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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

2024 #12 **April 5, 2024**

INSIDE:

ABC Advocates for Exclusion of LDTs Used by Blood Centers in Congressional RFI Response

America's Blood Centers (ABC) has submitted comments in response to the request for information (RFI) for reforms to diagnostics regulation from Sen. Bill Cassidy, MD (R-La.), ranking member of the Senate Committee on Health, Education, Labor, and Pensions. The comments from ABC urged that an exemption for laboratory developed tests (LDTs) used by blood centers should exist to exclude such LDTs, "from any reforms to diagnostics regulation since these tests do not fall within the categories of laboratory services and diagnostic products that Congress and FDA are looking to regulate."

The comments explained that, "[b]lood centers have significant safeguards in place when developing and utilizing LDTs. Their laboratories work within the Clinical Laboratory Improvement Amendments (CLIA) regulations to create the reagents and procedures. Additionally, blood center laboratories ensure the quality and validity of tests through the existing regulatory framework and safeguards." ABC also stated in the comments that, "LDT procedures in blood centers are already highly regulated. They are usually performed in urgent, life-saving situations and are always performed for patients being treated in a healthcare setting. Given the oversight and inspection already in place for blood centers, adding an additional layer of regulation is unnecessary."

The ABC RFI response described how safe and effective, "[b]lood centers' LDTs are." ABC also discussed in the comments, "the importance of ongoing efforts to mass screen donors as part of several LDT Red Cell Genotyping (RCG) platforms used by blood centers across the country. These RCG platforms are able to provide more targets for rare blood groups…Without the ability to mass screen donors for these rare blood types, blood centers would not be nearly as successful as they are today in finding the right blood for these patients with difficult transfusion requirements."

ABC concluded the comments by explaining that, "[i]f blood centers' LDTs are included in reforms to diagnostics regulation, there will be significant patient harm due to delays in care and the lack of patient access to medically necessary tests…The unique nature of a biologic substance taken from a donor can sometimes require extensive matching to ensure a recipient patient does not have a dangerous transfusion reaction. If these tests are unavailable, physicians must still make a prompt decision about the transfusion, and they will have less information available to them to determine the safest course of action. Suppose blood centers are required

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RFI Response to Sen. Cassidy (continued from page 1)

to follow the proposed regulatory framework for LDTs. In that case, many of these tests will not be available, and/or patient access to the tests will be seriously delayed, potentially causing significant patient harm."

ABC will continue to provide updates of its advocacy efforts on this issue. An archive of all ABC letters and comments is also available.

(Source: ABC Comments, 4/2/24)

New Slate of ABC Board Officers

America's Blood Centers recently announced its new slate of board officers for fiscal year 2025. As of April 1st, the officers of the ABC Board of Directors are:

- Vitalant's Rob Van Tuyle (President)
- LifeSouth Community Blood Centers' Kim Kinsell, JD (President-elect); and
- Community Blood Center of the Ozarks' Anthony Roberts (Secretary/Treasurer).

The other members of the ABC Board of Directors include:

- LifeShare Blood Center's Chad A. Douglas, MHA;
- Rock River Valley Blood Center's Lisa Entrikin;
- OneBlood's Martin Grable; and
- New York Blood Center Enterprises' Rick Youngblood, MBA.

ABC thanks both LIFELINE Blood Services' John B. Miller, MBA and Carter BloodCare's Laurie Sutor, MD, MBA for their commitment to ABC and its member blood centers following the completion of their terms on the ABC Board of Directors at the conclusion of fiscal year 2024 on March 31st.

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

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DHS Proposed Rule on Cyber Incident Reporting includes Blood Centers

The Department of Homeland Security's (DHS) Cybersecurity and Infrastructure Security Agency (CISA) has published a proposed rule titled, "Cyber Incident Reporting for Critical Infrastructure Act (CIRCIA) Reporting Requirements." The proposed rule would require blood centers and other covered critical infrastructure organizations to report covered cyber incidents to the federal government within 72 hours and ransom payments within 24 hours, in addition to other provisions.

