

A B C N E W S L E T T E R

URRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2025 #16

May 5, 2025

Please Note: The *ABC Newsletter* will not be published on May 12th. We will resume regular publication on Monday, May19th. Thank you for your continued interest.

FDA Withdraws and Reissues Two HCT/Ps Final Guidances with Draft Guidances

The U.S. Food and Drug Administration (FDA) has withdrawn two human cells, tissues, and cellular and tissue-based products (HCT/Ps) final guidance documents regarding recommendations to reduce the transmission risk of <u>Mycobacterium tu-berculosis</u> (*Mtb*) and sepsis. The agency reissued each as draft guidances on May 2^{nd} .

FDA had previously recommended that final guidance documents be implemented by May 4th, which is no longer required following the withdrawals.

The <u>sepsis draft guidance</u> released by the agency further defined and changed a risk factor to, "[p]ersons who, currently, are known to have a medical diagnosis of sepsis or suspicion of sepsis from their most recent healthcare facility stay or visit preceding HCT/P recovery that is not documented as resolved." It previously stated in the withdrawn final guidance that when screening a donor, a risk factor would be considered, "[p]ersons who, currently, are known to have a medical diagnosis of sepsis or suspicion of sepsis."

The *Mtb* final guidance previously listed, "a number of symptoms or signs that can mimic or overlap with other medical conditions," and noted that these symptoms, "should be considered when making a donor eligibility determination." The draft guidance narrows this. Thus, if a person has the relevant symptoms, and falls into specific categories described in the draft guidance, such as frequent travel to areas where tuberculosis (TB) is common or, "there is physical evidence or suspicion of latent tuberculosis infection (LTBI) or TB disease," only then is it required to obtain additional information from the donor's physician regarding their patient's potential for LTBI or TB infection.

Comments for both draft guidances are due by July 7th. America's Blood Centers (ABC) is working with its committees to determine whether comments will be submitted. Please contact ABC's Director of Regulatory Affairs and Public Policy <u>Justine Coffey, JD, LLM</u> with any questions or feedback.

ABC, the Association for the Advancement of Blood & Biotherapies (AABB), and the American Red Cross previously submitted joint <u>sepsis comments</u> and <u>*Mtb* joint</u> <u>comments</u> to the FDA regarding the withdrawn final guidance documents.

INSIDE:

WORD IN WASHINGTON

Register for the ABC Advocacy Summit......4

Register for the June ADRP Webinar: "From Partnership to Purpose:4

Strengthening Hospital Relationships"......4

Nominations Deadline Approaching for HOSA Partnership Recognition

••••••	-
INFECTIOUS DISEASE	_
UPDATES	5
MEMBER NEWS	5
RESEARCH IN BRIEF	6
GLOBAL NEWS	7
COMPANY NEWS	8
CALENDAR	9
POSITIONS1	0

WORD IN WASHINGTON

The U.S. Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) have <u>announced</u> the creation of the, "next-generation, universal vaccine platform, Generation Gold Standard, using a beta-propiolactone (BPL)-inactivated, whole-virus platform." A news release from the agencies described the initiative as, "a decisive shift toward transparency, effectiveness, and comprehensive preparedness, funding the NIH's in-house development of universal influenza and coronavirus vaccines, including candidates BPL-1357 and BPL-24910. These vaccines aim to provide broad-spectrum protection against multiple strains of pandemic-prone viruses like H5N1 avian influenza and coronaviruses including SARS-CoV-2, SARS-CoV-1, and MERS-CoV. [Additionally,] the program realigns the Center for the Biomedical Advanced Research and Development Authority's (BARDA) operations with its statutory mission under the Public Health Service Act — to prepare for all influenza viral threats, not just those currently circulating." The initiative has been developed by NIH's National Institute of Allergy and Infectious Diseases (NIAID) and specifically:

- *"Recalibrates America's pandemic preparedness.*' Unlike traditional vaccines that target specific strains, BPL-inactivated whole-virus vaccines preserve the virus's structural integrity while eliminating infectivity. This approach induces robust B and T cell immune responses and offers long-lasting protection across diverse viral families. Moreover, the intranasal formulation of BPL-1357 is currently in Phase Ib and II/III trials and is designed to block virus transmission an innovation absent from current flu and COVID-19 vaccines;
- *'Embodies efficient, transparent, and government-led res*earch.' The BPL platform is fully government-owned and NIH-developed. This approach ensures radical transparency, public accountability, and freedom from commercial conflicts of interest; and
- *Marks the future of vaccine development.*' In addition to influenza and coronavirus, the BPL platform is adaptable for future use against respiratory syncytial virus (RSV), metapneumovirus, and parainfluenza. It also offers the unprecedented capability to protect against avian influenza without inducing antigenic drift—a major step forward in proactive pandemic prevention."

