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NEWSLETTER

A weekly chronicle of events and issues impacting the blood community

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First Freeze-Dried Plasma Product Licensed by FDA

The U.S. Food and Drug Administration (FDA) recently licensed the first freeze dried plasma (FDP) product for use in the U.S. An agency news release on July 29th stated that Vascular Solutions, LLC, a subsidiary of Teleflex, was granted the biologics license for Ezplaz FDP which is, "intended for transfusion in adult patients who need plasma and for whom other plasma products are not available." Specifically, the product is, "indicated for transfusion in adults when plasma is required and other plasma products are not available, including bleeding patients, patients needing massive transfusion or certain patients on warfarin who are bleeding."

The FDA announcement described, "Ezplaz [as] a freeze-dried (lyophilized) plasma product derived from a single unit of fresh frozen plasma collected from FDA-licensed blood establishments. It is available in Group AB and Group A with low-titer anti-B blood types, chosen to mitigate [the] risk of giving to patients in emergencies before their blood type is determined."

It also noted that, "[u]nlike conventional plasma products that must be stored frozen and thawed before use, Ezplaz can be stored at room temperature, is stable after exposure to temperature fluctuations and is rapidly reconstituted. [Ezplaz can be] packaged in a plastic bag rather than a glass bottle, reducing the risk of breakage during handling and transport[ing]. FDA expects that these features will make the use of Ezplaz compatible with austere environments, potentially including combat zones, remote areas, and disaster response settings."

The agency announcement further explained that all Ezplaz kits are, "a complete, self-contained package containing: one unit of freeze-dried plasma sealed in an outer foil pouch, one 250 mL bag of sterile water for injection, one sterile fluid transfer set, and one sterile blood transfusion set." FDA also noted that, "[f]or uses of Ezplaz that are approved under the license, FDA has found that the benefits of Ezplaz transfusion outweigh the risks. The safety profile of Ezplaz is consistent with other plasma products used for transfusion. As with all plasma products, patients and healthcare providers should be aware of [the] risks associated with transfusion. Healthcare providers should review the full prescribing information before use."

(Sources: FDA News Release, 7/29/26)

FDA Details Changes to Inspection Model, Processes, and Oversight as Part of Transformation and Administrative Consolidation Efforts

The U.S. Food and Drug Administration (FDA) has announced plans to improve organizational efficiencies through administrative consolidation according to a notice in the *Federal Register*. As a part of these efforts, the agency has outlined changes to the traditional inspection model in a published post on the *FDA Voices* blog titled "Investing in FDA's Inspectional Enterprise: Strengthening Our Operations and Workforce to Advance Public Trust" authored by Elizabeth Miller, PharmD, associate commissioner for Inspections and Investigations and Lowell Zeta, JD, acting chief of staff and deputy commissioner for Strategic Initiatives at the agency. The communication explains that the FDA is undergoing a, "transformation of our inspectional enterprise, including how we plan, coordinate, and execute inspections across the agency. We are advancing that transformation through a more aligned, risk-informed, and transparent approach to inspectional operations that is already taking shape across the FDA."

In the blog, the agency highlights the challenges of the current inspection model, "[r]ecognizing that traditional inspection models and increasing travel demands can limit annual inspection capacity and that workforce sustainability is inseparable from mission effectiveness, the FDA is pursuing approaches that enhance surveillance and better support the investigators who carry out this critical work while avoiding gaps in surveillance coverage. To address these challenges the agency is pursuing the opportunity to better align at the enterprise level."

FDA has created the Inspectional Affairs Council (IAC) to act as, "a cross-agency governance body focused on inspectional matters. The IAC brings together leadership from across the FDA, including each of the Centers, the Human Foods Program, the Office of the Chief Scientist (OCS), the Office of Global Policy and Strategy (OGPS), the Office of Operations, the Office of the Chief Counsel, and the Office of Inspections and Investigations (OII). It is co-chaired by the Deputy Commissioner for Strategic Initiatives (DSCI) and the Associate Commissioner for Inspections and Investigations (ACII)."