As explained by America's Blood Centers (ABC) Vice President of Government Affairs Diane Calmus, JD in MCN 24-023, blood centers are specifically included in the healthcare critical infrastructure sector. Thus, blood centers will need to determine if they are a covered entity through one of two means:

- Size: "exceed the U.S. Small Business Administration's (SBA) small business size standard based on either number of employees or annual revenue, depending on the industry (which can be determined online – for NAICS code 621991 'Blood and Organ Banks' with less than $40,000,000 average annual revenue over the past 5 years);" or
- By meeting any one of three "sector-based criteria:
  - certain entities providing direct patient care; or
  - manufacturers of drugs listed in Appendix A of the report Essential Medicines Supply Chain and Manufacturing Resilience Assessment, sponsored by the U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR); or
  - manufacturers of Class II (moderate risk) and Class III (high risk) devices, as defined in 21 U.S.C. 360c."

While blood and blood products are not currently included on the list of Essential Medicines referenced in the second sector-based criteria, ABC and the blood community have urged the U.S. Department of Health and Human Services (HHS) to include blood and blood components on this list due to the importance of blood during disasters including pandemics. If blood were included, all blood centers would need to report under this proposed rule.

The proposed regulation is pursuant to the Cyber Incident Reporting for Critical Infrastructure Act of 2022, which was signed into law in March 2022 in response to a failure of entities to voluntarily report breaches and disjointed federal responsibility that lacked information sharing. The rule broadly construes covered critical infrastructure to require a comprehensive grouping of entities to report breaches with the goal of improving available information to allow for counter measures and patching of vulnerability.

The reports submitted by those that have experienced attacks will not be public, though anonymized information from the reports may be released to warn against similar attacks. Comments regarding the proposed rule are due June 3rd. ABC will continue to provide updates on the proposed rule and its advocacy efforts. Please contact us with questions.

(Sources: *Federal Register* Proposed Rule, 4/4/24; MCN 24-023, 3/28/24)

STATE ADVOCACY BRIEFS

On April 2nd, the Louisiana State Legislature introduced a bill (HB822) that would, "require[e] any person donating blood to disclose whether he/she has received a COVID-19 vaccination or messenger ribonucleic acid (mRNA) vaccination. [The proposed law also] requires any person collecting blood to clearly label the receptacle containing the collected blood with a donor's vaccination status. [Additionally, the proposed law] permits a recipient of a blood transfusion to request blood based on if an individual has received a COVID-19 or mRNA vaccination during a non-emergency situation, as determined by a licensed healthcare professional if the blood is available. [The proposed law] tasks the Louisiana Department of Health with developing rules and regulations to implement the provisions of proposed law."

(Source: HB822, 4/2/24)

RESEARCH IN BRIEF

Efficient Blood Utilization on a Remote Island. A study in *Vox Sanguinis* aimed to, "investigat[e] the feasibility of implementing a novel operational framework, the blood rotation (BR) system, which employs the active transport refrigerator (ATR). This system is designed to enable the efficient return and redelivery of blood products while maintaining optimal temperature control, aiming to streamline the supply chain (SC) for medical institutions in remote islands." The authors noted that this study also, "evaluated whether the BR system could establish an effective SC that maximizes the utilization of red blood cell (RBC) products." They explained that an ATR is, "capable of maintaining RBC products at a precise temperature of 4.0 ± 2.0ºC, for >7 hours." For this study, "[t]ype O, Rh-D-positive, irradiated RBC products were stored in an ATR and transported from the Japan Red Cross Nagasaki Blood Center (JRCNBC) to Nagasaki Goto Chuoh Hospital (NGCH) via [a] ship. RBC products in the ATR were stored for one week [then] the unused RBC products were returned to the JRCNBC in the ATR." The authors noted that the study took place from January to December 2019. They described the study's primary endpoint as, "the utilization rate of products redelivered to Nagasaki University Hospital (NUH) during the planned period. The secondary endpoints included the wastage rate of stored blood products delivered to the NGCH and the frequency of temporary transportation from the JRCNBC to the NGCH…Of the 107 RBC product preparations stored in the ATR and shipped to NGCH, 4 were used for patients, resulting in 103 products being returned to JRCNBC…Among the 103 returned products reissued to the NUH during the study period, 101 (98.1 percent) were transfused into patients." Additionally, the researchers explained that, "[a]t NGCH, 597 RBC products were used, whereas 80 products were discarded during the entire study period…Consequently, the overall wastage rate was 10.2 percent over the study period compared with 24.2 percent in the previous year…During the research period, 74 scheduled and 103 quick deliveries of RBC products to the NGCH were similar to 76 and 110 deliveries, respectively, during the same period in the previous year." The authors concluded that, "the establishment of a BR system supported by robust quality management and transportation technology demonstrated [it] can contribute to the effective utilization of valuable blood products."

