

A B C N E W S L E T T E R CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2022 #19

May 27, 2022

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ABC & ADRP High School Biology Education Program Now Available

America's Blood Centers (ABC) and ADRP, an International Division of ABC, recently <u>launched</u> *Vein to Vein: The Science of Blood Donation*. This new high school education program aims to help educators in creating lesson plans to develop student leadership skills and a lifelong interest in supporting blood donation.

"Vein to Vein provides free, groundbreaking resources at a critical time," said Kate Fry, MBA, CAE, chief executive officer of ABC in a <u>news</u> <u>release</u>. "It is developed by educators to give teachers the ability to craft lesson plans that bring the importance of blood donation to life. This program will teach students leadership skills, in-



spire them to become lifelong blood donors, and give them information to pursue rewarding careers in the blood community that can help save lives."

This turn-key resource has been designed to meet Next Generation Science Standards, though all states can benefit from this resource. Implementation goes beyond the field of science to also offer opportunities to integrate English Language Arts and Mathematics. This program was developed to complement rather than replace existing blood center programs.

ConnectLife, Blood & Organ Donor Network, and New York Blood Center Enterprises collaborated with ABC and ADRP in developing this program, along with a grant from Johnson & Johnson.

Vein to Vein offers a suite of tools to bring blood donation into the classroom, including:

- multiple educational tools designed to meet Next Generation Science Standards;
- a teacher preparation guide and student education video, creating a foundation for learning; and
- extensive facts, a glossary, student activities, career exploration opportunities, and much more.

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High School Biology Education Program Available (continued from page 1)

Additional resources have been developed for blood centers to use in the implementation of this program in their local schools. ABC and ADRP are also working with national education groups to expand the reach of the program.

ABC and ADRP will share updates as they become available and encourage blood centers to share feedback on the program.

(Sources: MCN 22-046, 5/24/22; ABC and ADRP <u>News Release</u>, 5/24/22) •

FDA Updates vCJD Guidance and Publishes Two Others

This week, the U.S. Food and Drug Administration (FDA) released an updated <u>Guidance for Industry:</u> <u>Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant</u> <u>Creutzfeldt-Jakob Disease by Blood and Blood Components</u>. This update supersedes the August 2020 guidance and was posted for immediate implementation.

The updated guidance removes the deferral recommendations associated with the geographic risk of vCJD:

- for time spent in the UK from 1980-1996;
- time spent in France and Ireland from 1980-2001; and
- receipt of a blood transfusion in the UK, France, or Ireland from 1980-present.

FDA recommends that blood collection establishments update their donor history questionnaires (DHQ) to incorporate these changes. The guidance also includes recommendations for the requalification of donors previously deferred for these risk factors (provided they meet all other eligibility requirements).

Assessing, and permanently deferring donors for a history of receiving a human cadaveric (allogeneic) dura mater transplant remains. In addition, permanent deferrals remain in place for donors who volunteer the following information:

- suspected of having vCJD, CJD or any other transmissible spongiform encephalopathies;
- who have a blood relative diagnosed with familial prion disease; or
- who received cadaveric pituitary human growth hormone.

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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.

America's Blood Centers

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FDA Releases Multiple Guidances (continued from page 2)

Product retrieval and quarantine requirements for post donation information received about the above permanent deferrals remain in effect, and the Circular of Information warning statement regarding vCJD/CJD remains unchanged. Blood centers may implement these recommendations once their DHQ and accompanying materials are updated. Licensed blood establishments utilizing a DHQ prepared by the AABB Donor History Task Force report the change in their annual report to FDA, noting the date the process was implemented.

ABC issued a <u>statement</u> of support and <u>talking points</u> for these changes.

FDA Publishes Two More Guidances. The FDA also released a <u>draft guidance</u> titled "Blood Pressure and Pulse Donor Eligibility Requirements - Compliance Policy." This draft guidance is for comment purposes only (not for implementation) and was developed in response to feedback from blood establishments regarding donor pulse and blood pressure (BP) requirements outlined in 21 CFR 630.10 and 630.5.

