

ABCNEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2022 #39 October 28, 2022

Please Note: The *ABC Newsletter* will not be published on Nov. 4th. We will resume regular publication on Nov. 11th. Thank you for your continued interest.

HHS Announces "Giving=Living Blood & Plasma Challenge"

The Office of Infectious Disease and HIV/AIDS Policy OIDP within the U.S. Department of Health and Human Services (HHS) has launched the "<u>Giving=Living Blood & Plasma Innovation Challenge</u>." Through this initiative, OIDP is inviting participants to submit ideas for:

- "[i]nnovative, community-driven solutions for increasing the blood and/or plasma supply in the short-term;
- [o]ffer solutions to address sustainability to help create a steady, ongoing supply in the long-term;
- [m]eaningfully involve a range of stakeholders so that innovations are community-led; and
- [d]eliver solutions that drive donations among diverse populations of donors, specifically in Black and Latino communities."

Up to 10 winners will be chosen to receive prizes up to \$10,000 with \$100,000 in total cash prizes available. Eligibility <u>rules</u> and judging <u>criteria</u> are available on the challenge website in addition to registration/submission <u>requirements</u>, as ideas will be scored on:

- framework:
- innovation:
- impact; and
- equity.

The submission deadline is December 5th. Participants may contact OIDP with questions or comments using the contact <u>form</u> on the challenge website. The "Giving=Living Blood and Plasma" campaign was called for as part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act passed by Congress, in which HHS "has undertake[n] a national communications campaign to promote blood and plasma donations to address the severe and, in some ways, novel shortages of both blood and plasma that occurred during the COVID-19 pandemic...The goal of the campaign is to encourage Americans to donate blood and plasma regularly and to increase diversity in the supply." The national awareness campaign <u>began</u> in August 2022.

(Source: HHS Announcement, 10/25/22)







WORD IN WASHINGTON

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) Office of Advanced Therapies (OTAT) will host a virtual town hall on "What Are Chemistry, Manufacturing, and Controls for Cell Therapy and Tissue-engineered Products?" The town hall will take place on December 7th from 12-1:30 p.m. EST. This event aims to "answer stakeholder questions related to cell therapy chemistry, manufacturing, and controls (CMC), including tissue-engineered medical products regulated by OTAT. This event is part of a series to answer questions from stakeholders about a variety of topics on which OTAT has regulatory oversight."

(Source: FDA Announcement, 10/26/22)

The FDA published a guidance on October 14th titled "Comparability Protocols for Postapproval Changes to the Chemistry, Manufacturing, and Controls Information in a New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or Biologics License Application (BLA); Guidance for Industry." The guidance is "intended to assist original applicants and holders of approved new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs) with implementing a chemistry, manufacturing, and controls (CMC) postapproval change through the use of a comparability protocol (CP)...Th[e] guidance recommends a framework to promote innovation and continuous improvement in the manufacturing of quality products by encouraging employing: [e]ffective use of knowledge and understanding of the product and manufacturing process; [r]isk management activities over the life cycle of a product; and an effective pharmaceutical quality system." This guidance does not apply to blood or blood products.

(Source: FDA Guidance, 10/14/22)