The IAC will, "coordinate strategic decision-making and enhanc[e] alignment between OII and the Centers on inspectional activities. It provides a forum to modernize operations, strengthen workforce strategy, and streamline processes that directly affect the FDA's ability to oversee regulated products." To assist with inspectional enterprise calibration, OII, the Centers, and OGPS, which houses investigators stationed in the foreign offices, are developing operating agreements that define responsibilities in specific terms. OII maintains responsibility for field execution, evidence collection, and operational planning."

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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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FDA Details Changes to Inspection Model, Processes, and Oversight (continued from page 2)

The FDA also explains that it is modernizing inspectional approaches through, "the use of new and already existing inspectional tools to ensure maximized inspectional capacity and oversight. Alternative tools include—but are not limited to—records requests under statutory authority, remote interactive evaluations, and the use of inspection reports from trusted regulatory partners under mutual recognition agreements. These tools allow the FDA to gather high-quality information without always needing to conduct a full on-site inspection, which helps allocate resources more effectively. A key pillar of this modernization effort is continuing to establish parity in our inspectional posture between domestic and foreign facilities."

The agency further notes that it is, "intensifying its use of unannounced foreign inspections as a more effective tool for assessing true manufacturing quality, particularly in countries on which the United States relies for critical drug supplies. These shifts represent a meaningful change in how the FDA assesses and verifies compliance at high-priority foreign manufacturing sites."

The communication also emphasizes that, "[t]he next-generation OII workforce model is not a move to generalists—far from it; [the model] has been carefully designed to deepen talent by expanding investigators' capabilities, strengthening specialized expertise, and creating better career pathways that support mobility and retention across the [agency]. The FDA is strengthening investigator training and readiness through expanded partnerships, including with federal training programs, to accelerate the time from hiring to full field certification. This includes more structured onboarding, standardized training modules, and cross-functional development opportunities to ensure investigators can operate effectively across different product areas when needed." The communication concludes by explaining that, "[t]he work of modernizing the FDA's inspectional enterprise is ongoing. For industry, more consistent processes support better planning and more efficient interactions with the agency."

(Source: FDA Communication, 8/3/26)

RESEARCH IN BRIEF

How Do We Quantify the MINT Trial Results: Liberal vs. Restrictive Transfusion Strategy After Myocardial Infarction? Authors of a paper published in *JAMA Network Open* sought to, "reexamin[e] the MINT trial using a bayesian framework to better quantify the potential benefit associated with a liberal strategy on the composite outcome of death or myocardial infarction (MI) and its potential harm from heart failure events." The researchers explained the benefits of the bayesian approach as, "[u]nlike the frequentist approach, bayesian posterior distributions allow for estimation of the probabilities that the liberal strategy is superior to the restrictive one and that the absolute differences in event rates exceed predefined clinically meaningful thresholds." The authors found that, "the bayesian reanalysis estimated that the probability that the liberal transfusion strategy is superior to the restrictive strategy is 89.1 percent or greater, even when the prior belief reflects that the restrictive strategy is superior. Although the estimated absolute risk of heart failure was higher in the liberal strategy group by 0.2 percent to 0.6 percent, our analysis indicates the restrictive strategy group had excess risk ranging from 1.4 percent to 2.4 percent for death or MI and from 0.8 percent to 2.2 percent for the composite of death, MI, or heart failure compared with the liberal strategy group. Across all prior distributions, there was at least a 62.7 percent probability (>50 percent for decision-making) that the liberal strategy would result in 1 less outcome per 100 participants for the composite of death or MI at 30 days compared with the restrictive strategy. Alternatively, the probability that the liberal strategy would result in 1 more outcome per 100 participants for heart failure at 30 days was 29.3 percent or less. Assuming a noninformative prior effect distribution, we estimate that adopting a liberal strategy prevents approximately five deaths or MIs while causing approximately 1 heart failure, after treating approximately 200 patients." The researchers concluded that their