The current regulations for systolic and diastolic BP (90-180 mm and 50-100 mm of mercury, respectively), and pulse (regular, and between 50-100 beats per minute(bpm)) allow for exceptions if the responsible physician examines the donor and determines the donor's health would not be adversely affected by donating.

The draft guidance allows for the acceptance of the following donors, without consultation with the responsible physician, as long as standard operating procedures (SOPs) outline the requirements for:

- a donor with a pulse below 50 bpm, who self-reports being a healthy athlete; and
- medical criteria for donation by a donor with an irregular pulse.

The agency also published a <u>draft guidance</u> titled "Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements." This draft guidance is also for comment purposes only but is a step forward to making permanent, the temporary exceptions and alternatives set forth in the <u>Alternative Procedures for Blood and Blood Components During</u> the COVID-19 Public Health Emergency; Guidance for Industry, April 2020.

ABC continues to advocate on behalf of member blood centers that these changes be made permanent, beyond the Public Health Emergency (PHE), as they have increased availability of the blood supply without compromising the health of blood donors. While the April 2020 guidance is to remain in effect only for the duration of the PHE, the procedures in the draft guidance could be finalized and therefore remain in effect.

To recap, the exceptions and alternatives currently in place allow for:

- the release of blood components from donations considered as unsuitable because of failure to follow SOPs that ensure the donation would not adversely affect the health of the donor (i.e., blood pressure, pulse, weight, donation frequency);
- the release of Source Plasma collected after a quarantine hold of 45 calendar days (instead of 60 days); and
- the ability to clarify or obtain donor eligibility information from a donor within 72 hours of collection (instead of 24 hours).

The draft guidance adds two additional categories to components eligible for release: pregnancy (21 CFR 630.10(e)(2)(v), and red blood cell loss for plasma collected by plasmapheresis (21 CFR 630.15(b)(6).

In addition, the FDA will apply the aforementioned compliance policy provided blood establishments that elect to release units, report annually, the number and type of donations released, along with corrective actions taken to prevent recurrence of errors and to ensure compliance with the applicable regulations.



<u>FDA Releases Multiple Guidances</u> (continued from page 3)

Comments for both draft guidances may be submitted to: <u>https://www.regulations.gov</u>.

The ABC QA Blood Regulatory Review and Scientific, Medical, and Technical (SMT) Committees, along with the ABC Policy Council will further review the guidances, to assess impacts to blood center policies and procedures, and provide feedback for comments to be submitted to the FDA. Please contact ABC Director of Regulatory Affairs <u>Jill Mastin</u> with questions.

(Sources: MCN 22-045, 5/23/22; FDA Guidances, 5/23/22)

RESEARCH IN BRIEF

Risks of Prehospital Whole Blood Transfusion to English Trauma Patients. A study in Vox Sanguinis "aimed to model risks of harm from transfusing group O D-positive red blood cells (RBC) to trauma recipients in England in the prehospital setting." The authors "calculated the probability of causing immediate and future harm to a D-negative patient resuscitated with D-positive RBCs...The harms model[ed] [were] the same for RBCs or low-titer group O whole blood (LTOWB)." The study "model[ed] three specific harms: hemolytic transfusion reaction (HTR) associated with transfusion of D-positive blood, HTR associated with future transfusion of D-positive blood and hemolytic disease of the fetus and newborn (HDFN)...[T]wo patient populations [were assessed]: (a) all trauma patients who require D-positive RBCs or LTOWB in the prehospital setting, and (b) patients who are D-negative females of childbearing potential (CBP, <50 years of age)...Results of the model showed that for every 14,000 D-positive transfusions administered to [trauma patients,] one of three specific harms would occur." The study explained that, "[f]or D-negative females under age 50, for every 520 D-positive transfusions, one of the three specific harms would occur. The main risk [was] HDFN, where for every 570 transfusions, one fetal death or disability would occur...The results demonstrated that the number of years required for any of the three specific harms to occur is 2.5 for all recipients and 5.2 for D-negative females of CBP. HDFN would be expected to occur every 5.7 years in the latter group...[A] survival increase of at least 1.0 percent from the use of LTOWB compared to current standard of care would lead to life years gained exceeding life years lost due to HDFN in the future if D-positive whole blood was transfused to D-negative females under 50...The risk of an HTR due to a D-positive transfusion was 1:27,000 transfusions for all recipients and 1:6,600 for Dnegative females under 50; this [is] one event every 4 years and 65 years, respectively." The authors concluded that, "reallocation of D-negative RBCs away from prehospital use would facilitate provision of these scarce RBCs to patients who are already D-alloimmunized, and patients who require antigen-matched RBC such as sickle cell disease patients for whom alloimmunization could pose dire long term health consequences."