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

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RECENT REVIEWS

Predictors of Transfusion in Trauma and Utility in the Prehospital Environment. A scoping review in Prehospital Emergency Care "aims to characterize the existing quantity and quality of literature regarding predictor scores for transfusion in injured patients. Secondarily, th[e] review aims to analyze the utility of identified predictor scores for transfusion in the prehospital setting." The authors explained that the study's design was "based on the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews framework...[A] search strategy was developed. Embase, Cochrane Database of Systematic Reviews, and Medline from 1946 to present were searched...Of the 5,824 studies identified, 72 total studies were included in [the] review." The reviewers noted that of the "52 scoring systems [that were] identified, forty-two percent were applicable in the prehospital setting, 42 percent were potentially applicable, and 11 percent were not applicable. In contrast, 94 percent of identified individual variables were applicable or potentially applicable (63 and 33 percent, respectively) to the prehospital setting...Of the available scoring tool[s] that [are] applicable to the prehospital setting, the Shock Index and Modified Shock Index had the greatest sensitivity (both 96 percent) for predicting massive transfusion protocols (MTP), while the Prearrival Model had the greatest specificity for MTP activation (95 percent)...Of the individual prognostic variables applicable in the prehospital setting, administered fluids and systolic blood pressure had the highest sensitivity (100 percent) and specificity (89 percent) for MTP prediction, respectively...Overall, 20 scores were identified as applicable to the prehospital setting, 25 scores were identified as potentially applicable, and seven scores were identified as not applicable." The authors recognized that "[t]he prehospital environment provides a crucial window of opportunity to optimize time-totransfusion for patients who require blood products. If at-risk patients for requiring transfusions can be identified early and blood products requested to the trauma bay in advance, preventable mortality and morbidity from delays may be reduced." They concluded that "there is evidence that several predictors for transfusion have good sensitivity and specificity properties that can identify at-risk patients, and that these can reasonably be used prior to arrival at hospital with resources available in the prehospital setting."

Citation: Yin G., Radulovic N., O'Neill M., Lightfoot D., Nolan B. <u>Predictors of Transfusion in Trauma</u> and Their Utility in the Prehospital Environment: A Scoping Review. *Prehospital Emergency Care*. 2022

Contributed by Richard Gammon, MD, Medical Director at OneBlood

RESEARCH IN BRIEF

Optimal Cut-off Value in Assays Identifying Hepatitis C Virus-Reactive Blood Donors. A study published in *Transfusion Medicine* "sought to establish an optimal signal-to-cutoff ratio (S/CO) utili[z]ing a chemiluminescent immunoassay (CMIA) for hepatitis C virus (HCV) serological screening, and to verify the HCV status on reanalysis of HCV-positive donors." The authors explained that an estimated 3.4 million transfusions of blood components take place each year in Brazil. "In one of the largest blood banks in Latin America, approximately 110,000 units of blood are collected annually and between 2011 and 2016, 2.3 percent of donated blood was discarded, with 0.23 percent due to the detection of HCV-related biomarkers. An unknown percentage of these discarded donations were likely false-positive results, since HCV serological screening tests have a low positive predictive value (PPV) in low HCV prevalence populations. Rejection of false-positive samples negatively impacts the blood supply in blood banks and results in unnecessary trauma for donors." For this study, a "cross-sectional retrospective study of 193,973 volunteer blood donors at Fundação Pró-Sangue/Hemocentro de São Paulo-Brazil, who were routinely screened from June 2016 to December 2017 for hepatitis B virus, HCV, HIV-1/2, Chagas disease, syphilis, and HTLV-1/2 antibodies and/or antigens and who underwent nucleic acid testing (NAT) for HIV/HCV/HBV. In this period, 379 of 578 serum samples that were positive in one or more of the HCV screening tests (HCV-

(continued on page 4)

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RESEARCH IN BRIEF (continued from page 3)

antibody and/or HCV-NAT) and had sufficient volume available for subsequent analysis were included in this study." The researchers found that of the "193,973 volunteer blood donations screened for HCV using CMIA and HCV-NAT from June 2016 to December 2017, 578 samples were positive, corresponding to a discard rate of 0.3 percent. Among discarded samples, 434 (75.1 percent) were HCV antibody-positive, 92 (15.9 percent) were in the HCV antibody-grey zone, 51 (8.8 percent) were HCV antibody-positive/HCV-RNA-positive and 1 (0.2 percent) was positive only for HCV-RNA. Confirmatory testing was performed on 379 of the 578 HCV positive blood samples that had sufficient volume to allow for re-analysis, 321 that were antibody positive in CMIA and 58 with results in the grey zone. The INNOLIA assay confirmed the initial screening test reactivity in only 71 cases (18.7 percent), one being from the grey zone (S/CO =0.797). The INNOLIA assay was negative in 233 (61.5 percent) samples, while 75 (19.7 percent) were indeterminate. The study also noted that, "the positive predictive value increased from 27.3 percent to 66.7 percent when the S/CO was ≥4.32 in the CMIA screening test. The threshold S/CO ≥4.32 improved the accuracy compared to the threshold used in screening (S/CO ≥1.00)...The proposed cutoff of 4.32 can help distinguish true positives from false positives results, mainly in NAT-negatives samples. This high threshold could help evaluate donors who return to the blood bank, allowing better recognition and separation of true and false positives." The study concluded that "screening of blood donors for HCV by the CMIA has a high risk of false-positive results in low-seroprevalence populations. Furthermore, the most highly positive samples could not be confirmed on subsequent analysis. Using a higher threshold for an HCV-positive blood sample enhances the CMIA screening test's accuracy and helps to improve donor counselling and notification processes. Improvements are needed to encourage and reinforce the importance of donors to return to repeat an indeterminant HCV test and for those who are infected to know their status to allow for referral for treatment and blocking transmission."