Citation: Nagai, K., Tomari, N., Egawa, S., *et al*. "Feasibility evaluation of a blood rotation system for efficient blood product utilization in remote island settings." *Vox Sanguinis*. 2024.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

NEW on Coll*ABO*rate

COLLABORATE

SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

Recent discussion topics on the ABC Coll*ABO*rate Online Member Community include:

- Low-volume RBCs (QUALITY BYTES)
- Phlebotomy Start Times (COLLECTIONS & DONOR SERVICES)
- Adverse Reaction Time of Departure (ALL MEMBER FORUM)
- Abnormal Kleihauer Betke Staining (ALL MEMBER FORUM)
- Electronic Young Donor Parental Consent (MEMBER RESOURCES)
- Freeze Dried Plasma (MEDICAL ISSUES)
- Type A Liquid Plasma (MEDICAL ISSUES)
- Testosterone and Aromatase Inhibitors (MEDICAL ISSUES)
- Tracking Blood Center Equipment (QUALITY BYTES)
- New Hire Supports (EMPLOYEE TRAINING and DEVELOPMENT)

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INSIDE ABC

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

Special Members Meeting and Bylaws Vote Set for April 10th

America's Blood Centers (ABC) is holding a special Members Meeting on April 10th at 3 p.m. EDT to electronically vote on proposed changes to the ABC Bylaws. Additional details regarding the meeting are available in MCN 24-019. Attachments accompanying the MCN included:

- ABC's current Bylaws with redline proposed changes;
- an overview of the proposed changes as presented at the ABC Members Meeting on March 5th;
- a proxy ballot for any member voting representative (MVR) unable to attend the call (please complete and return no later than April 9th); and
- a ballot for designated MVRs attending the call.

The results of the vote will be announced by 12 p.m. EDT on April 11th. Please contact ABC Chief Executive Officer Kate Fry, MBA, CAE with questions or to receive the attachments.

(Source: MCN 24-019, 3/21/24)

ABC Economic Outlook Survey Open

ABC recently launched the Economic Outlook Survey. This new resource consolidates what were formerly known as the ABC Financial Ratio and Median Service Fee surveys while offering a comprehensive look at blood center finances, including 19 of the most frequently used ratios for benchmarking the financial health of an organization as well as median service fees for 30 different blood products and blood center procedures.

The aggregate data of this survey is important to both members and ABC as we advocate for fair and accurate reimbursement policies. Survey results are anonymized and aggregated. The ability to download final trend reports and create customized reports based on selected filters will be available to participants via ABC's benchmarking portal in early May and are complimentary to all survey participants. Non-participants may purchase the report here. The survey will remain open until April 19th. Please contact us with questions.

Meet Us in St. Louis for the ABC 2024 Quality and Technical Workshop!

Registration remains open for the 2024 America's Blood Centers (ABC) Quality and Technical Workshop. Check out our program as this year's workshop is centered around highlighting collaboration amongst blood banking professionals to allow for an exchange of innovative ideas and best practices. Sessions have been developed to emphasize the important topics that are affecting you and your blood center. The workshop will feature experts in their field presenting topics that include implementation of new devices and blood products, regulatory and licensure round tables, and peer to peer strategic discussions to name a few. Don't miss the opportunity to network with your peers and gain greater insights into the challenges that the blood industry is facing now.

