to use because of challenging cold chain logistics and short dating...Velico's development program has been funded in whole or in part with federal funds from the Department of Health and Human Services, Administration for Strategic Preparedness and Response, and the Biomedical Advanced Research and Development Authority."

(Source: STB&T and Velico Medical Joint News Release, 10/20/23)

**Vitalant** recently held a ribbon-cutting <u>ceremony</u> to unveil its new Scottsdale, Ariz. national office. The event also "commemorated [a] milestone" as the organization celebrated its 80<sup>th</sup> anniversary after being found in 1943 "as the Salt River Valley Blood Bank in Phoenix, and later renamed to United Blood Services." According to the announcement, "[t]he new national office at 9305 E. Via De Ventura in Scottsdale replaces its previous Scottsdale location on Oak Street. About 150 employees work out of the new site, providing



support and resources to its nationwide operations. This is the second investment Vitalant has made in the area in recent years. In 2020, Vitalant opened a state-of-the-art blood collection and processing facility in Tempe, Ariz. It also operates a blood donation center at 15170 N. Hayden Road in Scottsdale along with six other donation centers throughout the state." Daivd R. Green, president and chief executive officer of Vitalant, added in the announcement, "[f]rom humble yet bold beginnings in 1943, we have grown and evolved to meet the modern transfusion needs of patients. Our new national office marks another chapter in our rich history, providing the foundation to continue our lifesaving mission to save and improve lives."

(Source: Vitalant Announcement, 10/25/23)



#### Letter to the Editor Regarding PPTA Study in Transfusion

\*\*Please note: The views/comments expressed in submitted letters from external parties are those of the author(s) and are not to be interpreted as the viewpoint of America's Blood Centers.\*\*

Dear Editor,

I am responding to Dr. Ipe's letter in the October 13<sup>th</sup> <u>ABC Newsletter</u> outlining concerns with the recent <u>Plasma Protein Therapeutics Association (PPTA) publication</u>. Regarding conflict of interest (COI) and funding, all authors were transparent to possible COI and funding was disclosed. Additionally, the study protocol was approved by Sterling IRB and accepted for publication following peer review, under supervision of an associate editor who is a well-respected transfusion medicine expert.

Regarding the use of self-reporting, the primary survey used for analysis was the SF-36v2® Health Survey, a validated survey instrument for measuring self-reported health related quality of life and well-being in general and specific populations. Except for a single question not included in the PCS and MCS scoring, the questions have a 4-week recall period. The SF-36v2 and similar survey instruments have been used in published studies, including blood research. The statistical analysis was performed by professional statisticians from WCG Clinical, Inc., and QualityMetric Inc. The latter licenses the SF-36v2 and is experienced in using the instrument in all populations.

Regarding the "healthy donor effect," we noted this in the publication and attempted to reduce this effect by including comparisons with active donors at different donation frequencies, not just against the general population. As the participating donors were self-selected by the SP donation process, frequent SP donors passed multiple health screenings to reach the higher frequency groups, including donors who may have been temporarily deferred.

Dr. Ipe asserts that the "study subjects were likely influenced by both cash compensation and by their vendor relationship to the plasma centers administering the tool." Study participants were given \$5 for their time to complete the survey and center staff had no access to their responses. Research participants are commonly reimbursed for costs incurred for their inconvenience. As an example, participants in the recently published ADVANCE study were compensated up to \$85.

PPTA believes this publication provides additional data on the impact of SP donor self-reported health and well-being. The importance of reporting this data is further underscored by the growing need for plasmaderived therapies for ever increasing indications globally; 70% of this need is met by US SP donations. This research is important in demonstrating the safety for US SP donors in assuring the availability of these therapies, which we believe is an important issue for the transfusion medicine community.

Michelle Fransen, MPH, MPS, Senior Manager, Lead for Project and Study Management at PPTA On behalf of the PPTA and study Investigators

#### We Welcome Your Letters

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



# **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.

#### **Registration Opens for 2024 ABC Annual Meeting**

Registration is open for the America's Blood Centers (ABC) 2024 Annual Meeting. The meeting will take place March 4<sup>th</sup>-6<sup>th</sup> 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 and 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. The call for AoE nominations is open. Secure your room today to take advantage of the group rate. The deadline to book a room is February 16<sup>th</sup>. Sponsorship opportunities are also available. Contact us with any questions.

#### ABC Advocacy Forum Set for November 1st

ABC will hold its next Advocacy Forum: Congressional, Agency, and State Updates on November 1<sup>st</sup> at 2 p.m. EDT. The forum will include updates and discussions on:

- the ABC meeting on surge capacity and preparedness with the Biomedical Advanced Research and Development Authority (BARDA) and the Office of the Assistant Secretary for Preparedness and Response (ASPR);
- congressional updates;
- licensure reform efforts; and
- state advocacy and the ABC Council of States.