The news release also noted that, "[c]linical trials for universal influenza vaccines are scheduled to begin in 2026, with U.S. Food and Drug Administration (FDA) approval targeted for 2029. The intranasal BPL-1357 flu vaccine, currently in advanced trials, is also on track for FDA review by 2029."

(Source: HHS & NIH <u>News Release</u>, 5/1/25

(continued on page 3)



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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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WORD IN WASHINGTON (continued from page 2)

Jeffery Taubenberger, MD, PhD has <u>been named</u> acting director of NIH's NIAID. He is joined NIAID in 2006 and is a, "senior investigator in the intramural research program, and serves as Chief of the Viral Pathogenesis and Evolution Section, and Deputy Chief of the Laboratory of Infectious Diseases [at] NIAID. Dr. Taubenberger's research interests include influenza virus and coronavirus biology and evolution, path-ophysiology, clinical and translational research, and development of broadly-protective vaccines. [His] past research accomplishments include the sequencing, reconstruction, and characterization of the virus responsible for the 1918 influenza pandemic, which killed 50-100 million people worldwide. He has published over 300 papers and book chapters. [Before joining] NIAID, he served as Chief of Molecular Pathology at the Armed Forces Institute of Pathology (AFIP) in Washington, D.C. He received a B.S. in Biology from George Mason University in 1982, and an MD in 1986 and a PhD in 1987 from the Medical College of Virginia of Virginia Commonwealth University. He did his residency in anatomic pathology at the National Cancer Institute [and] holds dual board certifications in Anatomic Pathology and in Molecular Genetic Pathology."

(Source: NIAID <u>Announcement</u>, 4/28/25)

NIH has launched a new initiative that aims to, "expand innovative, human-based science while reducing animal use in research." Through this initiative the agency plans to, "establish the Office of Research Innovation, Validation, and Application (ORIVA) within NIH's Office of the Director. The new office will coordinate NIH-wide efforts to develop, validate, and scale the use of non-animal approaches across the agency's biomedical research portfolio and serve as a hub for interagency coordination and regulatory translation for public health protection. ORIVA will expand funding and training in non-animal approaches and awareness of their value in translational success. New funding opportunities will include evaluation criteria that assess methods based on their suitability for the research question, context of use, translatability, and human relevance. Infrastructure for non-animal approaches will also be expanded to make these methods more accessible to researchers...NIH will also publicly report on research spending annually to measure progress toward reduction of funding for animal studies and an increase in funding for human-based approaches." The agency news release further explained that, "developing and using cuttingedge alternative nonanimal research models aligns with the FDA's recent initiative to reduce testing in animals. While traditional animal models continue to be vital to advancing scientific knowledge, using new and emerging technologies can offer unique strengths that, when utilized correctly or in combination, can expand the toolbox for researchers to answer previously difficult or unanswerable biomedical research questions." The agency explained in the announcement that, "[s]ome bodies of research have been inconclusive on the efficacy of translating the results of animal models to human diseases, such as Alzheimer's disease and cancer. These translational challenges to humans may be due to differences in anatomy, physiology, lifespan, and disease characteristics. While humans and animals may share genes, some studies have shown there could be functional differences between organ and body systems that may result in some translational limitations. New and emerging technologies have begun to allow researchers to study health and disease using human information, making them an alternative avenue to yield replicable, translatable, and efficient results either alone or in combination with animal models. These technologies include: [0]rganoids, tissue chips, and other in vitro systems that allow scientists to model human disease and capture human variability and patient-specific characteristics; [c]omputational models which simulate complex biological human systems, disease pathways, and drug interactions; [and] [r]eal-world data that allow scientists to study health outcomes in humans at community and population levels."