Citation: Nishiya, A., de Almeida-Neto, C., Witkin, S., et al. <u>Improved detection of hepatitis C virus-positive blood donors and determination of infection status</u>. *Transfusion Medicine*. 2022.

Seasonality of Human Coronaviruses Explored. Researchers at the Centers for Disease Control and Prevention (CDC) published a synopsis in *Emerging Infectious Diseases* that investigated the seasonality of the four most common human coronaviruses (HCoVs) from July 2014 through November 2021. The authors identified four of the most common HCoVs as "two alpha (HCoV-NL63 and HCoV-229E) and two beta (HCoV-HKU1 and HCoV-OC43) types [that]generally cause mild upper respiratory illness. The HCoVs are endemic among humans, as evidenced by sustained, widespread, continuous transmission, unlike the betacoronaviruses SARS-CoV (detected in 2002), Middle East respiratory syndrome coronavirus (detected in 2012), [and SARS-CoV-2 (detected in 2019) spurring the global pandemic]. For this synopsis, the researchers "analyzed circulation of HCoVs by using data from the National Respiratory and Enteric Viruses Surveillance System (NREVSS), a passive surveillance system established by CDC...[They] excluded HCoV results without virus typing and data from laboratories that did not report any positive HCoV test results during the study period. We compiled total HCoV testing and positive detections by HCoV type, season, and U.S. Census region." The researchers "detected an HCoV of any type in 104,911 (3.6 percent) of 2,878,479 specimens with results submitted to NREVSS during the week ending July 5, 2014, through November 6, 2021. Among these 104,911 specimens, 40.1 percent were positive for HCoV-OC43, 27.8 percent for HCoV-NL63, 19.9 percent for HCoV-HKU1, and 12.2 percent for HCoV-229E. Weekly testing volumes were higher during March 2020, the onset of the COVID-19 pandemic, than during any other week in July 2014 and November 2021. The predominant common HCoV type fluctuated by surveillance year." They found that "[i]n the six HCoV seasons before the COVID-19 pandemic (i.e., excluding the 2020–21 season), seasonal onsets were during October-November, peaks during January-February, and seasonal offsets during April-June... 93.2 percent of all HCoV detections occurred between the onset and offset. The mean duration of the six seasons before the 2020-21 season was 25 weeks. The 2020-21 common

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RESEARCH IN BRIEF (continued from page 4)

HCoV season onset was delayed by 11 weeks compared with mean onset of prior seasons... The predominant type of alpha HCoV was HCoV-NL63 during four of the seven seasons... Among 82,768 specimens from PHLIP tested for the 4 HCoVs from June 29, 2014, through November 29, 2021, any HCoV was detected in 5,204 (6.3 percent)." The authors concluded that "the predominant type of HCoV varied from season to season, but at least one alpha HCoV and one beta HCoV circulated each season, often in a biennial pattern...According to our analysis, a typical common HCoV season in the United States generally starts during October-November, peaks near the end of January, and ends during April-June. This knowledge of expected seasonal variation in HCoV circulation is useful for public health preparedness and clinical management of patients. Clinicians and the public health community should be aware that patterns of HCoV circulation changed during 2020-21 and that trends in future seasons may also deviate from trends before the COVID-19 pandemic."