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INSIDE ABC (continued from page 5)

Schedule Available 2024 ADRP Annual Conference

The schedule is available for the 2024 ADRP Annual Conference. Register today! Join more than 400 blood center professionals in St. Louis, Mo. May 14th-16th at The St. Louis Union Station Hotel. This year's conference will feature keynotes Jason Kotecki, an expert at helping people "Escape Adulthood" in order to beat burnout and become more innovative and creative by breaking rules that do not exist, and Candy Whirley, a recognized motivational speaker, leadership, and team building expert. The 2024 ADRP Annual Conference is your opportunity to gain insights into industry trends, exchange ideas, and share information with your peers, while taking advantage of networking opportunities. Attendees will be able to participate in pre-conference workshops, educational sessions, roundtables, and have access to an expansive exhibit hall. Learn more about available exhibitor and sponsorship opportunities. Remember to book your hotel room by April 19th for the discounted rate. Please contact us with questions.

BRIEFLY NOTED

The American Society for Clinical Pathology (ASCP) has launched the 2024 Vacancy Survey. According to the announcement from the organization, the survey aims to, "determine the extent and distribution of workforce shortages within the nation's medical laboratories. All responses will be confidential, and data will only be reported in aggregate. Individual-level data will not be reported." Additionally, this year's survey features, "in an effort to collect data on emerging technologies, the ASCP also included questions on artificial intelligence (AI), to determine the current and potential uses of AI in the laboratory." ASCP asks all laboratory professionals to complete the survey and encourages individuals to forward the survey link to their peers. The survey closes on Tuesday, April 30th.

(Source: ASCP Survey, 4/1/24)

Medical Laboratory Professionals Week (Lab Week) is set to take place April 14th-20th. According to the American Society for Clinical Laboratory Science (ASCLS), Lab Week occurs in, "April each year [and] is coordinated by a collaborative committee with representatives from 17 national clinical laboratory organizations, including ASCLS. Now in its 49th year, it is important to reflect on the important history of Lab Week. Medical Laboratory Professionals Week originated in 1975 as National Medical Laboratory Week, or NMLW, under the auspices of the American Society for Medical Technology, now called ASCLS. In subsequent years, other organizations have served as cosponsors and campaign supporters." Additional resources are available on both the ASCLS and ASCP websites.

(Sources: ASCLS Website, 4/1/124; ASCP Website, 4/1/24)

MEMBER NEWS

LIFELINE Blood Services recently welcomed Rep. David Kustoff (R-Tenn.) for a blood center tour to their Jackson facility. While at LIFELINE, Rep. Kustoff learned about the blood center's impact within the community and its commitment to the 21 counties it serves. LIFELINE Chief Executive Officer (CEO) John B. Miller, MBA also provided Rep. Kustoff with information on the intricacies of the blood donation process from the steps taken for blood product collection to patient transfusion.

(Source: LIFELINE Blood Services Announcement, 4/2/24)

The Community Blood Center (Appleton, Wis.) held a ribbon cutting ceremony on March 25th for a new donor center in Chicago, Ill. According to *The Beverly Review*, "the donation center marks the first permanent location [for The Community Blood Center] in the city helping to support the supply of blood in Chicago. [The] Community Blood Center [currently] provides blood to the University of Chicago Medicine Hyde Park and the University of Chicago Medicine Ingalls Memorial." John Hagins, president and CEO of The Community Blood Center, stated in the article, "[t]he grand opening of our newest donor center in Chicago is a significant milestone for The Community Blood Center. When we first expanded our mission to Chicago in 2019, we knew, with the help of this community, we could help fulfill blood needs that may otherwise be unmet as the need for blood in Chicago is substantial. We're excited to continue to grow in the city," said Hagins, "and save even more lives by providing convenient, regular blood donation opportunities at our donor center, in addition to the many blood drives we hold throughout Chicago."