(Source: NIH <u>News Release</u>, 4/19/25)





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

Register for the ABC Advocacy Summit

Registration is open for America's Blood Centers (ABC) Advocacy Summit. This event will take place in Washington, D.C. at the Hamilton Hotel June 10th-11th. Book your room before Thursday, May 15th to take advantage of the discounted rate. The full agenda is available and don't miss this opportunity to let your voice be heard as this event connects the blood community with national leaders in public policy and advocacy including meetings with members of Congress and their staff. Join us for a full day of advocacy training and group preparations for meetings with congressional offices on June 10th before heading to Capitol Hill on June 11th for group meetings with members of Congress and their staff. ABC will coordinate and schedule meetings on behalf of all attendees and conclude the day with a reception for all attendees. The training will feature insights from former members of Congress, seasoned lobbyists, and public policy staff from partner organizations, and ABC's government affairs team. Please contact us with questions.

Register for the June ADRP Webinar: "From Partnership to Purpose: Strengthening Hospital Relationships"

Registration is open for the Wednesday, June 25th ADRP Webinar: "From Partnership to Purpose: Strengthening Hospital Relationships," This event aims to, "help blood centers deepen their hospital partnerships and elevate the donor-to-patient journey." Hear speakers share programs and strategies to deliver value-added services that keep hospital clients engaged and loyal, while gaining practical ideas for successfully onboarding new hospital partners and ensuring long-term collaboration using ADRP's newest Hospital Partnership Idea Book. Whether you're strengthening existing connections or forging new ones, this session is packed with actionable takeaways to help.

Nominations Deadline Approaching for HOSA Partnership Recognition

ABC encourages member blood centers to submit nominations recognizing the HOSA-Future Health Professionals chapters that they are partnering with. The submission deadline is May 15th as the nominationbased categories highlight outstanding contributions from HOSA chapters and state associations in strengthening the nation's blood supply during times of critical need and/or through support of blood donation or a blood drive. The winning HOSA chapters will be honored at the HOSA International Leadership Conference in June. More information is available here. Also, please remind your HOSA student partners to upload their blood donation data for the 2024-25 school year by May 15th. The goal is to surpass last year's 33,000 donor record, and your support is crucial in achieving this. For more information on data submission and our HOSA partnership, please visit www.AmericasBlood.org/HOSA.



-4-

May 5, 2025



INFECTIOUS DISEASE UPDATES

BABESIOSIS

A paper published in the *Journal of Medical Entomology*, "provides critical insights into the emergence of babesiosis in the Mid-Atlantic region, documenting human cases and the presence of *Babesia microti* in local tick populations," according to a news release. The authors explained in the announcement that, "[t]he study confirms that babesiosis, historically concentrated in the Northeast and Upper Midwest, is now expanding in the Mid-Atlantic region. The research highlights an increasing number of locally acquired (autochthonous) human cases and the detection of *Babesia microti*, the primary causative agent of human babesiosis, in blacklegged ticks (*Ixodes scapularis*) and *Ixodes keiransi* ticks." Key findings from the authors of the paper include:

- "Autochthonous human babesiosis cases were reported for the first time from the Mid-Atlantic U.S. jurisdictions of Maryland, Virginia, West Virginia, and the District of Columbia between 2009 and 2024.
- *Babesia microti* was detected in ticks collected from Delaware, Maryland, Virginia, West Virginia, and DC.
- The study provides the first report of *Ixodes keiransi* as a potential vector of *Babesia microti*.
- The data suggest that babesiosis is becoming a growing concern in areas where it was previously considered rare or absent."

Study lead Ellen Stromdahl, PhD added in the news release, "[t]he findings underscore the need for increased surveillance, public awareness, and preventive measures against tick-borne diseases in the Mid-Atlantic region. Healthcare providers should consider babesiosis in the differential diagnosis for patients with febrile illness, particularly during peak tick-activity seasons." The article also explained that, "babesiosis, caused by microscopic parasites that infect red blood cells, can range from asymptomatic to severe illness, particularly in immunocompromised individuals...Additionally, coinfection of *Ixodes scapularis* with *B. microti* and *B. burgdorferi* is common. In this study, half of the ticks positive for *B. microti* were also infected with *B. burgdorferi*, and one was triple-infected with *Anaplasma phagocytophilum*, *B. burgdorferi*, and *B. microti*. Further, additional *I. scapularis* from Maryland and Virginia were found concurrently infected with *A. phagocytophilum*, *B. burgdorferi*, *B. microti*, and *Borrelia miyamotoi*."