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RESEARCH IN BRIEF (continued from page 3)

findings, "suggest that a liberal transfusion strategy may result in a lower risk of 30-day death or MI, outweighing the increased risk of heart failure. This finding supports recent guideline recommendations that a liberal transfusion strategy may be reasonable in this population. Limitations of the analysis acknowledged by the authors include: "[w]e used the probability of exceeding any minimal clinically important differences above 50 percent as corresponding with clinical relevance in our interpretation; however, these thresholds and the probability for clinical relevance could reasonably vary depending on factors such as cost, blood product availability, transfusion-related risks, institutional policy, and individual patient goals and values; this bayesian analysis was not prespecified, thus potentially introducing biases and increasing the overall error rates; we did not analyze less-common adverse effects associated with liberal transfusion strategies, although these added risks are unlikely to affect the results of these analyses; [and] although this analysis suggested that the probability of heart failure was lower in the restrictive arm, the MINT trial did not collect detailed data regarding peri-transfusion volume management strategies (e.g., diuretic administration or mechanical circulatory support), which may influence heart failure outcomes and could modify the estimated treatment effect in specific subgroups."

Citation: Bertolet, M. Carrier, F.M., Glynn, S., *et al*. "Restrictive vs Liberal Transfusion Strategy After Myocardial Infarction: A Post Hoc Analysis of the MINT Randomized Clinical Trial." *JAMA Network Open*. 2026.

WORD IN WASHINGTON

Following the July 24th statement by the Association for the Advancement of Blood & Biotherapies (AABB) Interorganizational Task Force on Domestic Disasters and Acts of Terrorism, of which America's Blood Centers (ABC) is a part, several federal officials and national organizations encouraged blood donations. Specifically, the social media accounts for the U.S. Surgeon General, the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Health, and the U.S. Centers for Medicare & Medicaid Services (CMS) Administrator urged individuals to schedule appointments to donate. Additionally, the American Hospital Association (AHA) published a blog post titled "Meeting a Critical Need: Answering the Call to Donate Blood." The association is, "encouraging hospitals and health systems to work with community partners to raise awareness about the importance of blood donation and help[ing] connect eligible donors with opportunities to give. [AHA is] also urg[ing] members of the public to consider making an appointment to donate if they are eligible."

Erica Schwartz, MD has been confirmed by the Senate as director of the U.S. Centers for Disease Control and Prevention (CDC). She succeeds National Institutes of Health (NIH) Director Jay Bhattacharya, MD, PhD who has been serving as acting director of CDC. President Trump nominated Dr. Schwartz in April 2026. She earned a medical degree from Brown University and served in the U.S. Navy until 2005. "[She previously] served in the U.S. Public Health Service Commissioned Corps, as the Coast Guard Chief Medical Officer and as Deputy Surgeon General from 2019 to early 2021, during the first Trump administration."

(Source: ABC News, "Senate votes to confirm Dr. Erica Schwartz as CDC director," 8/5/26)

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WORD IN WASHINGTON (continued from page 4)

***Politico* is reporting that, Steven Quay, MD, PhD is being "vetted" to be the director of NIH's National Institute of Allergy and Infectious Diseases (NIAID).** The publication explained that Dr. Quay is a pharmaceutical executive and is currently being considered by U.S. Department of Health and Human Services (HHS) Secretary Robert F. Kennedy Jr. for the position that, "comes with control over $6.5 billion in health research funding."

(Source: *Politico*, "A lab-leak proponent is in line for Fauci's old job," 8/4/26)

The U.S. Government Accountability Office (GAO) published a report on July 30th titled "Public Health Preparedness: Experts Identified Actions to Improve Surveillance for Emerging Disease Threats." According to the announcement, the GAO convened an expert roundtable who, "suggested a range of actions that the federal government could take to improve U.S. emerging infectious disease surveillance. GAO categorized experts' suggestions across four areas related to collaboration, data, methods, and communication." Specifically, the report noted that, "[t]he CARES Act includes a provision for GAO to monitor and report on the federal pandemic response. This report describes how HHS has conducted surveillance of emerging infectious disease threats and actions experts suggested for the federal government to improve surveillance of emerging infectious diseases." Recommendations include:

- "[i]ncrease coordination by creating a multisectoral, multidisciplinary leadership group;
- [s]trengthen data quality by identifying, developing, and using standards for surveillance data;
- [o]ptimize surveillance by evaluating cost-effectiveness of surveillance systems and methods; [and]
- [i]mprove awareness and perception of public health and surveillance by developing a communication strategy."