Citation: Cardigan, R., Latham, T., Weaver, A., Yazer, M., Green, L. <u>Estimating the risks of prehospital</u> transfusion of D-positive whole blood to trauma patients who are bleeding in England. *Vox Sang.* 2022.

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

Upcoming ABC Webinars – Don't Miss Out!

- The Clinical Laboratory Workforce: Understanding the Challenges to Meeting Current and Future Need-ASCP Blueprint Webinar July 20th from 3-4 PM EDT. More information coming soon.
- ABC SMT Journal Club Webinar August 10th from 3-4 PM EDT. More information coming soon.



America's Blood Centers^{*} It's About Life. INSIDE ABC

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

ADRP Shares World Blood Donor Day Resources

With World Blood Donor Day (WBDD) (June 14th) a little more than two weeks away, ADRP, an International division of America's Blood Centers (ABC) has created a centralized <u>hub</u> of WBDD resources to assist blood centers in celebrating and thanking blood donors for their lifesaving work. Assets include logos in multiple languages from the World Health Organization (WHO) which selected Mexico as this year's host nation. Additional resources will be added as they become available.

ABC MD Workshop and Summer Summit

Mark your calendar for the <u>ABC Medical Directors Workshop and ABC Summer Summit</u> taking place August 2-4 in Minneapolis, Minn. Over the course of two days, attendees will hear case study rounds, engaging discussions, and have many networking opportunities to connect with peers and colleagues. <u>Hotel</u> reservations can be made now through the ABC block.

BRIEFLY NOTED

ABC Newsletter

The Blood Emergency Readiness Corps (BERC) <u>activated</u> this week for the fourth time to respond to the tragic school shooting in Uvalde, Texas. According to a news release, several blood centers within the BERC network helped BERC and ABC member South Texas Blood & Tissue meet the needs of trauma patients at local hospitals including fellow ABC member blood centers:

- SunCoast Blood Centers;
- Carter BloodCare;
- The Community Blood Center (Appleton, Wis.);
- The Blood Connection;
- The Blood Center (New Orleans, L.A.);
- Vitalant;
- Rock River Valley Blood Center;
- Community Blood Center of the Ozarks;
- Miller-Keystone Blood Center; and
- LifeServe Blood Center.

(Source: BERC <u>News Release</u>, 5/25/22)

The American Society for Clinical Pathology (ASCP) is <u>seeking</u> input to the 2022 ASCP Vacancy Survey. According to an ASCP announcement, the survey aims to "help [ASCP] determine the extent and distribution of workforce shortages within the nation's medical laboratories and to help inform change...[It] will help ascertain the current staffing needs in the laboratory and the ongoing impact of the COVID-19 pandemic on the field. In addition to general staffing questions, the survey asks about hiring, recruitment,

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BRIEFLY NOTED (continued from page 5)

and retention challenges participants face in their institutions." Results from the 2020 ASCP Vacancy Survey have been <u>published</u>.