(Source: Entomological Society of America <u>News Release</u>, 4/29/25) •

MEMBER NEWS

Inova Blood Donor Services recently <u>celebrated</u> the 20th anniversary of its Loudoun, Va. facility with county leaders, according to *Loudoun Now*. The publication noted that a celebration took place to recognize the, "milestone and highlight the important partnerships that make the center successful. 2025 also marks the 60-year anniversary of [Inova] providing blood in the Metro Washington, D.C. area. The 23,000-square-foot [Loudoun] facility receives approximately 11,000 donations a year and processes 75,000 blood products from a variety of locations annually." Inova Vice Presi-



dent of Professional Services Sean McCleary added in the article, "I had no idea of the impact that an organization like Inova and blood donor services can have for a community. I always just thought it was the American Red Cross. But in order to make these successful partnerships and these successful operations, they can't happen without amazing partnerships with our community partners, whether that's our governmental agencies, whether it's our church communities, our nonprofit communities. Without people being

MEMBER NEWS (continued from page 5)

willing to roll up their sleeves, we could not do the work that we do at blood donor services. And being the largest hospital-based blood center in the country, takes those strong partnerships and relationships to make it happen."

(Source: *Loudon Now*, "<u>Value of Partnerships Highlighted During 20-Year Inova Blood Services Celebra-</u> tion," 4/24/25)

Community Blood Center of the Ozarks (CBCO) has <u>opened</u> a new donor center in Joplin. KSNF Joplin reported that, "[t]he move has been a couple of years in the making. This facility can handle more donors at once." Specifically, CBCO's Michelle Teter explained to the news organization that, "the move was to expand and be able to collect more blood donations at one time. So, we [went] from four donor beds to eight donor beds. That is beneficial to meet the local need of the hospitals that we service, so that we can [meet our collection needs] of 200 blood donations a day."

(Source: KSNF Joplin, "Joplin Blood Center of the Ozarks Relocates," 4/28/25)

RESEARCH IN BRIEF

How Much Furosemide is Needed to Treat TACO. The aim of a study in Vox Sanguinis, "was to establish a reliable furosemide dose-response curve in patients at risk for transfusion-associated circulatory overload (TACO)." The authors explained that, "[t]his observational cohort study was conducted at two academic hospitals in Toronto, Canada [and included] inpatients 50 years of age or older without exclusion criteria: active bleeding, hemodynamic instability, glomerular filtration rate (GFR) <30 mL/min/1.73 m², non-furosemide diuretic administered less than 24 hours (h) prior to furosemide therapy, or albumin administered less than 8 h prior to index furosemide." The paper explained that, "[t]he primary outcome was 6-h urine output post furosemide administration." A multiple comparisons procedure and modeling (MCP-Mod) methodology, "identified a statistically significant dose-response curve after data from 149 patients were analyzed." The researchers noted that, "[t]he median (O1, O3) administered IV furosemide dose was 40 mg (20, 40), and doses ranged from 20 to 120 mg. [Additionally, median] (Q1, Q3) urine output at 6 h was 935 mL (655, 1,250)...Urine output varied significantly between patients for a given IV furosemide dose: 6-h urine output following a 20-mg dose ranged from 340 to 1,850 mL, and following a 40-mg dose it was 170-2,800 mL...Median (Q1, Q3) weight-based dose was 0.41 mg/kg (0.28, 0.57)." The authors explained that, "one patient [had] very large diuresis (>2,500 mL) after a 1.0 mg/kg furosemide dose...This result was felt to be an outlier and reflected the poor precision of the dose-response curve at doses above 0.6 mg/kg due to the relative paucity of patients receiving doses this high...Therefore, a decision was made to limit the range of the dose-response curve to a maximum dose of 0.6 mg/kg." The researchers also noted that, "[w]hen MCP-Mod analysis was subsequently applied to this smaller sample of 132 patients receiving furosemide doses of 0.2–0.6 mg/kg, the linear-log model was identified as achieving statistical significance with a precision of ± 100 mL. [The dose-response] formula identified in this study would suggest that a 55year-old, 70-kg woman with a GFR of 60 mL/min/1.73 m², albumin of 40 g/L and no history of chronic diuretic usage would require a pre-transfusion dose of only 10 mg IV furosemide to achieve a diuresis of approximately 400 mL, which is sufficient to compensate for the fluid challenge of a single unit of red blood cells." The study concluded by highlighting that, "through the novel application of MCP-Mod methodology to urine output data following furosemide administration to hospitalized patients with TACO risk factors, [it] report[ed] for the first time a dose-response model."