(Source: GAO Report, 7/30/26)

BRIEFLY NOTED

The Cybersecurity & Infrastructure Security Agency (CISA), in collaboration with [the] National Security Agency (NSA), Federal Bureau of Investigation (FBI), Defense Cyber Crime Center (DC3), and international partners has published a cybersecurity advisory titled "Improve Router Hygiene to Protect Against Russian State-Sponsored Targeting." The joint communication warns that, "Russian cyber threat actors are targeting vulnerable networking devices in critical infrastructure sectors globally, especially communications, defense industrial base, energy, financial services, government services and facilities, and healthcare and public health. Led by NSA, the advisory highlights how threat actors primarily leverage poorly configured routers but are also known to exploit common vulnerabilities and exposures (CVEs) to gain unauthorized access, exfiltrate sensitive configurations, and facilitate malicious activity. To defend against these threats, the advisory outlines actionable mitigation steps, such as:

- "[r]estrict access to management interfaces and firewall devices;
- [a]dopt stronger authentication and data encryption protocols;
- [s]ecure weak and vulnerable internet-facing systems; [and]
- [m]onitor for suspicious activity."

(Source: Joint Cybersecurity Advisory, 7/14/26)

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BRIEFLY NOTED (continued from page 5)

A recording and slides are now available from the July 23rd National Highway Traffic Safety Administration's (NHTSA) EMS Focus Prehospital Blood Webinar Series inaugural session titled "Defining Prehospital Blood Transfusion." The event featured "remarks from NHTSA Administrator Jonathan Morrison and featured an expert panel discussing the role of prehospital blood transfusion in improving survival for patients with life-threatening hemorrhage, including those injured in serious motor vehicle crashes. Panelists explored the essential components of a prehospital blood transfusion program, the blood products EMS can administer in the field, the fundamental role of blood in the body, and the differences between whole blood and component therapy. The discussion also highlighted NHTSA's mission and role in advancing strategies that save lives on U.S. roadways." Registration is open for the August 18th session titled "Establishing a Prehospital Blood Transfusion Program." This virtual event will include a panel discussing, "the science (both military and civilian) that strongly supports the safety and lifesaving efficacy of prehospital blood components delivered to those who are severely bleeding from a wide range of trauma, including a motor vehicle crash. Discussion will include the risks of blood transfusion (prehospitally and otherwise) before transitioning into the specifics an EMS agency needs to start building their own transfusion program, including gathering and understanding their data and creating a stakeholder group."

(Source: NHSTA Announcement, 7/31/26)

MEMBER NEWS



Iowa Governor Kim Reynolds recently visited **LifeServe Blood Center** to donate blood and raise awareness of the ongoing need for blood donations, according to a report for the *Iowa Capital Dispatch*. The article explained that Governor Reynolds was joined by members of her staff and LifeServe Chief Executive Officer Stacy Sime as the two "led by example" in hopes of motivating Iowans to donate. "I want to lead by example, I want to show that it's easy," said Governor Reynolds to the *Iowa Capital Dispatch*. "It doesn't take a lot of time, and it's really important. [We're] Iowans, and so we see a need and we step in. I'm here to ask Iowans to consider this, step up, and especially if you're under 30, we'd love to see you participate, be a blood donor, and truly make a difference in our state and for those that need it."

(Source: *Iowa Capital Dispatch*, "Gov. Kim Reynolds calls for Iowans to donate blood amid national shortage," 8/5/26)

The Blood Connection recently announced the release of a video, "from Beast Philanthropy [that] pulls back the curtain on the massive Greenville, North Carolina event hosted by MrBeast and Beast Philanthropy, where The Blood Connection (TBC) served as the blood drive partner for an extraordinary mission: helping save up to 1,000 lives in a single day." A blood center announcement also noted that, "[h]undreds of donors answered the call, turning one young leukemia survivor's wish to help other children battling blood cancers into a day of powerful community impact. MrBeast also sponsored a $10,000 raffle for participating donors, raising the stakes even higher on an already lifesaving event."