(Source: ASCP <u>Announcement</u>, 5/19/22) •

WORD IN WASHINGTON

U.S. Surgeon General Vice Admiral (VADM) Vivek Murthy, MD, MBA issued an advisory addressing burnout and resignations among health workers. In the advisory from the U.S. Department of Health and Human Services (HHS), VADM Murthy stated, "[health workers] have long faced systemic challenges in the health care system even before the COVID-19 pandemic, leading to crisis levels of burnout. The pandemic further exacerbated burnout for health workers, with many risking and sacrificing their own lives in the service of others while responding to a public health crisis. Promoting the mental health and wellbeing of our nation's frontline health workers is a priority for the Biden-Harris Administration and a core objective of President Biden's national mental health strategy." He provided several <u>recommendations</u> for health care organizations including:

- "[t]ransform workplace culture to empower health workers and be responsive to their voices and need;
- [s]how health workers how much they are valued;
- [b]uild a commitment to the health and safety of health workers into the fabric of health organizations;
- [r]eview and revise policies to ensure health workers are not deterred from seeking appropriate care for their physical health, mental health and/or substance use challenges;
- [i]ncrease access to high-quality, confidential mental health and substance use care for all health workers;
- [d]evelop mental health support services tailored to the needs of health workers;
- [r]ebuild community and social connection among health workers to mitigate burnout and feelings of loneliness and isolation;
- [h]elp health workers prioritize quality time with patients and colleagues;
- [c]ombat bias, racism, and discrimination in the workplace;
- [w]ork with health workers and communities to confront health misinformation; and
- [i]nvest in health prevention and social services to address health inequities."

(Source: HHS Advisory, 5/23/22)

The Biomedical Advanced Research and Development Authority (BARDA) has <u>published</u> its 2022-26 strategic <u>plan</u>. It specifically references "next-generation blood products" under "objective 1.3 key milestones" and mentions the agency's support of efforts to collect and distribute COVID-19 convalescent plasma throughout the COVID-19 pandemic. The four main goals of the plan include:

- "preparedness rapidly develop safe, effective medical countermeasures accessible to all Americans;
- response maintain a sustainable, mission-ready response posture;
- partnerships leverage mechanisms to foster flexible partnerships; [and]
- workforce build and support a world class workforce."

(Source: BARDA <u>Announcement</u>, 5/24/22) •



MEMBER NEWS

ABC Newsletter

Versiti Blood Center of Wisconsin has <u>announced</u> a new community resource and fixed site location in Milwaukee within the ThriveOn Collaboration's ThriveOn King development. According to a news release, Versiti will be an anchor tenant with the nearly 3,500 square-foot facility "[serving] as a com-

Versiti^{*}

munity hub for Versiti, focused on providing resources to address healthcare disparities in Milwaukee neighborhoods and beyond through training and employment, education, and blood donation." Chis Miskel, MBA, president and chief executive officer at Versiti, added in the news release, "Versiti has proudly been part of the Milwaukee community for 75 years. While we have made great strides to address racial disparities in blood and organ donation, we know there is much work yet to do. Through advocacy and community outreach, Versiti hopes to further establish itself as a trusted resource and agent of change for the donors and patients we serve." Co-lead of the ThriveOn Collaboration, Greg Wesley, stated in the release, "Versiti's commitment to health equity and resources for the community aligns with the dedication of ThriveOn Collaboration to make generational investments in the well-being of Milwaukee communities aimed at eliminating racial, health, economic and social disparities. Offering new resources and opportunity to the community, based on their feedback and collaboration, is a key goal coming to fruition."

(Source: Versiti News Release, 5/24/22)

Correction

Last week's *ABC Newsletter* misidentified the Emmy-nominated video from Central California Blood Center. The "<u>Romance Novel</u>" video from the "It's Amazing What you Can Do" campaign is the video nominated for this achievement. We apologize for any confusion and thank you for your continued interest.

GLOBAL NEWS

Austria is implementing individual risk-based blood donation deferrals for all individuals "regardless of their gender or sexual orientation," according to a <u>report</u> from *Euronews*. "We are putting an end to discrimination from another age," said Green party Health Minister Johannes Rauch in a statement to the media outlet. "[I]f someone wants to help by donating, there is no reason why they should be prevented from doing so because of their sexual orientation or gender identity." The policy change will take place this summer as the previous policy had "prevented anyone in Austria from donating blood if they had 'risky sex' in the last 12 months. Transsexuals and non-binary citizens were completely banned from donating blood."