(Source: *The Beverly Review*, "CBC cuts ribbon for facility," 4/2/24)

COMPANY NEWS

Grifols recently announced that its Procleix ArboPlex Assay® has received the CE mark from the European Union's (EU) European Commission (EC), "the first for an automated nucleic acid test (NAT) specifically validated for screening blood donors to detect four major arboviruses: chikungunya, dengue, West Nile and Zika viruses," according to a company news release. The CE marking signifies that the assay has been assessed to meet the safety, health, and environmental protection requirements for sale in the European Economic Area (EEA). Grifols explained in the news release that the four aforementioned arboviruses are the, "most significant arboviruses of concern, all spread through mosquito vectors." The company also stated that the assay, "uses plasma or serum samples to detect arboviral RNA. Currently, risk for arboviruses in blood donors is evaluated either with a monoplex test, duplex test or through a questionnaire in which donors who declare having traveled to or prior residence in arbovirus-endemic areas are temporarily deferred. Blood banks and collection centers could decide that deferrals are unnecessary if donors were tested and found negative using the Procleix ArboPlex Assay." Grifols anticipates the assay being, "available in all markets accepting the CE mark certification after completion of any additional registration and notification requirements."

(Source: Grifols News Release, 4/4/24)

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COMPANY NEWS (continued from page 7)

The U.S. Food and Drug Administration (FDA) recently granted, "special 510(k) clearance [for] expanded use of **HemoSonics**' arterial blood samples with its Quantra QStat® Cartridge. [The cartridge] used with the Quantra Hemostasis Analyzer first received 510(k) clearance from the U.S. FDA in 2022 for use in venous whole blood samples." According to a company news release, the FDA clearance, "enables hospitals to further standardize and operationalize viscoelastic testing with an arterial and venous indication for both HemoSonics' QStat Cartridge and the QPlus® Cartridge." HemoSonics added in the news release that, [t]he Quantra System allows healthcare professionals to make individualized and evidence-based decisions on how to manage a bleeding patient and give a patient only medically appropriate therapy — an approach that supports global initiatives to reduce inappropriate transfusions of blood products…[It] provides fast, comprehensive whole-blood coagulation analysis at the point of care or in laboratory-based settings, typically in less than 15 minutes."

(Source: HemoSonics News Release, 4/3/24)

Vertex Pharmaceuticals Inc. announced that Health Canada accepted the company's New Drug Submission (NDS) for exagamglogene autotemcel (exa-cel) to treat sickle cell disease patients who are 12 years of age or older, "with recurrent vaso-occlusive crises (VOCs) and for the treatment of patients aged 12 years and older with transfusion-dependent beta thalassemia (TDT). Canada's regulatory authority has designated the submission for priority review. According to the news release, "[w]ith [p]riority [r]eview, the conventional review timeline of 300 days is reduced to 180 days. The NDS is supported by results from the ongoing [p]hase III studies, CLIMB-111 and CLIMB-121, as well as an ongoing long-term follow-up study, CLIMB-131…The NDS will be part of an aligned review with Health Technology Assessment (HTA) organizations, the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Institut national d'excellence en santé et en services sociaux (INESSS) in Quebec."

(Source: Vertex Pharmaceuticals Inc. News Release, 4/1/24)

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

- **ADRP Webinar: Conference 2024: Know Before You Go** – April 17th. Registration is open. More information available here.
- **ADRP Master Class** – Sept.18th-19th. More information is coming soon.

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.)*

2024

Apil 10. **ABC Special Members Meeting (Virtual).** More information available to ABC members in MCN 24-019 including a link to registration.

April 11-12. **International Haemoviglance Network Symposium. Athens, Greece.** Registration is open. More information available here.

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CALENDAR (continued from page 8)

April 12-13. **BEST Meeting. Amsterdam, Netherlands.** More information available here.

April 16-17. **International Plasma Protein Congress. Athens, Greece.** Registration is open. More information available here.

April 17. **ADRP Webinar: Conference 2024 "Know Before You Go."** Registration is open. More information available here.

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

May 3-4. **California Blood Bank Society (CBBS) Annual Meeting.** More information is coming soon.

May 14-16. **2024 ADRP Annual Conference. St. Louis, Mo.** Registration is open. More information available here.

May 15-16. **International Plasma and Fractionation Association/Paul-Ehrlich Institut[e] 30th International Workshop on Surveillance and Screening of Blood-borne Pathogens. Aarhus, Denmark.** Registration is open. More information available here.

June 7-8. **2024 South Central Association of Blood Banks (SCABB) Annual Meeting and Exhibit Show. Orlando, Fla.** More information is coming soon.