The Blood Connection also announced that it is assuming operations of Cape Fear Valley Blood Donor Center as of August 1st. The center will change its name to the Fayetteville Community Blood Center.

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MEMBER NEWS (continued from page 6)

The Blood Connection also noted in the communication that, "Cape Fear Valley Health announced that this transition is part of a strategic resource planning change where The Blood Connection will become the sole supplier of blood products for the health system. This transition allows the hospital to focus on patient care, while The Blood Connection dedicates its full resources to recruiting donors, collecting blood, and maintaining a safe blood supply."

(Sources: The Blood Connection Announcements, 7/31/26; 7/30/26)

Carter BloodCare has relocated its Rockwall Donor Center to a new, larger space in the rapidly growing suburb east of Dallas. The relocation provides added room to accommodate staff and donors. Carter BloodCare officials said blood, platelet and plasma collections had outgrown the prior facility's 2,300 square feet. The new site expands the workspace to 3,000 square feet.

(Source: Carter BloodCare Announcement, 8/5/26)

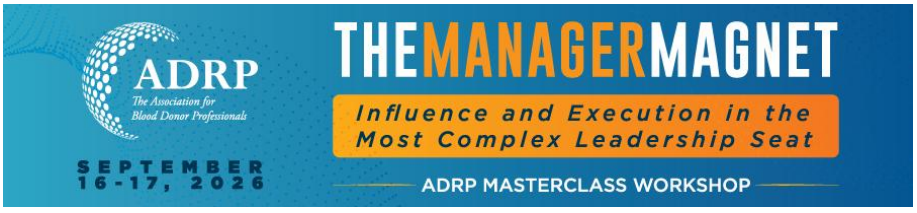
Contributed by James Black, Senior Public Relations Specialist at Carter BloodCare

IN MEMORIAM



Gene A. Erickson passed away on July 25th. An announcement from The Blood Connection, where Mr. Erickson previously served as chief executive officer (CEO), noted that, "[Gene] will be remembered by colleagues across the country for his unwavering support of community, transformation leadership, and commitment to saving lives locally. For more than five decades, Mr. Erickson devoted his life to the belief that a community should care for its own. In 1978, [he] left his role as executive director of United Blood Services in Chicago, Illinois to lead Greenville Blood Assurance Plan in Greenville, South Carolina. [Guided by] his vision to shape the community service of blood donation, Mr. Erickson's tenure as CEO meant the growth of the organization—expanding their presence to become the blood supplier of the entire South Carolina Upstate and a trusted partner of hospitals in Northeast Georgia. Mr. Erickson's success was known well beyond Greenville. He was a member of the American Association of Blood Banks (now the Association for the Advancement of Blood & Biotherapies) [serving] twice on the organization's Board of Directors. He also was a member of the America's Blood Centers Board. Additionally, he was honored with the Bernice Hemphill Memorial Award as the national premier blood center administrator for his leadership at The Blood Connection." Delisa English, MBA, president and CEO of The Blood Connection added in the announcement, "Gene will be deeply missed. He touched the lives of generations through his belief in our responsibility to care for one another. It's been my honor and privilege to carry on the legacy that Gene left, and to bear the responsibility for ensuring a safe, reliable blood supply. Rest easy Gene, your memory lives on in the lives saved every day by local blood donors." The announcement noted that, "the Erickson family requested that a blood donation be made at The Blood Connection or a charitable donation be made in his honor to the Erickson Family Scholarships at Cornell University."

(Source: The Blood Connection Announcement, 7/29/26)



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.

Registration Is Open for the Rise & Lead Workshop

Register for the America's Blood Centers (ABC) Women's Executive Leadership Community (WELC) Rise & Lead Workshop taking place in San Antonio, Texas November 5th-6th at The Westin Riverwalk, San Antonio. Join blood community professionals and industry partners for a dynamic leadership experience focused on Executive Presence and Personal Brand to develop the skills needed to increase your visibility, strengthen your influence, and confidently communicate your value while building meaningful connections with peers and industry leaders. For chief executive officers (CEOs) seeking a more intimate leadership experience, an optional CEO Retreat on November 4th offers a dedicated opportunity to connect with fellow executives, discuss shared challenges, and engage in meaningful peer-to-peer conversations before the workshop begins. WELC empowers leaders throughout the blood community through networking and professional development. Whether you are an emerging leader, experienced manager, or seasoned executive, the workshop creates space for meaningful conversations, shared learning, and the development of lasting professional relationships. Please contact us with any questions.