Additional information including a link to registration is available to ABC members in MCN 23-083.

(Source: MCN 23-083, 10/5/23)

### Register for the 2023 ADRP International Showcase on November 15th

The 2023 ADRP International Showcase will take place on November 15<sup>th</sup> from 1-2:30 p.m. EST. Registration is open. Blood center professionals worldwide are encouraged to take part in this annual event that provides them a forum to share, connect and learn from each other. The featured speaker this year is Iryna Slavinska, chief executive officer and founder of DonorUA, an initiative to recruit and coordinate blood donors in Ukraine, who will share experiences of managing blood donations during a crisis. Other topics and speakers include: Perceptions and Effects of a Loyalty Program for Plasma Donors, Marloes Spekman, Sanquin, The Netherlands; Recruiting and Retaining Donors at the Western Cape Blood Service, Michelle Vermeulen, Western Cape Blood Service, South Africa; Bringing Customer Experience to Donor Experience, Mark Croucher, NHS Blood and Transplant, United Kingdom; Creating an Attitudinal Segmentation, Based on Motivations and Barriers, that Incorporates Donors and Non-donors, David Stephen, Australian Red Cross Lifeblood; and High Volume TikTok Presence – How to Do It!, Tracy-Lee Lewis, South Wales Police.

(continued on page 8)

<u>INSIDE ABC</u> (continued from page 7)

#### Save the Date: SMT Journal Club Webinar Set for December15th

The next ABC Scientific, Medical, and Technical Journal Club Webinar will take place on December 15<sup>th</sup> at 12 p.m. EST. The webinar is free to all ABC members. An email announcement is forthcoming with additional details including a link to registration and the articles to be reviewed on the webinar.

#### **GLOBAL NEWS**

The Health Sciences Authority (HSA) in Singapore has revised its donor eligibility criteria for variant Creutzfeldt-Jakob disease (vCJD) deferrals. According to an announcement earlier this month, "[e]ffective October 2<sup>nd</sup>, donors with geographical risk exposure to vCJD (stayed or lived in the United Kingdom, France, Ireland and other European countries during the affected period) can now make apheresis donations (plateletpheresis, plasmapheresis or double red cell donation)...Based on the experience of blood transfusion services overseas, the risk of transfusion-transmitted vCJD can be mitigated by removing white blood cells from the donated blood of at-risk donors. HSA has done a comprehensive review of these new scientific findings before deciding to ease vCJD restrictions. The easing of restrictions will only be applicable to apheresis donation for now because apheresis donation allows direct collection of blood components without collecting the white blood cells. A phased approach is an important safeguard to ensure the safety of our blood supply while we work towards including whole blood donation."

(Source: HSA Announcement, 10/2/23)

The Irish Blood Transfusion Service (IBTS) and Royal College of Surgeons in Ireland (RCSI) have announced a partnership to, "address the ever-growing challenge of meeting the demand for blood products – and in particular platelets." According to RCSI in a partnership announcement, the joint research initiative called CRIMSON, the Cent[er] for Research Into Major Haemorrhage and Transfusion, will include researching, "ways to optimi[z]e shelf-life for donated platelets and ways to derive more benefit from platelet transfusions for patients...CRIMSON will also investigate the role that blood type plays in how platelets work, particularly in patients who are actively bleeding."

(Source: RCSI Announcement, 10/23/23)

#### **COMPANY NEWS**

**Blizzard Entertainment** is promoting blood donation using its "Diablo IV" game. The company will be "giving away a high-end Diablo IV-themed gaming PC whose water-cooling system is infused with 'real human blood' if players donate enough of the life-giving liquid." The promotion, Diablo IV Blood Harvest, is specifically encouraging individuals in the gaming community to collectively donate, "666 quarts of blood. The entire Diablo community will benefit from this, as hitting 220 quarts, 440 quarts, and 666 quarts will also unlock various cosmetic items in the Diablo IV game. Once the blood donation goal has been reached, the competition for the custom gaming PC [will start,]" according to *PC World*. The donations can be made at any blood center according to Bizzard Entertainment.

(Source: *PC World*, "Win this liquid-cooled Diablo IV PC with human blood if players donate 666 quarts," 10/23/23)

(continued on page 9)

#### **COMPANY NEWS** (continued from page 8)

Valneva SE has submitted a marketing application to the European Medicines Agency (EMA) for the company's investigational single-shot chikungunya vaccine candidate. According to a company news release, the EMA's Committee for Medicinal Products or Human Use (CHMP) also designated the application for an "accelerated assessment." Earlier this year, Valneva SE submitted a biologic license application (BLA) to the U.S. Food and Drug Administration, which is, "currently under priority review" by the agency. Another marketing application submission is currently being reviewed by Health Canada. "If approved, [the investigational vaccine candidate] could become the first licensed chikungunya vaccine available."

