

ABCNEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

2022 #20

June 3, 2022

INSIDE:

WORD IN WASHINGTON
2
RESEARCH IN BRIEF3
INFECTIOUS DISEASE UPDATES4
June <i>Blood Bulletin</i> Published5
ADRP Partners with Global Blood Fund5
ADRP Shares World Blood Donor Day Resources5
Registration Opens for MD Workshop and Summer Summit5
GLOBAL NEWS6
COMPANY NEWS6
CALENDAR7
EQUIPMENT AVAILABLE:7
POSITIONS8

Congressional Sign-on Letter Regarding FDA's Temporary Donor Deferral Changes Made During COVID-19 Public Health Emergency

America's Blood Centers (ABC) recently notified member blood centers on May 25th of a letter circulating within the U.S. House of Representatives. The letter encourages the U.S. Food and Drug Administration (FDA) to make permanent temporary blood donor deferral changes, without delay, which were implemented during the COVID-19 public health emergency (PHE). ABC asked member blood centers to contact their members of the U.S. House of Representatives by Friday, June 3rd (the deadline for Congressional offices to support the letter by signing-on has now been extended until June 10th) and request that they show their approval by signing the letter.

Specifically, the letter urged the agency to "finalize the revised recommendations to reduce the risk of transfusion-transmitted malaria and for reducing the risk of human immunodeficiency virus (HIV) transmission by blood and blood products, including source plasma, released April 2020." It stated that the agency's guidance "in effect under the COVID-19 PHE has prevented potential donors from being deferred and has allowed for thousands of individuals to re-enter donor pool who had been previously deferred."

The letter also explained that "[a]lthough the PHE is still in effect, blood centers are aware the existing guidance is tied to the PHE declaration, resulting in uncertainty about the future applicability of these guidance documents. While we recognize the FDA's stated intent to issue revised guidance within 60 days of the expiration of the PHE...Finalizing these guidance documents prior to the conclusion of the PHE will eliminate unnecessary uncertainty, allow blood centers to produce contingency plans should the temporary guidance not be replaced with permanent guidance, and avoid donor confusion." It concluded by requesting that the FDA, "finalize these important guidance documents that have safely expanded the donor base to assist blood centers in their essential job of ensuring all patients in need of lifesaving blood have a safe product available when needed."

Ensuring permanence of the guidance documents beyond the PHE is one of ABC's top three <u>advocacy agenda</u> issues. The House sign-on letter directly addressed concerns raised by ABC member blood centers during the March 2022 Advocacy Day where individuals from ABC member blood centers virtually met with members of Congress and their staff. ABC thanks all members for their assistance with this advocacy initiative and urges anyone that has not already done so, to reach out to their U.S. House Representative now to encourage signing this important letter. For more information, please contact ABC's Senior Director of Federal Government Affairs Diane Calmus, JD.







The U.S. Food and Drug Administration's (FDA) Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) will hold a second meeting virtually this month on June 29-30, according to a notice <u>published</u> in the *Federal Register*. The meeting will include discussion on "the current regulatory expectations for xenotransplantation products. The discussion topics include human cells that have had ex vivo contact with animal cells, and animal organs and cells for transplantation into human subjects, both of which are xenotransplantation products." Additional information can be found on the FDA <u>website</u>. The CTGTAC previously announced that it would meet virtually June 9-10, according to a notice <u>published</u> in the *Federal Register* on April 14th, to discuss "two biologics license applications (BLAs) from bluebird bio, Inc." including a therapy for "the treatment of patients with beta thalassemia who require regular red blood cell transfusions." Additional information on that meeting can be found here.

(Source: Federal Register Notice, 5/31/22)

The U.S. Department of Health and Human Services (HHS) <u>published</u> a withdrawal in the *Federal Register* of the "Securing Updated and Necessary Statutory Evaluations Timely" (SUNSET final rule). The agency had previously <u>postponed</u> the effective date. The original SUNSET rule was finalized on January 19th, 2021, the day before the inauguration of President Biden. The enforcement of the rule had also been previously <u>delayed</u> pending judicial review. During this administrative delay, HHS reconsidered comments and proposed to withdraw or repeal the SUNSET final rule in its entirety. If the SUNSET final rule took effect, unless HHS "assessed" and, if required, "reviewed" most regulations within a certain timeframe specified in the rule (for most existing regulations, within two years) and every 10 years thereafter, the regulations would expire.