Economic Outlook Survey Report Available

America's Blood Centers (ABC) recently announced that the ABC Economic Outlook Survey Report has been released. The report is complimentary to participants and instructions on accessing it have been distributed to the designated contact. Non-participating ABC members may purchase the report. The ABC Economic Outlook Survey provides 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. Please contact us with questions.

Register for Part Two of the ABC Executive Fellows Capstone Project Webinar Series

The first cohort of ABC Executive Fellows are pleased to present their final capstone projects in part two of a special webinar series on Tuesday, August 18th at 2 p.m. EDT. Registration is open as the capstone projects are designed to address opportunities and challenges that impact the broader blood community. Covering a wide range of timely and relevant topics, these presentations offer valuable insights for professionals across all areas of blood center operations. Attendees will have the opportunity to learn from the project teams, engage directly with the authors during Q&A, and bring new ideas back to their organizations. Please contact us for more information.

Schedule Released for the 2026 ADRP MasterClass

Join us for the 2026 ADRP MasterClass: "The Manager Magnet: Influence and Execution in the Most Complex Leadership Seat!" This virtual event will take place September 16th-17th. View the schedule and register now. In today's competitive market, businesses that prioritize both employee and customer experience gain a significant edge. Join us as we explore:

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- "the connection between employee engagement and customer satisfaction;
- strategies for creating a positive workplace culture;
- how technology and data improve experiences for employees and customers; and
- real-world examples of companies excelling in both areas."

Whether you're in collections, recruitment, marketing, a customer experience professional, or business executive, this event will equip you with actionable insights to enhance both employee and customer journeys.

ADRP Trends in Donor Relations Study Results Are Available

Participants can now access the results of the *ADRP Trends in Donor Relations Study*. This survey is a strategic tool for blood centers to use in evaluating the performance of collection and recruitment operations and marketing strategies in comparison to your domestic and international colleagues. A key feature of the reporting platform is the ability to view how your operations compare to others using a variety of dynamic filters, including blood center location, collection levels, and employee count. Only centers that participated in the survey will have access to this information. Blood centers that did not participate can purchase the survey report for $599. Please contact us with any questions.

ADVANCED THERAPIES NEWS

The U.S. Food and Drug Administration (FDA) has published the draft agenda on the meeting page for the agency's virtual scientific public workshop titled "Next-Generation Sequencing (NGS) for Adventitious Agent (AA) Detection in Biologics." Registration is open for this event that will take place on September 23rd from 8:30 a.m. to 5 p.m. EDT. The workshop will feature, "subject matter experts and key stakeholders to discuss the readiness of NGS technologies for AA detection, identify challenges, and explore potential solutions to accelerate the adoption of NGS-based methodologies for AA detection in biological products. NGS-based AA detection methods have emerged as new approach methodologies (NAMs) that can broadly detect AA to enhance the safety of biological products while reducing reliance on testing in animals. Contamination with AA, such as viruses, bacteria, fungi, mycoplasma, and parasites, can jeopardize the safety, efficacy, and supply integrity of CBER-regulated biological products including cell and gene therapies, xenotransplantation products, blood products, and vaccines. The detection of adventitious viruses can be particularly challenging, given the high degree of sequence diversity inherent to viral populations, which drives the continual emergence of viral variants and novel viruses. For additional information on FDA's current thinking on NGS for adventitious agent testing, please refer to the FDA Q5A(R2) Guidance for Industry (January 2024), adopted from the ICH Q5A(R2) Guideline." Stated objectives of the workshop are:

- "[f]acilitate scientific exchange among key stakeholders and regulators regarding current advances in NGS technology and their application to AA detection in biological products;
- [g]ather perspectives on existing methodologies, implementation challenges, and emerging technical requirements for NGS-based AA detection;
- [u]nderstand challenges associated with the adoption of NGS-based methods, including analytical validation, data interpretation, and integration into existing safety testing frameworks; [and]
- [i]dentify knowledge gaps that must be addressed to support the broader application of NGS-based methods for ensuring the safety of biological products."