Citation: Rotin, L., Zhang, L., Armali, C., Malkin, A., Massin, S., Meirovich, H., *et al.* "<u>How much furo-</u> semide should be administered to prevent transfusion-associated circulatory overload? Results of a dosefinding study." *Vox Sanguinis.* 2025

GLOBAL NEWS

ABC Newsletter

A paper published in *Scientific Reports*, examines, "the lifetime prevalence of blood donation among college students and faculty members [in Iran], their attitudes toward blood donation, and their preferences for monetary versus non-monetary incentives using a discrete choice experiment (DCE) model." The researchers explained that the, "questionnaires for both college students and faculty members consisted of four parts [including questions related to] age, sex, marital status, place of birth, self-assessed household economic status, self-assessed health status, and personal and family history of blood donation; knowledge and attitudes toward blood donation; willingness to accept payment for blood donation; [and] questions about willingness to accept payment for blood donation." They found that, "faculty members were significantly more likely to have donated blood than students likely reflects a combination of factors including age, greater awareness of the importance of donation, and more established social roles that encourage community engagement. [The study also found that,] participants generally accepted both economic and non-economic incentives for blood donation. However, monetary incentives and receiving blood in return were not the primary motivators. Instead, standard screening, travel time, paid leave, and monetary donations to charity emerged as the main motivators for blood donation. These findings align with the principles of Voluntary Non-Remunerated Blood Donation (VNRBD), which emphasizes that individuals should donate blood willingly and without receiving payment or substitutes for money in return." The paper concluded that, "individuals are open to accepting incentives for donating blood, suggesting that these can be effective tools. Understanding the underlying motivations for blood donation is essential for creating targeted strategies that can increase participation rates. [The] research identified several key incentives that are particularly appealing to potential donors, including reduced travel time, standard screening tests, paid leave, and connection to blood recipients. Additionally, well-designed incentive programs may help address common barriers to blood donation, such as fear and perceived inconvenience." The authors suggested that, "[f]uture research should explore the preferences of the general population regarding various incentives for blood donation; this broader understanding can further improve donation strategies."

Citation: Rezaei, S., Amiri, F. and Delangizan, S. "Discrete choice experiment to determine preferences of blood donation in Iran." *Scientific Reports*. 2025

Valneva SE recently <u>announced</u> that France's regulatory authority, the Haute Autorité de Santé (HAS), "updated its recommendation for use of Valneva's single-dose chikungunya vaccine Ixchiq® for the prevention of disease caused by the chikungunya virus (CHIKV) following reports of serious adverse events (SAEs) in elderly people with comorbidities during the ongoing vaccination campaign in La Reunion and Mayotte." A company news release stated that regulators had, "initially prioritized vaccination of adults aged 65 and over, especially those with comorbidities. On April 25th, the French health authorities decided to suspend the use of [the vaccine] in persons aged 65 years and older pending further investigation. This is a response to an ongoing investigation of three cases of SAEs resulting in hospitalization, including one death, after vaccination with Ixchiq® among people in La Reunion. The three individuals who were hospitalized were over 80 years old and had pre-existing comorbidities. These SAEs were reported through the pharmacovigilance system set up by the French health authorities, and causality has not been definitively established. The HAS maintains its current recommendation for Ixchiq® for people aged 18 to 64 years old as part of the ongoing vaccination campaign. Valneva is also actively working with regulators on next steps." Valneva added in the news release that the chikungunya outbreak in La Reunion has resulted in 40,000 confirmed cases in 2025.