June 23-27. **38th International Society of Blood Transfusion (ISBT) Congress. Barcelona, Spain.** Registration is open. More information available here.

Sept. 3-6. **American Society for Clinical Pathology (ASCP) Annual Metting. Chicago, Ill.** Registration is open. More information is available here.

Sept. 18-19. **2024 ADRP Master Class.** More information is coming soon.

Sept. 30-Oct. 3. **American Association of Tissue Banks (AATB) Annual Meeting. Denver, Colo.** More information is coming soon.

Oct. 19-22. **Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting. Houston, Texas.** More information is coming soon.

Nov. 6-7. **ABC Women's Executive Leadership Community (WELC) Workshop. San Antonio, Texas.** More information is coming soon.

2025

May 20-21. **International Plasma Protein Congress. Warsaw, Poland.** More information is coming soon.

Oct. 12-15. **AATB Annual Meeting. Atlanta, Ga.** More information is coming soon.

Oct. 25-28. **AABB Annual Meeting. San Diego, Calif.** More information is coming soon.

CLASSIFIED ADVERTISING

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

POSITIONS

Supervisor, Immunohematology Reference Lab (San Diego Blood Bank). The San Diego Blood Bank is currently seeking a motivated, knowledgeable professional to lead the Immunohematology Reference Lab. This person will oversee the daily operation of the department as well as support the greater Lab Management Team following safety, cGMP, and Quality Plan. Additionally, the ideal candidate will supervise the flow of samples, blood, and blood components through the department from satellite centers, mobile collection vehicles, hospitals, blood banks, and laboratories. **Qualifications** include a minimum of 2 years in blood bank related fields to include leadership experience and IRL experience. **Certification/Licensure** required include MLS(ASCP)CM/ MT(ASCP) or equivalent experience and a California Clinical Laboratory Scientist License (CLS). Certification as a Specialist in Blood Bank (SBB) or equivalent is preferred. For a full description of this job posting and to apply, visit: Careers | San Diego Blood Bank (recruitingbypaycor.com).

Immunohematology Reference Laboratory CLS (San Diego Blood Bank). Under the direction of the department leadership, the Medical Laboratory Scientist I will assist the Immunohematology Reference Laboratory in daily operations according to cGMP compliant policies and Standard Operating Procedures implemented by the San Diego Blood Bank (SDBB). The ideal candidate will successfully complete/pass an initial training program resulting in the ability to provide guidance and expertise for the laboratory to meet the needs of SDBB customers, in accordance with accepted standards and regulations. **Requirements:** Bachelor's degree, MLS/MT (ASCP)CM or equivalent experience, Clinical Laboratory Scientist (CLS). Certification as a Specialist in Blood Banking (SBB) preferred. For a full description of this job posting and to apply, visit: Careers | San Diego Blood Bank (recruitingbypaycor.com).

Sr. Policy & Documentation Specialist (San Diego Blood Bank). The Senior Policy and Documentation Specialist proactivity guides and oversees policy management and technical documentation needs of San Diego Blood Bank. Creation, implementation, and maintenance of a document management system that can manage both internal and external controlled documents. This role provides relevant training on document control procedures and good documentation practices, assists Quality Assurance and Compliance Department in creating quality plans and procedures. The Sr. Policy & Documentation Specialist assists in the initiation, investigation and closure of product and process deviations/non-conformances. This position will author and revise policies, procedures, and manage document processes and systems to ensure control and availability of documentation to personnel. This role requires a bachelor's degree in a related field from an accredited college or university, or equivalent combination of education, training and experience. Click here to view the job description and apply.

Marketing Manager (Blood Centers of America). This position develops and executes a marketing strategy for BCA and for individual business units including budget planning and measurement of success. The position manages the social media accounts and website content and supports the needs of the Advanced Therapy Network including newsletter, search engine optimization, and maintaining a record of member capabilities. Other responsibilities include press releases, presentations with input from internal stakeholders and trade show participation. A bachelor's degree in business is required; major in marketing preferred. Requires three (3) or more years of marketing experience with a proven track record of success. Social media management experience required. Blood center or related industry experience preferred. Remote work is available for a candidate who does not reside within a reasonable commuting distance of BCA's headquarters in West Warwick, RI; 10%-20% of overnight travel required. Please click here to view the full job description and apply.