(Source: Euronews, Austria to lower hurdles for LGBT+ citizens to donate blood, 5/20/22)

Tedros Adhanom Ghebreyesus, PhD has been <u>elected</u> to a second term as World Health Organization (WHO) Director-General. His new 5-year-term officially begins on August 16th and his re-election was confirmed at the 75th World Health Assembly in Geneva. "I am humbled by the opportunity provided by Member States to serve a second term as WHO Director-General," said Dr. Ghebreyesus in a WHO news release. "This hon[o]r, though, comes with great responsibility and I am committed to working with all countries, my colleagues around the world, and our valued partners, to ensure WHO delivers on its mission to promote health, keep the world safe and serve the vulnerable." Prior to being elected as WHO Director-General for his first term in 2017, Dr. Ghebreyesus "served as Minister of Foreign Affairs, Ethiopia from 2012–2016 and as Minister of Health, Ethiopia from 2005–2012."

(Source: WHO <u>News Release</u>, 5/24/22) ♦



COMPANY NEWS

ABC Newsletter

The U.S. Food and Drug Administration (FDA) has received and accepted for priority review a Biologics License Application (BLA) <u>submission</u> from **CSL Behring** for a gene therapy to treat hemophilia B in adults. The investigational gene therapy created by **uniQure N.V.**, who is partnering with CSL Behring on the global commercialization of the therapy, is "specifically designed to make near-normal blood-clotting ability possible by addressing the underlying cause of hemophilia B: a faulty gene that causes a deficiency in clotting Factor IX (FIX). Etranacogene dezaparvovec has been shown in clinical trials to significantly reduce the rate of annual bleeds in trial participants after a single one-time infusion and, if approved, would be the first ever gene therapy treatment option for the hemophilia B community," according to a uniQure news release. The BLA submission is based on findings from the phase III HOPE-B clinical trial in which, "participants [had] a reduction in adjusted annualized bleeding rate (ABR) of 64 percent and superiority to prophylaxis treatment at 18 months post-treatment compared to a 6-month run in period (p=0.0002)."

(Source: uniQure N.V. News Release, 5/24/22)

Embleema Inc. and **CDISC** have <u>announced</u> a partnership to "develop standards" for monitoring activity of cell and gene therapy products. The collaboration on these standards also aims to "drive operational efficiencies, expediting the regulatory review process and reducing the time it takes to bring safe and effective treatments to market."

(Source: Embleema Inc. and CDISC <u>News Release</u>, 5/24/22)

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.)

2022

June 4-8. 37th Annual International Congress of ISBT (Virtual). More information available here.

June. 7-9. U.S. Food and Drug Administration (FDA) Virtual Public Workshop — Building Medical Device Supply Chain Resilience: A Healthcare and Public Health Ecosystem-wide Collaboration. More information available <u>here</u>.

June. 6-10. FDA Regulatory Education for Industry (REdI) Annual Conference 2022 (Virtual). More information available here.

June. 9-10. **FDA Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) Meeting (Virtual)**. More information available <u>here</u>.

Aug. 2-4. ABC Summer Summit and Medical Directors Workshop, Minneapolis, Minn. More information coming soon.

Aug. 29-30. National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) and the Office of the of the Assistant Secretary of Health (OASH) of the Department of Health and Human Services (HHS) 2022 State of the Science in Transfusion Medicine Workshop (Virtual). More information coming soon.

Sept. 19-22. American Association of Tissue Banks Annual Meeting, San Antonio, Texas. More information available <u>here</u>.

Sept. 21-22. 28th IPFA/ Paul-Ehrlich-Institut[e] (PEI) International Workshop on Surveillance and Screening of Blood-borne Pathogens, Porto, Portugal. Registration is <u>open</u>. More information available <u>here</u>.

<u>CALENDAR</u> (continued from page 8)

Sept. 28-29. 2022 ADRP Master Class (Virtual). More information coming soon.

Sept. 28-29. BEST Meeting LXIV, Cocoa Beach, Fla. More information available here.

Oct. 1-4. Association for the Advancement of Blood & Biotherapies Annual Meeting, Orlando, Fla. More information available <u>here</u>.