(Source: FDA Announcement, 8/6/26)

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ADVANCED THERAPIES NEWS (continued from page 9)

Repligen Corporation has agreed to acquire BioLife Solutions, Inc for approximately $1.5 billion. A news release describing the proposed transaction stated that, "BioLife's products are deeply embedded in the cell therapy workflow and highly complementary to Repligen's existing offering in this market. BioLife's differentiated biopreservation media portfolio, led by CryoStor®, supports 18 commercially approved therapies and the majority of U.S. commercially sponsored cell-based therapy trials."

(Source: Repligen Corporation News Release, 7/22/26)

GLOBAL NEWS

***QNews* in Australia has published an article examining the country's recent shift to individual donor assessments.** The article noted that the LGBTQIA+ advocacy group (Let Us Give) has communicated with Australian Red Cross Lifeblood, the country's national blood provider, regarding, "some of the outstanding problems with the new blood donation rules." Key points highlighted and questions asked by Let Us Give included:

- "[t]he new six-month monogamy requirement doesn't apply in other countries. It sends the message that there is still a higher risk associated with gay blood donation. When will this be reviewed?
- Lifeblood's communications fail to mention that the deciding factor for donation is anal sex with a new partner in the last three months. This gives the impression that monogamy is the only requirement, potentially losing new donors. Will Lifeblood amend its communications?
- Lifeblood should ask only trans donors for their sex recorded at birth once, not before every donation. Will this change?
- Lifeblood should have a dedicated page for the new rules on its website. It should acknowledge the pain and hurt caused by the former ban. Will this occur?
- People taking PrEP should be off the drug for twelve months before donating, but only three months in the U.S. and United Kingdom. Why the difference?
- The Plasma Pathway has fallen far short of expectations. Why has this happened and how can plasma donation be increased?"

QNews noted in the story that, "[i]n April, new sexual activity rules for blood donations took effect. Men were no longer asked in the pre-donation questionnaire if [they were sexually active] with another man. Instead, all donors were asked the same sexual activity questions, regardless of gender."

(Source: *QNews*, "Blood donation rule changes still create barriers for gay, bi and trans donors," 7/29/26)

The World Health Organization (WHO) recently announced the delivery and installation of, "13 blood bank refrigerators, complete with solar power systems, in health facilities across all 10 States and the 3 Administrative Areas (AAs) of South Sudan." The organization explained in the announcement that, "[t]he equipment was procured through funding from the Health Sector Transformation Project (HSTP), managed by the World Bank. The project is funded through the Multi Donor Trust Fund, supported by key development partners including the World Bank group, UK International Development, GAVI, The Global Fund, Canada, and the European Union (EU). The investments form part of a broader effort to equip health facilities across the country with infrastructure, equipment, and systems needed to deliver quality healthcare services." Additionally, the WHO has worked with Sudan's Ministry of Health and the country's national transfusion service on the, "development of the National Blood Transfusion Services Strategy 2026–2030, which provides a strategic framework for strengthening governance, improving blood collection and safety systems, enhancing quality management and ensuring equitable access to safe blood nationwide. To maximize the impact of these investments. WHO [also] developed standardized blood and blood donor management training materials, donor education materials, and

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GLOBAL NEWS (continued from page 10)

Standard Operating Procedures (SOPs) to support harmonized implementation of blood transfusion services across the country. This was complemented by a Training of Trainers (ToT) for 14 National Blood Transfusion Services staff, equipping them with the technical and facilitation skills required to lead capacity-building efforts at sub-national level. Following the ToT, an integrated training progra[m] on blood and blood donor management was launched and is currently being cascaded to all 13 health facilities where the blood bank refrigerators were installed."