Citation: Shah, M., Winn, A., Dahl, R. et al. Seasonality of Common Human Coronaviruses, United States. 2014–2021. Emerging Infectious Diseases. 2022. ♦

PEOPLE



Simone Glynn MD, MSc, MPH has announced her retirement effective at the end of October 2022 from the National Institutes of Health's (NIH) National Heart, Lung, and Blood Institute (NHLBI) Division of Blood Diseases and Resources'(DBDR) Blood Epidemiology and Clinical Therapeutics Branch. According to a communication from NHLBI DBDR Acting Director Julie Panepinto, MD, MSPH, "Dr. Glynn has had a very impressive career. She received her Medical Degree and a Master of Science in Blood Cell Physiology from McGill University, a Master of Public Health in Epidemiology and Biostatistics from George Washington University and completed a Cancer Prevention Fellowship at the NIH National Cancer Institute. Before coming to the Division of Blood Diseases and Resources of the National Heart, Lung, and Blood Institute (NHLBI) as Branch Chief of the Transfusion Medicine and Cellular Therapies Branch in 2006 (later assuming Branch Chief of the newly

formed Blood Epidemiology and Clinical Therapeutics Branch), Dr. Glynn was a physician at Fairfax Hospital and later a Co-Principal Investigator with the Westat Corporation. Her scientific expertise is well recognized in clinical methodologies, including clinical trial and observational study methods and management. Her research accomplishments are broad and include the areas of hematology, cellular therapies, blood banking, adult and pediatric transfusion medicine, and infectious diseases. She has authored or coauthored more than 100 publications in peer-reviewed journals in the hematology field. Dr. Glynn has a long track record of providing oversight and support of clinical trials and has overseen the branch's portfolio of epidemiologic, observational, and implementation science research in hematology on behalf of the Division, Dr. Glynn is currently the Project Officer for the Recipient Epidemiology and Donor Evaluation Study (REDS) program. This program includes domestic and international research and addresses blood donor and donation safety and availability issues as well as transfusion recipient safety concerns. She has led and grown the REDS program through multiple phases and contributed to its long-time success. She is also the NHLBI representative on the FDA-led Transfusion-Transmissible Infection Monitoring Study (TTIMS). In addition to serving on several NHLBI and trans-NIH committees, Dr. Glynn was the 2021 chair of the American Society of Hematology (ASH) Scientific Committee for Transfusion Medicine and also served on the ASH Working Group on Innovations in Clinical Trials. She is a NIH-NHLBI representative on the Department of Health and Human Services/Office of the Assistant Secretary for Health (HHS/OASH) Blood Organ and Tissue Senior Executive Council (BOTSEC). Dr. Glynn is the recipient of multiple awards at NIH/ NHLBI and nationally for her contributions to the field. She was recognized for



PEOPLE (continued from page5)

her work to help facilitate research for COVID-19, as well as the safety and availability of the blood supply and transfusion strategies. Her work to support HIV research, sexual and gender minority research, as well as her participation in trans-NHLBI groups looking at innovative ways to impact the clinical trial enterprise, the NHLBI Strategic Visioning and Initiative Development team, and the NHLBI Small Business Topic Review Advisory Committee have been recognized nationwide. She is also the recipient of the 2018 AABB (Association for the Advancement of Blood & Biotherapies) President's Award in recognition of her dedication to public service and leadership in fostering crucial collaborations between U.S. federal government agencies, industry, and AABB...She received the Assistant Secretary for Health's Special Recognition Award from DHHS in 2012 for Exemplary Team Performance for Evaluating Xenotropic Murine Leukemia Virus-Related (XMRV) Virus, a potential threat to the blood supply."

(Source: NHLBI Communication, 10/26/22)

Upcoming ABC and ADRP Webinars – Don't Miss Out!