2023

Mar. 6-8. ABC Annual Meeting, Washington, D.C. More information coming soon.

May 9-11. 2023 ADRP Conference. 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 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: <u>newsletter@americasblood.org</u>

EQUIPMENT AVAILABLE:

For Sale. New and Unused CompoMat G5 Units. The Blood Bank of Alaska has three new and unused CompoMat G5 Units for sale. These units have not been validated or used. If interested, please contact Bryan Baynard at <u>bbaynard@bbak.org</u> or (907) 222-5664.

POSITIONS

President/CEO. Shepeard Community Blood Center is seeking a President/CEO to succeed a very effective CEO who is retiring December 31, 2022. Shepeard, located in Augusta, GA, is a successful (and financially sound), notfor-profit, independent organization proudly serving 29 hospitals and helicopter ambulatory services spanning 40 counties in Georgia and South Carolina. The preferred candidate is one who has demonstrated leadership experience in the blood/blood product collection industry, although persons with related health care industry experience may be considered. The successful candidate must possess exceptional strategic planning abilities and have strong interpersonal skills to maintain and develop mission-supporting relationships in the health care and local communities we serve. This executive leadership position is accountable for operational objectives and providing leadership and direction to the organization and working closely with the Board of Directors to strategically plan and ensure strategic plan is implemented to conform to Shepeard's mission, vision, and core values. That includes the demonstrated ability to build cohesive teams to drive operational success in a challenging, forward moving blood industry with highly regulated environments. Candidates must be able to formulate a clear vision of how best to respond to ever-changing challenges in the industry. Candidates must have at least ten years of progressive managerial experience and hold a baccalaureate degree and either an MHA or MBA (or

equivalent) from an accredited college or university. EOE/M/F/Vet/Disabled compliant. Please submit a resume with salary history and a cover letter explaining why you meet the requirements of this position to Jerry@GeraldWoods.net or mail to Shepeard Community Blood Center, Attn: Jerry Woods, 1533 Wrightsboro Road, Augusta, GA, 30904. The deadline for applications is **June 15, 2022**.

Director of Finance. LifeSouth Community Blood Centers is currently seeking an individual to join our team as the Director of Finance in Gainesville, FL. This position is charged with ensuring the stability of LifeSouth's finances through planning, directing, and controlling financial functions, including establishing appropriate control environments, financial reports for management on the company's financial status, preparing financial reports and analysis, and overseeing the development and implementation of effective financial and accounting systems. The selected candidate will also manage the Purchasing and Accounting departments. Applicants should apply <u>here</u>.

Research and Commercial Protocol Coordinator. Oversees City of Hope (COH) research protocols, sponsored research protocols, and commercial protocols for

POSITIONS (continued from page 9)

CAR T Cell program and other cellular therapy programs including genetically modified CD34 cells and cytotoxic lymphocytes. This person is responsible for maintaining current versions of lab protocols, attending site visits and other related meetings, writing SOPs, training, updating protocol binders with new versions and patients on study. corresponding with protocol personnel regarding studyrelated issues, receipt of products and infusion orders, and product quality certificates. Prepares and participates in audits conducted by protocol personnel, and assumes other related activities as delegated by the Supervisor of Stem Cell Lab and Director of Transfusion Medicine Laboratories. Additionally, performs cryopreservation procedures used to store Stem Cell products used for patient transplantation, performs thawing procedures used for Stem Cell infusion, and performs all procedures in compliance with written SOPs and FACT, AABB and FDA regulations. Basic education, experience and skills required for consideration: Bachelor's Degree, one year related experience and MT(ASCP) or California Clinical Laboratory Scientist License (CLS). Additional Information: As a condition of employment, City of Hope requires staff to comply with all state and federal vaccinamandates. tion Apply online: https://aa067.taleo.net/careersection/ex/jobdetail.ftl?lang=en&job=10016395.EOE