Supply Chain Contract Manager (Blood Centers of America). This position is responsible for the day-to-day activities specific to BCA and national GPO supplier contract relationships. Position will identify, develop, coordinate, and implement supplier contracts working with blood center Materials Directors and Purchasing Managers driving contract savings and increased revenue. A primary responsibility will be to oversee and manage the Third Party Logistics (3PL) operations, adding new product categories to be distributed in this program to increase overall program value and efficiency. A bachelor's degree in a related field is preferred. Requires 3-5 years of supply chain experience in a related industry. Ability to travel regularly throughout the year to meet member needs. Remote work is available for a candidate who does not reside within a reasonable commuting distance of BCA's headquarters in West Warwick, RI; 20%-30% of overnight travel required. Please click here to view the full job description and apply.

Lab Technical Director. The Central California Blood Center (CCBC) is seeking a Laboratory Technical Director for our operations based out of Fresno, California. This position provides exceptional, mission-focused leadership to the blood component manufacturing, testing lab, research, and immunohematology reference laboratory and assures cost-effective, lean operations and compliance with all regulatory agencies and best practices as defined in AABB Standards and AABB Technical Manual. Assures that the department strives for optimal performance by providing the necessary re

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POSITIONS (continued from page 10)

sources and developing a highly competent team. This position works in close collaboration with CCBC senior leadership and the Medical Director, who holds the CLIA licensure for the organization. The ideal candidate must have a current California Clinical Laboratory Scientist (CLS) license or eligible, a minimum of six (6) years of experience working in a blood center, and a minimum of three (3) years of direct supervisory experience managing teams and assets. Certified as an SBB/BB or equivalent is preferred. We offer a generous benefits package including a great 401k matching program, PTO, paid sick leave, medical, dental, vision, electronic vehicle charging, wellness program, and employee assistance program (EAP). Prospective candidates may be eligible for relocation assistance. For full description and to apply click here. The Central California Blood Center is an Equal Opportunity Employer.

Regulatory and Audit Compliance Specialist. The Regulatory and Audit Compliance Specialist ("Specialist") is responsible for developing and maintaining a risk based quality auditing program for the New York Blood Center Enterprise division. The Specialist monitors and evaluates divisional compliance with regulatory requirements, professional accreditation standards and internal policies and procedures to ensure the ongoing quality and safety of products and services. Manages Audits: The Specialist manages the quality audit program for the division, including planning, risk assessment, scheduling, executing, and reporting on audits of the organization's facilities and operations. The auditor makes recommendations on areas of improvement based on audit observations and findings. Advises on Compliance: The Specialist represents the division as a direct liaison to regulators, managing communications, Biologics License Applications (BLA) submissions, regulatory reporting, and ongoing compliance matters, including the filing of Biological Product Deviation Reports (BPDRs). The incumbent serves as a subject matter expert, advising divisional leadership of new or changed regulations and standards, and providing interpretation for successful implementation. Please click here to view the full job description and apply.

Vice President, Quality & Regulatory Affairs (VPQRA). The Vice President, Quality & Regulatory Affairs (VPQRA) leads the Organization's adherence to regulations and standards established by governing agencies (AABB, FDA, CLIA, State, OSHA, NRC, EU, etc.). Kentucky Blood Center is seeking qualified candidates to fill this key executive leadership role which is responsible for our Quality Assurance (QA) program and regulatory compliance activities. The position has oversight of the QA department and team, and reports to the CEO. Qualifications include MLS/CLS (ASCP) with preference given to candidates with a graduate degree, and blood banking experience. Relocation to the Lexington, Kentucky area required (assistance provided). For more information or to apply, visit https://www.kybloodcenter.org/about-us/careers.