(Source: Valneva SE <u>News Release</u>, 4/26/25)

(continued on page 8)

<u>GLOBAL NEWS</u> (continued from page 7)

The CSL Seqirus has <u>announced</u> that it has been awarded a, "contract to support the pandemic preparedness plans of 17 European Union (EU) and European Economic Area (EEA) member states and the European Commission by the Health Emergency Preparedness and Response Authority (HERA)." According to the CSL Sequiris news release, "27 million doses of pandemic influenza vaccine have been reserved with CSL Sequirus, which can be ordered by the participating countries in the event of an influenza pandemic. The contract requires CSL Seqirus to be prepared to rapidly manufacture and deliver these vaccine doses to help protect Europeans against the influenza strain identified by the World Health Organization (WHO) when an influenza pandemic is declared."

(Source: CSL Seqirus <u>News Release</u>, 4/29/25) •

COMPANY NEWS

BBG Advanced Therapies, a subsidiary of BioBridge Global has <u>announced</u> the world's first <u>mobile</u> <u>leukapheresis center</u>, "a highly specialized type of bloodmobile that safely and comfortably allows the collection of immune cells. These cells are used in advanced treatments for cancer, autoimmune conditions, genetic disorders, and other serious illnesses," according to an announcement from organization. "[The] 'first-of-its-kind innovation' aims to expand access to advanced therapies by bringing immune cell collections directly to patients."

(Source: BBG Advanced Therapies <u>Announcement</u>, 4/29/25)

Cellenkos, Inc. has received the U.S. Food and Drug Administration's (FDA) Orphan Drug Designation for a novel advanced therapy to treat aplastic anemia. A company news release explained that the, "designation supports the development of medicines for rare disorders that affect fewer than 200,000 people in the U.S, and qualifies a company for incentives, including tax credits, exemptions from certain FDA fees for clinical trials, and the potential for seven years of market exclusivity following drug approval. Aplastic Anemia has an incidence of 1.0-2.3 per million in the U.S and a projected prevalence of 5.000 patients." Data from a phase I clinical trial published last year in The New England Journal of Medicine Evidence, "demonstrate[ed] that the [advanced therapy] leads to durable transfusion independence up to 3.5 years in patients with Aplastic Anemia, a rare and life-threatening bone marrow failure disorder. The trial (NCT03773393) also highlight[ed] the excellent safety profile of [the advanced therapy] (CK0801) and its potential to offer a novel, non-immunosuppressive treatment for patients who have not responded to conventional therapies. Specifically, patients were able to receive CK0801 infusions in an outpatient setting, intravenously through a peripheral intravenous line without any need for hospitalization and without any conditioning chemotherapy. The study, which included nine patients with bone marrow failure syndromes, found that a single infusion [resulted] in a 67 percent overall response rate at the one-year follow-up. Notably, patients with Aplastic Anemia showed remarkable outcomes, with 75 percent of patients achieving partial responses, including two individuals who became transfusion-independent within months of treatment. These patients remained transfusion-independent for up to 41 months, marking a significant milestone in the treatment of Aplastic Anemia. CK0801, Cellenkos' [is advancing] toward the filing of a registration trial intended to support regulatory approval for the treatment of transfusion- dependent Aplastic Anemia."

(Source: Cellenkos® Inc. News Release, 4/14/25)

(continued on page 9)



Delcon recently <u>announced</u> a strategic partnership with **Versiti**, **Inc.**, a member of America's Blood Centers (ABC). A news release stated that the, "partnership brings Delcon's advanced blood collection scale technology to the Versiti organization [which] becomes the first blood center in the U.S. to implement customized, branded blood collection scales [that feature:]



- [b]etter accuracy and flow control for smoother, more efficient donations;
- [e]asy-to-use system that works at both mobile drives and donation centers; and
- [c]ustom branding that reflects the identity and professionalism of the blood center."