(Source: Federal Register Notice, 5/27/22)

The Office of the Assistant Secretary for Health (OASH) in HHS announced B. Kaye Hayes, MPA has been named Deputy Assistant Secretary for Infectious Disease and the Director of the Office of Infectious Disease and HIV/AIDS Policy (OIDP). Ms. Hayes provided leadership within OASH for 25 years including most recently serving as the Acting Director of OIDP. During her career within the agency, she has worked on "the Presidential Advisory Council on HIV/AIDS (PACHA) to implement the *Ending the HIV Epidemic Initiative and the National HIV/AIDS Strategy* launch at the White House last December, along with the release of strategic plans on HIV, STI, Hepatitis and Vaccines, Blood Safety Report, and the Tick-Borne Disease Congressional Report." Ms. Hayes received her "bachelor's degree from the University

(continued on page 3)

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 2022 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 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

Chief Executive Officer: Kate Fry Chief Medical Officer: Rita Reik 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 newsletter@americasblood.org.

ABC Newsletter -3- June 3, 2022

WORD IN WASHINGTON (continued from page 2)

of Virginia and a master's degree in public administration from Georgia State University, with a concentration in strategic management and human resource management."

(Source: HHS Announcement, 5/25/22)

Adam H. Russell, D.Phil. has been appointed as Acting Deputy Director of the National Institutes of Health's (NIH) Advanced Research Project Agency for Health (ARPA-H). Dr. Russell currently serves as the Chief Scientist at the University of Maryland's Applied Research Laboratory for Intelligence and Security (ARLIS) and will begin his new role in June. As Acting Deputy Director, "he will guide the early stages of building the administrative structure of the agency and oversee the hiring of initial operational staff to ensure the agency is stood up as effectively and efficiently as possible. President Biden will appoint an ARPA-H Director who will be responsible for administration and operation of ARPA-H and will report to the HHS Secretary," according to an HHS news release. "We are ecstatic that Dr. Adam Russell has accepted the challenge to help launch ARPA-H, President Biden's bold, new endeavor to support ambitious and potentially transformational health research in this country," said HHS Secretary Xavier Becerra, JD in the news release. "ARPA-H will have a singular purpose: to drive breakthroughs in health, including the prevention, detection and treatment of diseases such as cancer, Alzheimer's and diabetes." Dr. Russell "holds a Bachelor of Arts in Cultural Anthropology from Duke University, and an M.Phil. and a D.Phil. in Social Anthropology from Oxford University, where he was a Rhodes Scholar."

(Source: HHS News Release, 5/25/22)

RESEARCH IN BRIEF

A Quality Assessment of Plasma from Apheresis vs. Whole Blood. A study in Lab Medicine evaluated the "impact of storage of thawed plasma (TP) on coagulation quality and posttransfusion outcomes of apheresis plasma (AP) vs. whole blood plasma (WBP)." The authors explained that the study included four categories: "50 AP units (Autopheresis-C), 50 AP units (Trima), 50 WBP stored at 4°C for <3 hours, [and] 50 WBP stored at 4°C for 24 hours." Their research "evaluated prothrombin time/international normalized ratio (PT/ INR), activated partial thromboplastin time (aPTT), fibringen, and factors V and VIII on days 0, 2 and the impact of twice freezing and thawing." The study "evaluated 70 patients [with] chronic cirrhosis...All received TP on day 2, either AP (Trima-35 transfusions) or WBP stored <3 hours (35 transfusions) prior to an invasive procedure and within 4 hours their INR [was assessed]." The researchers also "studied 25 patients with thrombotic thrombocytopenic purpura (TTP), who underwent plasma exchange (PE)...Patients were assigned to receive 2 paired PE using AP (Trima) and WBP (stored <3 hours) alternatively, and immediate coagulation changes were evaluated...Immediately on thawing AP, no significant differences of coagulation values were noted between [apheresis] machines (P > .05)." The study noted that, "[s]ignificant impairment of all coagulation parameters was observed in WBP, compared with AP (P < .05)...WBP prepared 24 hours after donation showed a significant drop of factor VIII, compared to that prepared <3 hours (P < .05)...Compared to immediately thawing, values of AP were not influenced by 24– 48 hours storage (P > .05)...A significant drop of factors V and VIII was noted with WBP (P < .05)...Compared to immediately thawing values, twice-frozen AP and WBP showed significant decreases in coagulation factors (P < .05)." In patients with cirrhosis, "the median correction of INR after transfusion of WBP was from 2.3 to 1.45 [and] after transfusion of AP was from 2.5 to 1.57 [and] not statistically significant (P > .05)...[D] ecrease in INR following PE was comparable with both AP and WBP (P > .05)... The authors concluded the "analysis revealed that coagulation factors were well-preserved in thawed specimens

(continued on page 4)

ABC Newsletter -4- June 3, 2022

RESEARCH IN BRIEF (continued from page 3)

from AP." They added, "[t]his can ultimately provide effective utilization and management of plasma units while maintaining the greatest coagulation quality."