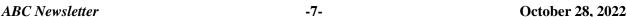
- ABC Reverse Mentoring: Future-Proof Your Organization Webinar November 2 from 2-3 PM EDT. More information including the link to join the webinar available to ABC members in MCN 22-089. Contact us for a copy of the MCN.
- ADRP 2022 International Showcase November 9 from 1-2:30 PM EST. Registration is open and free to all.
- ABC Blood Product Inventory Management: Donor Center & Hospital Transfusion Service **Perspectives** – November 15 from 3-4:30 PM EST. More information coming soon!
- ABC Scientific, Medical, and Technical Journal Club Webinar December 7 from 3-4 PM EST. More information coming soon!





ABC Calendar of Events

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







INSIDE ABC

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

October Blood Bulletin Published

America's Blood Center's (ABC) has published the October 2022 edition of the redesigned <u>Blood Bulletin</u>. This issue is titled: "Cryoprecipitate (Cryo) and Alternatives." The article was written by Courtney Hopkins, DO, Senior Chief Medical Officer at Vitalant, Samantha Ngamsuntikul, MD, Associate Medical Director at South Texas Blood & Tissue Center, a subsidiary of BioBridge Global, Richard Gammon, MD, Medical Director at OneBlood, Ruchika Goel, MD, MPH, Medical Director at ImpactLife, Nancy Van Buren, MD, Medical Director at Innovative Blood Resources and Community Blood Center of Kansas City, divisions of New York Blood Center. Louis Katz, MD, Chief Medical Officer Emeritus at ImpactLife was also a contributor. <u>Blood Bulletin</u> is reviewed and edited by ABC's Scientific, Medical, and Technical (SMT) Publications Committee. ABC publishes the Blood Bulletin for use by member blood centers in their educational programs as a value-added service for hospital customers.

(Source: MCN 22-092, 10/25/22)

Input Requested: 2023 ABC Advocacy Agenda

ABC, in consultation with the ABC Board of Directors and the ABC Policy Council, is currently developing its 2023 Advocacy Agenda. The input and feedback from member blood centers is important to this process. A link to a brief survey is available to all ABC members in MCN 22-093 (contact <u>us</u> to receive a copy of the MCN). Please provide your feedback by Friday, November 18th. The ABC Advocacy Agenda reflects the federal legislative and regulatory issues most important to blood centers. The 2023 Advocacy Agenda will build upon the work completed over the past year. ABC thanks the many volunteers and partners who helped advance the policy issues outlined in the <u>2022 Advocacy Agenda</u>. Please contact ABC Senior Director of Federal Government Affairs <u>Diane Calmus</u>, <u>JD</u> with questions or comments.

(Source: MCN 22-093, 10/26/22)

ABC Webinar: Reverse Mentoring: Future-Proof Your Organization

ABC will host a webinar titled "Reverse Mentoring: Future-Proof Your Organization" on November 2nd at 2 p.m. EDT. Attendees will "learn how General Electric, BNY Mellon, Labcorp, and many other Fortune 500 companies use reverse mentoring to future-proof their organizations and retain employees in this changing landscape. Whether you are a phlebotomist, director, human resources leader, work at a small or large blood center, you will learn how reverse mentoring can help engage, develop, and retain employees — and why it is more effective than surveys or exit interviews. Attendees will leave with a simple program outline and steps to get started right away. P.A.C.E credits will be available as well as a recording of the webinar and slides. This event will feature guest speaker Mary Schlegel, an award-winning thought leader and speaker who has been featured in *CLO* magazine, ATD's International Conference, and MentorCom for her work building a more equitable and inclusive workplace. Under her leadership, Labcorp's Reverse, Diverse Mentoring Program earned a Gold Brandon Hall Award for best advance in mentoring for DEI. A link to join the webinar and additional information is available to ABC members in MCN 22-089. Contact us to receive a copy of the MCN.