Manager, Stem Cell Laboratory. Manages the Stem Cell Laboratory ensuring that blood products are provided as needed for patient transplantation; ensures compliance with regulatory requirements. Responsible for managing all activities of the Stem Cell Processing Laboratory. Responsibilities include writing Standard Operating Procedures, reviewing quality control records, participating in clinical research protocols, evaluating staff performance, and participating in hiring and termination decisions. The Manager of the Stem Cell Lab will also work in partnership with the Director of Transfusion Medicine and the City of Hope Research Enterprise to set strategy to meet current and future needs of the stem cell laboratory. Basic education, experience and skills required for consideration: Bachelor's degree, five to seven years of stem cell lab experience, and one year of experience in a leadership capacity. Required Certification/Licensure: California CLS license. In lieu of California CLS license new hire may have MT(ASCP) license and obtain CA CLS license within one year of hire. Additional Information: As a condition of employment, City of Hope requires staff to comply with all state and federal vaccination mandates. Apply on-line: https://aa067.taleo.net/careersection/ex/jobdetail.ftl?lang=en&job=10014031.EOE

QA Specialist (R2216359) (Stanford Blood Center). Responsibilities: Cover the quality essentials and perform regulated tasks addressing organization, resources, equipment, supplier & customer issues, process control,



document and records, deviations and adverse events, assessments, process improvement, and facility & safety. Assist in training appropriate personnel pertaining to QRA and safety activities. Ensure compliance to current regulations, accreditation standards, guidance documents and policies and procedures consistent with the latest releases of Code of Federal Regulations, California Code of Regulations, Health & Safety Codes, Business and Professions Code, AABB Blood Bank and Transfusion Services and College of American Pathologist accreditation standards including local Bills (Assembly and Senate Bills) and applicable County Directives. Perform regulated document reviews of standard operating procedures, forms, training plans, other pertinent documents, change controls, and validations. Also, review and monitor incident and deviation management through the different Quality Management System applications. Act as member of the safety committee member and perform designated roles as Emergency Response Team (ERT), Assembly Point Coordinator (APC). Facilitate external inspection conducted by inspectors. Qualifications: Bachelor's degree required. Three plus years to five years in blood banking, laboratory, or manufacturing with solid familiarity of GMP, safety in a manufacturing setup, and CAL-OSHA regulations Required. Please click here to view the full job description and apply.

Director of Recruitment (Bradenton, FL). SunCoast Blood Centers is accepting applications for a Director of Recruitment to work at our Lakewood Ranch Head Quarters. This position directs and oversees mobile, fixed site and concierge recruitment activities. Other duties include Designs and directs a comprehensive donor recruitment and retention plan for the organization. Counsels and evaluates the performance of direct reports. Oversees processes related to the coaching and mentoring of recruitment management staff to assure a well-functioning team. Manages the data base of blood donors and donor groups to assure successful strategies to meet collection goals, standards, and efficiency measures, and other duties as required to fulfill the organizations mission vision. Qualified applications should possess a bachelor's degree in public relations, marketing, or other equivalent experience. Applicant must have five years recruitment, healthcare sales, or marketing, plus three years in a senior leadership role. To apply and view a complete job description of this position please visit https://suncoastblood.org/careers/. EOE. Applicant drug testing required.

Director of Regulatory Affairs and Quality Compliance. The Blood Connection is looking for a Director of Regulatory Affairs and Quality Compliance. This is a newly created position reporting to the Vice President of Quality Systems. The Direct of Regulatory Affairs and Quality Compliance would be responsible for providing leadership with regulatory guidance ensuring ongoing

(continued on page 11)

POSITIONS (continued from page 10)

compliance for the organization. This role will monitor the release of new or revised regulations and standards, evaluating the impact on current processes and practices, and recommend changes if necessary to ensure continual compliance. The Director will evaluate investigations of incidents/occurrences reported and participate in the investigation, root cause analysis, and development of corrective action plans. This role will lead the Quality Unit staff by coaching, managing, monitoring, and evaluating compliance activities and promoting ongoing compliance and effective processes ensuring adherence to applicable regulations and standards. We offer a generous benefits package including a great 401k match, tuition reimbursement, yearly increases, company bonus, cell phone stipend, and 30 days PTO. How to apply: https://thebloodconnection.org/about-us/careers/.