Citation: Hussein, E., Enein, A.A. <u>Quality Assessment and Clinical Utility of Plasma Obtained Via Apheresis vs That Obtained from Whole Blood</u>. *Laboratory Medicine*. 2022.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

BRIEFLY NOTED

According to data <u>reported</u> in the "<u>National Hospital Flash Report</u>" from Kaufman Hall for the month of May, hospitals experienced declining margins in April for the fourth consecutive month. "The median Kaufman Hall Operating Margin Index for April was -3.09 percent, and the median change in Operating Margin was down 38.1 percent" from the previous month. The organization stated that hospitals are "struggl[ing] to rebound from the Omicron surge. Although volumes improved and costs abated slightly in March, this changed in April."

(Source: Kaufman Hall National Hospital Flash Report: May 2022, 5/31/22)

INFECTIOUS DISEASE UPDATES

MONKEYPOX

The Association for the Advancement of Blood & Biotherapies' (AABB) Transfusion Transmitted Diseases (TTD) Committee has published the Monkeypox Virus Outbreak <u>Summary</u>. According to AABB, the resource includes "background information and donor considerations including that the U.S. Food and Drug Administration (FDA) currently recommends no donor deferral for pre-exposure receipt of the Jynneos vaccine for smallpox and monkeypox, provided the donor is otherwise healthy as required under 21 CFR 630.10 and section 630.15." Monkeypox is not known to be transfusion transmissible and there have been no documented cases transmission via blood transfusion.

(Source: AABB Monkeypox Virus Outbreak Summary, 5/27/22)

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.

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 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.

June Blood Bulletin Published

America's Blood Center's (ABC) has published the June 2022 edition of the <u>Blood Bulletin</u>, titled "Obstetric Hemorrhage — Are You Prepared?" The article was written by Nanci Fredrich, RN, BSN, MM, Transfusion Safety & Blood Management Officer at Versiti, Richard Gammon, MD, Medical Director at OneBlood, Nancy Van Buren, MD and Jed Gorlin, MD, MBA, Medical Directors at Innovative Blood Resources and Community Blood Center of Kansas City, divisions of New York Blood Center, and Theresa Nester, MD, Co-Chief Medical Officer at Bloodworks Northwest. Contributors included Kerry O'Brien, MD, Medical Director of the Blood Bank at Beth Israel Deaconess Medical Center, and Rita Reik, MD, FCAP, Chief Medical Officer at America's Blood Centers. <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.

Please note: The MS Word version may not display properly for users with older versions of MS Word. For those individuals, we recommend viewing and using the PDF version of this publication instead.

(Source: MCN 22-050, 6/2/22)

ADRP Partners with Global Blood Fund

ADRP, an International Division of America's Blood Centers, and Global Blood Fund recently announced a partnership on a pilot International Mentoring Program to assist practitioners in Africa. Through this initiative, the organizations will remotely connect professionals across continents in a structured way to facilitate an effective exchange of knowledge and skills that can transform local blood banking practices. Volunteer ADRP Mentors will be connected with Mentees in Ghana and have the chance to guide and influence the way they approach their donor management and marketing responsibilities. If successful, this approach will be rolled out to other countries and embrace more blood banking disciplines. For more information contact info@adrp.org.

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.

Registration Opens for MD Workshop and Summer Summit

America's Blood Centers (ABC) launched <u>registration</u> this week for the <u>ABC Medical Directors Workshop</u> <u>and ABC Summer Summit</u> taking place August 2-4 in Minneapolis, Minn. A <u>preliminary program</u> is now available. 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 reservations</u> can be made now through the ABC block.

ABC Newsletter -6- June 3, 2022

GLOBAL NEWS

The Norwegian Ministry of Health and Care Services <u>intends</u> to have the country's Directorate of Health explore potential changes to its blood donor deferral for men who have sex with other men (MSM), according to a report from *The Local*. Currently, Norway has a 12-month MSM deferral. The review and any recommended changes are expected to be completed by the beginning of April 2023.