(Source: MCN 22-089, 10/20/22) •



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MEMBER NEWS



Carter BloodCare recently welcomed delegates from Ukraine in an international collaboration on blood donor recruitment and management. The six emissaries were hosted at the blood center's North Texas headquarters in Bedford October 17th— 21st. The weeklong visit included strategic sessions with Carter BloodCare leaders and health care professionals on all facets of blood resource management. Interactive presentations ranged from collection, testing, and processing to donor engagement, hospital services and quality assurance, along with in-person tours of donor centers and on-site mobile blood drives. "The need for blood unites us all," said Veronica Moore, vice president of Marketing and Operations Support with Carter BloodCare. "It is a need that our colleagues from Ukraine un-

derstand and experience all too well, on deeply personal and unprecedented levels. We are grateful to be able to support and build bridges of shared knowledge and healing."

(Carter BloodCare Announcement, 10/21/22)

Contributed by James Black, Public Relations Specialist at Carter BloodCare

San Diego Blood Bank recently <u>received</u> a \$50,000 donation from the Cushman Foundation. According to the blood bank, this contribution "will serve as the lead gift for the blood bank's new bloodmobile campaign." This charitable gift is the Cushman Foundation's largest in their 25-year giving history to San Diego Blood Bank and continues their ongoing support of the blood bank and its work within the community.



(Source: Sand Diego Blood Bank News Release, 10/21/22) ♦

We Welcome Your Letters

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

CALENDAR

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

2022

Nov. 2. America's Blood Centers (ABC) Reverse Mentoring: Future-Proof Your Organization Webinar. More information available in MCN 22-089. Contact us for a copy of the MCN.

Nov. 6-7. **Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting (Virtual).** More information available here">here.





CALENDAR (continued from page 8)

Nov. 9. **ADRP International Showcase (Virtual).** Registration is open and free. More information available here.

Nov. 15. ABC Blood Product Inventory Management: Donor Center & Hospital Transfusion Service Perspectives Webinar. More information coming soon.

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

Nov. 17. U.S. Department of Health and Human Services Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) Meeting (Virtual). More details available here.

Dec. 7. (HHS) Tick-Borne Disease Working Group Meeting (Virtual). More information available here.

Dec. 7. ABC Scientific, Medical, and Technical Journal Club Webinar. More information coming soon.

Dec. 8. U.S. Food and Drug Administration Blood Products Advisory Committee Meeting (Virtual). More details available here.

2023

Mar. 6-8. **ABC Annual Meeting, Washington, D.C.** Hotel and additional information are available <u>here</u>.

April. 24-28. ABC Blood Center Advocacy Week. More information coming soon.

Sept. 21-22. 29th IPFA/ Paul-Ehrlich-Institut[e] (PEI) International Workshop on Surveillance and Screening of Blood-borne Pathogens, Bologna, Italy. More information available here.

May 9-11. 2023 ADRP Conference, Charlotte, N.C. Call for abstracts, hotel information, and more are available here.

Sept. 17-20. American Association of Tissue Banks Annual Meeting, National Harbor, Md. More information available here.

Oct. 14-17. **AABB Annual Meeting, Nashville, Tenn.** More information available <u>here</u>.

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for ABC Newsletter subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: newsletter@americasblood.org

POSITIONS

Sr. Director, Biotherapies Quality. Vitalant is currently seeking a Sr. Director of Biotherapies Quality to provide support and leadership in advancing performance related to compliance, process improvement, and risk mitigation in the area of Biotherapies, including, but not limited to cellular therapy collections and processing, collection of starting materials for biotherapy treatments, apheresis therapeutic procedures and clinical laboratories such as HLA and Specialty Coag labs. This role will be located in our corporate headquarters in Scottsdale, AZ and lead a geographically dispersed team who comprise the quality staff overseeing these activities. This Sr. Director is a highly visible leader and an integral member of the Quality Leadership team who assures quality in their areas of

oversight. How apply: https://bloodsystems.taleo.net/careersection/jobdetail.ftl?job=222962&1 ang=en

Technical Director. Central California Blood Center based in Fresno, seeks ideal candidate for the position of Technical Director. Specialist in Blood Banking (SBB ASCP) preferred, at least 10 years blood donor testing and component manufacturing experience required, including leadership position(s). California CLS license strongly preferred. Seeking a proven leadership-skilled

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POSITIONS (continued from page 9)

individual who builds teams, collaborates, mentors, and innovates. The Technical Director is responsible for our blood donor testing laboratory, blood components manufacturing, phase III clinical trial research and biomanufacturing, immunohematology reference lab, and providing technical guidance to donor services when needed. Current area of responsibility includes over 25 FTE. Responsible for designing programs and tactics in line with company strategic goals, participating in senior leadership, assuring all processes and SOP are in compliance with state and federal regulations and AABB. Collaborates with Medical Director and other senior leaders to assure compliance, effectiveness, and positive culture within the company. Excellent salary and benefits package. How to apply: www.donateblood.org/careeropportunities/

President and CEO (MEDIC Regional Blood Center).