(Source: Valneva SE News Release, 10/25/23)

Excision BioTherapeutics, Inc. has announced positive clinical interim data from a phase I/II of its investigational gene therapy candidate to treat human immunodeficiency virus type 1 (HIV-1). According to a news release, "[a]ll participants in Cohort A (n=3) have been safely dosed. Initial results, as reported by Excision, indicate no serious adverse events or dose limiting toxicities. Although four mild (Grade 1) adverse events (AEs) possibly or definitely related to [the investigational gene therapy] were observed in the first three participants, all reversed without intervention. Across the Cohort, there were no withdrawals during IV administration, no infusion-related reactions, and no complement-mediated toxicity. Transient and reversible transaminase elevations were observed in two of the three participants. [The investigational gene therapy] is detectable in blood at four weeks in every participant. Peripheral exposure has been achieved with a single dose of [the investigational gene therapy] at the first dose level being evaluated in the study (9.0x10<sup>11</sup> vg/kg). Excision observed no evidence of horizontal transmission of gene vector shedding of [the investigational gene therapy] in two tissue compartments associated with male reproductive function. Data supports dose escalation to Cohort B and further development of [the investigational gene therapy.] Excision plans to dose escalate to its next dose level (3.0x10<sup>12</sup> vg/kg) in [quarter four of] 2023 and present additional data in 2024."

(Source: Excision BioTherapeutics, Inc. News Release, 10/25/23)

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

- **ABC Advocacy Forum: Congressional, Agency, and State Updates** Nov. 1. More information and a link to registration are available to ABC Members in MCN 23-083.
- ABC Scientific, Medical, and Technical Journal Club Webinar Dec. 15. More information coming soon!
- 2023 ADRP International Showcase Nov 15. <u>Registration</u> is open. More information available here.





#### **ABC Calendar of Events**

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

#### **CALENDAR**

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

#### 2023

- Oct. 31. U.S. Food and Drug Administration (FDA) Cellular, Tissue, and Gene Therapies Advisory Committee Meeting (Virtual). More information available <a href="here">here</a>.
- Nov 1. **ABC Advocacy Forum: Congressional, Agency, and State Updates (Virtual).** More information and a link to registration are available <a href="here">here</a>.
- Nov. 13-14. U.S. Department of Health and Human Services (HHS) Biomedical Advanced Research and Development Authority (BARDA) Industry Day 2023. (Hybrid), Washington, D.C. Registration is open. More information available here.
- Nov 15. **ADRP, The Association for Blood Donor Professionals International Showcase (Virtual).** Registration is open. More information available <a href="here">here</a>.
- Nov. 18-21. **ISBT Regional Congress, Cape Town, South Africa.** Registration is open. More information available here.
- Dec. 15. ABC Scientific, Medical, Technical (SMT) Journal Club Webinar. More information coming soon.

#### 2024

- Feb.7-8. International Plasma and Fractionation Association & EBA Symposium on Plasma Collection and Supply. Leiden, Netherlands. Registration is open. More information available <a href="https://example.com/html/>here">https://example.com/html/>
- Mar. 4-6. ABC Annual Meeting, Arlington, Va. Registration is open. More information available here.
- April 12-13. BEST Meeting, Amsterdam, Netherlands. More information coming soon.
- May 14-16. 2024 ADRP Annual Conference, St. Louis, Mo. More information available here.
- May 15-16. International Plasma and Fractionation Association/Paul-Ehrlich Institut[e] 30<sup>th</sup> International Workshop on Surveillance and Screening of Blood-borne Pathogens, Aarhus, Denmark. More information available <a href="here">here</a>.
- Sept. 4-6. American Society for Clinical Pathology (ASCP), Chicago, Ill. More information coming soon.
- Sept. 30- Oct. 3. American Association of Tissue Banks (AATB), Denver, Colo. More information coming soon.
- Oct. 19-22. Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting, Houston, Texas. More information coming soon.

#### **CLASSIFIED ADVERTISING**

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC 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: <a href="mailto:newsletter@americasblood.org">newsletter@americasblood.org</a>

#### **EQUIPMENT AVAILABLE**

**For Sale.** Two refurbished Aurora Plasmapheresis System devices with Certificate of Compliance for each device. Both devices have Software 2.0 installed. Asking for best offer. Location: Jackson, TN. Please contact LaTrina Morman, (731) 427-4431, or email <a href="mailto:latrinamorman@lifelinebloodserv.org">latrinamorman@lifelinebloodserv.org</a>.