(Source: The Local, Norway to make it easier for gay men to donate blood, 5/25/22)

COMPANY NEWS

BioMarin Pharmaceutical Inc. shared "updated results" this week from an ongoing phase I/II study of its investigational gene therapy to treat severe hemophilia A in adults. The company also announced in the news release its "plans" to resubmit a biologics licensing application (BLA) to the U.S. Food and Drug Administration (FDA) in September. Six-year results of the 6e13 vg/kg dose cohort and five-year results of the 4e13 vg/kg dose cohort continue to "demonstrat[e] sustained hemostatic efficacy" of the investigational gene therapy according to BioMarin. "All participants in the 6e13 vg/kg cohort remain off prophylactic Factor VIII treatment at the time of the data cut. The mean cumulative annualized bleed rate (ABR) remains less than one and substantially below baseline levels; the mean ABR in year six was 0.7 with a mean cumulative ABR reduction of 95 percent and Factor VIII use reduction of 96 percent through six years, compared to baseline. All participants in the 4e13 vg/kg cohort were off prophylactic Factor VIII at the time of the data cut. Six months prior to the data cut, one participant temporarily resumed prophylactic Factor VIII treatment for one month, after which he was bleed free through the last follow up. The mean ABR in year five for the 4e13 vg/kg cohort was 0.7 with a mean cumulative ABR reduction of 91 percent and Factor VIII use reduction of 93 percent through five years, compared to baseline."

(Source BioMarin Pharmaceuticals Inc. News Release, 5/31/22)

Gamida Cell Ltd. announced the "completion of the rolling BLA submission to the FDA for omidubicel for the treatment of patients with blood cancers in need of an allogenic hematopoietic stem cell transplant." The submission is based on findings from a phase III clinical trial whose results were previously published in *Blood*. According to the news release, "the study's primary endpoint, the median time to neutrophil engraftment in patients with hematologic malignancies undergoing allogeneic bone marrow transplant receiving omidubicel compared to standard umbilical cord blood (UCB), the median time to neutrophil engraftment was 12 days for patients randomized to omidubicel compared to 22 days for the comparator group (p < 0.001). In key secondary endpoints of this Phase 3 study: platelet engraftment was significantly accelerated [55 percent of patients randomized to omidubicel achieving platelet engraftment by day 42, compared to 35 percent for the comparator (p = 0.028)]; the rate of infection was significantly reduced [cumulative incidence of first grade 2 or grade 3 bacterial or invasive fungal infection for patients randomized to omidubicel of 37 percent, compared to 57 percent for the comparator (p = 0.03)]; and hospitalization in the first 100 days after transplant was significantly reduced [median number of days alive and out of hospital for patients randomized to omidubicel of 61 days, compared to 48 days for the comparator (p = 0.005)]."

(Source: Gamida Cell Ltd. News Release, 6/2/22)

Terumo Blood and Cell Technologies recently <u>recognized</u> the completion of a new manufacturing facility in Douglas County, Col. According to a company news release, the 170,000 square-foot facility "will serve source plasma collections customers with single-use collection sets for the recently FDA-cleared Rika Plasma Donation System." The company expects the facility to employ close to 300 people.

(Source: Terumo Blood and Cell News Release, 5/25/22)

ABC Newsletter -7- June 3, 2022

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. 6-10. FDA Regulatory Education for Industry (REdI) Annual Conference 2022 (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 <a href="https://example.com/here/health
- June. 9-10. FDA Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) Meeting (Virtual). More information available here.
- June. 29-30. FDA CTGTAC Meeting (Virtual). More information available here.
- Aug. 2-4. **ABC Summer Summit and Medical Directors Workshop**, **Minneapolis**, **Minn.** Registration is <u>open</u>. More information available <u>here</u>.
- Aug. 29-30. National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) and the Office 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 here.
- Sept. 21-22. **28**th IPFA/ Paul-Ehrlich-Institut[e] (PEI) International Workshop on Surveillance and Screening of Blood-borne Pathogens, Porto, Portugal. Registration is open. More information available here.
- 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.** Registration is <u>open</u>. 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: newsletter@americasblood.org

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 bbaynard@bbak.org or (907) 222-5664.

June 3, 2022

POSITIONS

ABC Newsletter

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 here.

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 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 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 change s 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/aboutus/careers/.

Medical Technologist - Overnight/Shift Differential. LifeSouth Community Blood Centers is currently seeking a skilled individual for a Medical Technologist position in our Immunohematology Reference Laboratory (IRL) in Jacksonville, FL. This position is responsible for performing and interpreting clinical laboratory tests that require the exercise of independent judgment. We are looking to fill an overnight/third shift. Starting salary range is \$27.00 - \$32.40 an hour. Shift differential of 15 percent - 20 percent may apply for working overnight hours. Applicants should apply here.