MEDIC Regional Blood Center is seeking a President and CEO. MEDIC, located in Knoxville, Tennessee, is a financially successful not-for-profit, independent blood center serving 25 hospitals in 22 counties throughout East Tennessee and Southern Kentucky. The preferred candidate is one who has demonstrated leadership experience in the blood industry, although related healthcare experience may be considered. The successful candidate must possess strategic planning abilities and have strong interpersonal skills to maintain the external relationships that have been developed. This position is accountable for operational goals and providing direction to the organization. The ideal candidate should possess an ability to build cohesive, high-performing teams focused on the achievement of MEDIC's goals. Candidates must be able to formulate a clear vision of how best to respond to challenges of the blood industry and do so in a highly regulated environment. The ideal candidate must have a least ten years of progressive managerial experience and hold a bachelor's degree from an accredited college or university. A graduate degree such as MBA, MHA, or equivalent is preferred. Please submit cover letter, resume, and salary requirements to Katy Stout, HR Manager at kstout@medicblood.org. The deadline for applications is October 31, 2022.

Director, Regulatory Affairs and Public Policy. America's Blood Centers (ABC), North America's largest network of community-based, independent blood programs, is seeking a Director, Regulatory Affairs and Public Policy. The position is a key role for ABC and will provide the successful candidate an opportunity to lead a strategic area of work while benefitting from the flexibility of a fully remote office environment. The Director, Regulatory Affairs and Public Policy will assist in the development, implementation, execution, and advancement of the ABC Advocacy Agenda before federal agencies and other stakeholders. Responsibilities: Analyze, evaluate, communicate, and track the impact of new

regulatory and science, medical, technical (SMT) developments on ABC member centers, including working with members and staff in the development of policy positions, public statements, and comment letters and responses to information requests from federal agencies. Build strategic relationships as a liaison with appropriate staff at FDA and other federal agencies as necessary (including HHS, OSHA, DOL, NCR, CDC, DOD, and others), and non-governmental industry partners. Serve as an ABC representative and spokesperson to industry coalitions. Conduct routine operational and ad hoc member surveys that support the ABC Advocacy Agenda. Work includes the creation of survey forms and protocols, analysis of data, and preparation and dissemination of reports. Educational Requirements: Bachelor's required. Experience, Knowledge, Skills, and Abilities: Seven plus years of experience with public policy and regulatory affairs, preferably with FDA. Click here to view the full job description. Interested applicants should send a cover letter and resume to careers@americasblood.org.

Medical Director (Gulf Coast Regional Blood Center).

Reporting to the Chief Medical Officer, this individual will assist in providing oversight of operational and implementation expertise across multiple areas of a large community blood center. Areas of responsibility include medical oversight of selection and care of donors, collection, processing, and testing of blood, and disease notification. In addition, this individual will provide guidance for The Blood Center's transfusion service activities and cellular therapy programs, as well as serving as a liaison with medical staff in the community to address transfusion concerns and assure the appropriate utilization of blood products. Requirements: Doctor of Medicine or Doctor of Osteopathy degree from an accredited university with at least four years of combined education and experience in blood banking/transfusion medicine or related field. Board certified or board -eligible in Pathology, Hematology, or related field. Specialty training and/or certification in Blood Banking, Hematology, or a similar related field is highly desirable. Eligible for medical license in the state of Texas. Applicants with additional medical or management experience in apheresis related to cellular therapy and transplant are strongly encouraged to apply. Click here to apply. •