**For Sale.** Two NEW Aurora Plasmapheresis System devices with Certificate of Compliance. NEVER USED. Currently, both have Software 2.0 installed. Asking for best offer. Location: Jackson, TN. Please contact LaTrina Morman, (731) 427-4431, or email latrinamorman@lifelinebloodserv.org.

#### **POSITIONS**

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

Manager of Donor Services | Manager of Donor Resources | Manager of Hospital Services. The Blood Connection is expanding our operations into Virginia! We are one of the fastest growing blood centers in the country and we are seeking a Manager of Donor Services, a Manager of Donor Resources, and a Manager of Hospital Services who will be responsible for day-to-day operations within each of their respective departments as we expand our services into this new territory. We offer a generous benefits package including a substantial 401k match, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help make an impact in your community today. These roles are based in Roanoke, VA. Prospective candidates may be eligible for relocation assistance. How to apply: Manager of Donor Services Application | Manager of Donor Resources Application | Manager of Hospital Services Application.

**Director of Human Resources (San Diego, CA).** The San Diego Blood Bank is seeking a dynamic Director of Human Resources. This role is directly responsible for the overall administration, coordination, and evaluation of the human resource function. This position facilitates

organization and leadership development efforts with employees and managers to address root causes of human resource issues. The Director of Human Resources plays a vital role in administering talent management, workforce planning, recruitment, and employee relations through a systematic approach. This position supports executive leadership and management in the development of solutions through cultural and process perspective organizational development and drives a culture of performance and results. A strategic planner and partner to all levels of leadership acting as a cultural champion, mentor and consultant for the organization building avenues of healthy and positive work environments. Salary Range: \$100,000 - \$125,000/annual. Education: Bachelor's degree in related field required. Master's degree preferred. Experience:10 years of directly related experience. Certifications: HR Certificate/SHRM professional certification preferred. Please click here to view the full job description and apply.

**Divisional Director.** The Blood Connection is expanding our operations into Virginia! We are one of the fastest growing blood centers in the country and we are seeking a Divisional Director who will be responsible for our day to-day operations and help direct our expansion of services into this new territory. The ideal candidate is a proven and results-focused self-starter with progressive leadership experience and the capacity and drive to help fulfill the needs of our community partners. We offer a generous benefits package including a substantial 401k match, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help make an impact in your community today. Open to candidates residing in localities state-wide. Prospective candidates may be eligible for relocation assistance. How to apply: Divisional Director Application

(continued on page 12)

# October 27, 2023

#### **POSITIONS** (continued from page 11)

Manager of Technical Services. The Blood Connection is seeking a proactive and results-driven Manager of Technical Services to oversee and manage the daily operations within our technical departments which include Hospital Services, Biologics Processing, and Reference Laboratory. This position requires an understanding of laboratory operations, including specialist (SBB) skills, and involves supervising staff while performing essential functions within the laboratory. The ideal candidate will hold their SBB and have a background in the Reference Laboratory. We offer a generous benefits package including a substantial 401k match, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help make an impact in your community today. This role is based in Morrisville, NC. Prospective candidates may be eligible for relocation assistance. How to apply: Manager of Technical Services Application.

Supply Chain Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The Supply Chain Manager at our headquarters location in Gainesville, FL is responsible for vendor selection, negotiation, establishment and maintenance of all purchased materials, supplies, equipment, and services used by the company. The Supply Chain Manager oversees daily operations of the Purchasing team, is organized and decisive, and can motivate the team to reach daily and long-range goals. 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!

Employee Relations Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management and HR experience, and a passion for making a difference. The Employee Relations Manager at our headquarters location in Gainesville, FL is responsible for facilitating employee relations and resolving personnel issues. The Employee Relations Manager deals with grievances and violations invoking disciplinary action, provides guidance, advice, and support to managers and employees on HR related issues, and oversees the work of eight Human Resources Coordinators. 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!

Immunohematology Reference Lab LifeSouth Community Blood Centers is seeking an individual who enjoys leading a team of lab professionals dedicated to providing high quality products and services for patients. Our Birmingham, AL IRL is supported by Board Certified Pathologists in Transfusion Medicine, and by LifeSouth's accredited HLA Lab, Molecular Lab, and IRLs in Gainesville, FL and Atlanta, GA. The IRL Manager is responsible for providing onsite day-to-day supervision of testing personnel, ensuring compliance with regulatory agency requirements, and reporting of test results under the direction of the laboratory director. 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!

Regional Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference in the community. The Regional Manager in The Villages, FL, oversees daily operations of the region, is organized and decisive, and can motivate the team to reach daily and long-range blood collection goals. 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!