(Source: Delcon <u>News Release</u>, 5/2/25)

Lytus Technologies has <u>acquired</u> "Blod.in, India's first on-demand blood component management and logistics platform." According to a news release, "Blod.in's artificial intelligence (AI) engine, which optimi[z]es blood inventory forecasting, real-time supply-demand mapping, and last-mile routing intelligence for temperature-sensitive deliveries. Blod.in is working on and pioneering the integration of Agentic AI, autonomous digital agents capable of reasoning, decision-making, and acting without human intervention. These intelligent agents operate across hospitals, blood banks, and logistics hubs to ensure uninterrupted, goal-driven healthcare delivery." Lytus further explained in the news release that, [f]ollowing a successful pilot phase, Blod.in is set to officially launch, transforming blood logistics through its flagship platform, Blod+. The pilot proved its ability to cut blood procurement time from hours to just 90-120 minutes, addressing India's 650,000-unit annual blood deficit, which contributes to 12,000 daily deaths." Lytus intends to expand Blod.in's AI platform to global markets.

(Source: Lytus Technologies <u>News Release</u>, 4/30/25)

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.)

2025

May 6-8. 2025 ADRP Annual Conference. Oklahoma City, Okla. <u>Registration</u> is open. More information available <u>here</u>.

May 14-15. International Plasma and Fractionation Association (IPFA)/Paul-Ehrlich Institut[e] (PEI) 30th International Workshop on Surveillance and Screening of Blood-borne Pathogens. Heidelberg, Germany. <u>Registration</u> is open. More information available <u>here</u>.

May 20-21. International Plasma Protein Congress. Warsaw, Poland. Registration is open.

June 1-4. International Society of Blood Transfusion (ISBT) 35th Regional Congress. Milan, Italy. <u>Registration</u> is open. More information available <u>here</u>.

June 10-11. ABC Advocacy Summit. Washington, D.C. Registration is open. More information is available here.

June 25. **ADRP Webinar: From Partnership to Purpose: Strengthening Hospital Relationships.** <u>Registration</u> is open. More information available <u>here</u>.

June 25-26. HHS OIDP TBDAIC Community Engagement Meeting (Hybrid). Portland, Maine. More information is coming soon.

Sept. 24-25. **2025 ADRP Master Class: "Building Brighter Experiences: Empowering Customers, Engaging Employ**ees (Virtual). More information is coming soon.

Oct. 12-15. American Association of Tissue Banks (AATB) Annual Meeting. Atlanta, Ga. More information is coming soon.

Oct. 14-15. International Protein Forum. Old Town Alexandria, Va. Registration opens in July.

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

Oct. 26-29. Blood 2025 and the ISBT 36th Regional Congress. Perth, Australia. More information available here.

Nov. 12. 2025 ADRP International Showcase. More information coming soon.

Nov. 17-20. American Society for Clinical Pathology (ASCP) Annual Meeting. Atlanta, Ga. <u>Registration</u> is open. More information available <u>here</u>.

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC 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

Medical & Laboratory Director. At Vitalant, we're on a mission to save lives and improve health-and we're looking for a Medical & Laboratory Director who shares that passion. Based in Las Vegas, NV (other U.S. locations may be considered with additional travel), this role provides medical oversight for donors, patients, staff, and healthcare partners in the region. You'll support core operations like component manufacturing, lab testing, donor counseling, and product management, while also overseeing transfusion support, therapeutic apheresis, and cellular therapy collections. This role includes medical and laboratory direction of centralized transfusion services, cellular therapies, and Immunohematology Reference Laboratory (IRL) services. You'll work closely with Corporate and Division teams to advance Vitalant's mission to unite blood and biologics donors, talent, and innovation to save and improve lives. As a Medical & Laboratory Director, you'll get to: Guide quality, regulatory, and operational initiatives. Provide medical direction and serve as a CLIA, FACT, or ASHI-defined lab director. Drive policy improvements and technology adoption. Offer medical consults and promote services to hospitals and physicians. Support leadership and field teams. Represent Vitalant in professional forums and inspections. Build strong partnerships to support compliance, service excellence, and growth. Interested applicants can apply on the Vitalant careers site:

https://prd01-hcm01.prd.mykronos.com/ta/6006708.careers?ShowJob=2063867915

Vice President, Blood Service Division Quality Services. At Vitalant, we're on a mission to save lives and improve health-and quality is at the core of everything we do. We're seeking a Vice President, Blood Service Division Quality Services in Scottsdale, AZ to lead our Blood Services Division with strategic vision, regulatory expertise, and a passion for continuous improvement. In this key leadership role, you'll help ensure our systems deliver safe, compliant, and reliable blood products to those who need them most. You'll guide both national and field quality teams, build cross-functional partnerships, and foster a culture rooted in our RITE values-Respect, Integrity, Teamwork, and Excellence. As VP, Blood Services Quality Services, you'll get to: Lead regulatory compliance, quality system design, and inspection readiness. Oversee regulatory reporting, deviation management, and resolution of nonconforming products. Guide SOP development to ensure efficiency, scalability, and adherence to standards. Analyze quality metrics, lead root cause investigations, and drive corrective actions. Support field teams with performance

(continued on page 11)



<u>POSITIONS</u> (continued from page 10)

improvement and operational excellence. Represent Vitalant in audits, industry forums, and professional networks. Manage departmental budgets and support strategic initiatives. If you're ready to make a measurable impact on public health through quality leadership, we invite you to join us. Interested applicants can apply on the Vitalant careers site: <u>https://prd01-hcm01.prd.mykronos.com/ta/6006708.careers?ShowJob=2047141031</u>

Clinical Laboratory Scientist (CLS). Join The Northern California Community Blood Bank, where we are dedicated to the health and well-being of our community. We are a value-driven organization committed to stability, balance, and building vibrant community relationships. We offer a low-stress environment and excellent worklife balance. This is a full-time position. Health, dental, vision, life insurance, and retirement plan offered. Generous PTO offering. Starting wage range is \$50 - \$55/hr. Hiring and Relocation Bonus potential. Responsibilities include blood processing and testing, immunohematologtraining, validation, ical testing, procedure implementation. This position requires on-call duties. The right candidate is quality focused with communication skills and attention to detail. This person will enjoy a collaborative and busy environment with opportunities for projects and quality improvement. Click HERE for the full job description and to apply.

Medical Laboratory Scientist - Blood Bank - 2nd and 3rd Shift (Florida). LifeSouth Community Blood Centers is looking for an experienced Medical Laboratory Scientist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Gainesville, FL. The position is responsible for following established policies and procedures, identifying problems that may adversely affect test performance or reporting of test results, and either correct the problems or immediately notify a supervisor, manager, or director. The Medical Laboratory Scientist will resolve complex immunohematology and compatibility problems to provide the safest donor blood for the patients in our community. We focus on providing the best possible customer service. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here! **Shift Differential Available**

Medical Laboratory Scientist - Blood Bank - 2nd and 3rd Shift (Georgia). LifeSouth Community Blood Centers is looking for an experienced Medical Laboratory Scientist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Atlanta, GA. The position is responsible for following established policies and procedures, identifying problems that may adversely affect test performance or reporting of test results, and either correct the problems or immediately notify a supervisor, manager, or director. The Medical Laboratory Scientist will resolve complex immunohematology and compatibility problems to provide the safest donor blood for the patients in our community. We focus on providing the best possible customer service. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and <u>apply here!</u> **Sign-On Bonus and Shift Differential Available**

Director, Quality Assurance/Regulatory Affairs. Hoxworth Blood Center (HBC) was founded in 1938 and serves more than 30 hospitals in 18 counties in Ohio, Kentucky, and Indiana. Annually, HBC collects more than 100,000 units of blood from local donors to help save the lives of patients in area hospitals. HBC is located within the University of Cincinnati (UC), College of Medicine, and is seeking a full-time Director, to oversee and direct the coordination of quality assurance and regulatory compliance for the collection, manufacture, storage and distribution of licensed and unlicensed blood and blood components, and for the testing of donor and patient samples. Essential Functions: Direct the coordination of regulatory compliance with the Food & Drug Administration (FDA), e.g., review of changes to regulations & guidance documents, submission of biological product deviation reports & response to observations/findings from FDA inspections. Support the Division Director in the preparation of license applications, annual report of minor changes & correspondence with the FDA. Manage the quality programs for maintaining applicable licensure and accreditation, e.g., internal and external audits, supplier qualifications, change control, deviation management, document control and record retention. Minimum Requirements: Bachelor's Degree and seven (7) years' experience. Click **HERE** for the full job description and apply. EOE