Quality and Regulatory Services Manager. The Quality and Regulatory Services Manager reports to the Director of QRS and is responsible for the quality and regulatory affairs, duties, and responsibilities by reviewing department procedures, forms, training documents, product and equipment quality control (QC), change control processes, and validations, and assist with the development, as necessary. Reviews applicable regulations and standards from FDA, AABB, CLIA, OSHA, NRC, State of Tennessee, and manufacturers to ensure compliance. Personnel Training: Perform Good Manufacturing Practice (cGMP) and safety training and assist in inter-departmental training and competency evaluation. Maintain compliance by enforcing applicable regulations and standards set by regulatory agencies and submit appropriate reports when required. Document Control: Maintain proficiency in Document Control within MediaLab. Able to revise and create SOPs, Forms, and Job Aids. Create, perform, and review validations. Manage the overall deviation management program to include investigation, root cause, analysis, corrective and preventative actions, and documentation. Responsible for developing, tracking, monitoring, and reporting quality indicators. Monitor and conduct trend analysis of quality indicators. Process improvement, including change control and corrective/preventative actions. Please click here to view the full job description and apply.

Manager of Donor Resources. The Blood Connection is seeking a Manager of Donor Resources for our operations based out of Augusta, GA. This position will be responsible for monitoring progress to goal proactively, and effectively coaching and managing their team to success. The ideal candidate for this position possesses strong leadership and organizational skills with a proven ability to meet organizational goals. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community! *Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Donor Resources – Augusta, GA.

Manager of Donor Services. The Blood Connection is seeking a Manager of Donor Services for our operations based out of Raleigh, NC and Rock Hill, SC. These positions will oversee donor collection operations within their assigned divisional territory. These positions provide leadership and discipline to direct reports, interviews, and hire staff, and ensure staff are appropriately trained. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell

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phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community! *Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Donor Services – Raleigh, NC. Manager of Donor Services – Rock Hill, SC.

Director, Quality Assurance & Regulatory Affairs (Hoxworth Blood Center). The University of Cincinnati College of Medicine (COM) has a reputation for training best-in-class health care professionals and developing cutting-edge procedures and research that improves the health and clinical care of patients. Hoxworth Blood Center (HBC) is located within the College of Medicine and is the only Regional Blood Center owned and operated by a University in United States. The HBC is seeking a **Director of Quality Assurance & Regulatory Affairs**. This position will oversee and direct the coordination of quality assurance and regulatory compliance for the Cellular Therapy, Therapeutic Apheresis and Transplantation Immunology divisions. Required Education & Experience: Bachelor's degree in Medical Technology, Biology, Chemistry, or related field. Seven (7) years of experience in a clinical laboratory, blood banking or other related experience. Additional Qualifications Considered: Previous experience in a FACT, AABB and HCT/P (21 CFR 1271) and GMP (21 CFR 211) for Phase I/II clinical manufacturing, Regenerative Medicines, Cleanrooms, and Aseptic Processing is ideal. Understanding of CAP requirements for histocompatibility (HLA) laboratories which includes disciplines of sequencing, molecular, serological, immunology, flow cytometry, and cellular analysis is preferred. For full description and to apply, visit https://bit.ly/489l7Gl. The University of Cincinnati is an Equal Opportunity Employer.

Division Director, Core Operations (Hoxworth Blood Center). Hoxworth Blood Center is recruiting for Division Director, Core Operations, to provide leadership, vision, and oversight of programs related to donor center core operations, including Biomedical Engineering, Materials Management, Physical Operations, and computer software informational systems. Experience in daily production of cleanroom environments, as well as recruitment and training of new employees with knowledge in cleanroom environment and regulatory framework in accordance with cGMP, FDA, and ISO regulations pertinent to the environmental control in ISO7/8 facilities is crucial. Enforce current strategic planning initiatives; develop new activities and establish goals in support of blood center strategic plans. Direct and facilitate cross functional activities that support the interdepartmental communications, productivity, and quality between various operating units. Develop innovative processes for monitoring operations to ensure high quality customer service and successful delivery of outputs. Required Education and Experience: Bachelor's Degree in related field of healthcare, biological or computer sciences. Seven (7) years of relevant experience in equipment management, computer and software information systems, blood banking, biotherapies, transfusion medicine, or scientific research. Three (3) years of direct supervisory experience managing employees, teams, and assets. For full description and to apply, visit: https://bit.ly/3OHlZet. The University of Cincinnati is an Equal Opportunity Employer.