(Source: WHO Announcement, 7/28/26)

COMPANY NEWS

Moderna, Inc. has received approval from the U.S. Food and Drug Administration (FDA) for the use of a seasonal influenza mRNA vaccine (mFLUSIVA) in individuals 50 years of age and older. An announcement from the company noted that, "[t]his approval follows unanimous recommendations from the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) supporting mFLUSIVA for adults 50 years of age and older. [The decision] is based on results from a randomized, observer-blind, active-controlled, phase III clinical trial, which enrolled 40,805 adults aged 50 years and older across 11 countries. The primary objectives in this study were to evaluate the safety and reactogenicity of mFLUSIVA, and to evaluate relative vaccine efficacy (rVE) of mFLUSIVA versus a standard dose (SD) active comparator against reverse transcription polymerase chain reaction (RT-PCR)-confirmed protocol-defined influenza-like illness (ILI) caused by any influenza A or B strains. Use in adults 65 years of age and older was granted accelerated approval based on results from a randomized, observer-blind, active-controlled clinical trial, which enrolled 2,992 adults 65 years of age and older in the United States. The primary objective in this study was to evaluate the immunogenicity of mFLUSIVA versus a high-dose (HD) inactivated influenza vaccine comparator. The phase III program demonstrated an acceptable safety profile for mFLUSIVA, with no new safety concerns identified, consistent with previously reported studies of mFLUSIVA. Moderna expects to have mFLUSIVA available for eligible populations in the U.S. for the 2026-2027 respiratory virus season.

(Source: Moderna, Inc. News Release, 8/5/26)

Octapharma recently announced that it is building the company's "first-ever U.S.-based manufacturing and production site at the Palmetto Research Park in Rock Hill, S.C. According to a news release, the $1.5 billion project is anticipated to result in 1,500 full-time jobs in the state and the facility will produce, "plasma-derived therapies, strengthening the domestic biomedical supply chain while also complementing the company's global manufacturing capabilities. Octapharma's Rock Hill site will also produce bleeding management and trauma care products for national security and emergency preparedness needs."

(Source: Octapharma News Release, 7/30/26)

Sign up for ABC's &ADRP's *Pulse of Leadership*



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.)*

2026

August 18. **ABC Executive Fellows Capstone Project Webinar Series Session II (Virtual).** More information including a link to registration is available to ABC members here.

August 18. **NHTSA Office of EMS "Establishing a Prehospital Blood Transfusion Program" Webinar (Virtual).** Registration is open. More information is available here.

September 16-17. **ADRP: The Association for Blood Donor Professionals Master Class (Virtual).** Registration is open. More information is available here.

September 22. **NHTSA Office of EMS Working with a Blood Supplier in Your Prehospital Blood Program Webinar (Virtual).** Registration is open. More information is available here.

September 23. **FDA Scientific Public Workshop: Next-Generation Sequencing for Adventitious Agent Detection in Biologics (Virtual).** Registration is open. More information is available here.

September 29. **FDA Blood supply Chain Roundtable Webinar (Virtual).** Registration is open. More information is available here.

October 4-7. **Association for Advancing Tissue and Biologics (AATB) Congress 2026. San Francisco, Calf.** Registration is open. More information is available here.

October 5-7. **ARM Cell & Gene Meeting on the Mesa. Phoenix, Ariz.** More information is available here.

October 14-15. **Biomedical Excellence for Safer Transfusion (BEST) Collaborative Member Meeting. Atlanta, Ga.** More information is available here.

October 17-19. **Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting. Atlanta, Ga.** More information is coming soon.

November 3-4. **Plasma Protein Therapeutics Association (PPTA) Plasma Protein Forum Alexandira, Va.** Registration is open. More information is available here.

October 20. **NHTSA Office of EMS Paying for Your Prehospital Blood Program Webinar (Virtual).** Registration is open. More information is available here.

November 5-6. **2026 ABC Women's Executive Leadership Community (WELC) *Rise &* Lead Workshop. San Antonio, Texas.** Registration is open. More information is available here.

November 17. **NHTSA Office of EMS Prehospital Blood Transfusion Policies, Protocols Guidelines & Training Webinar (Virtual).** Registration is open. More information is available here.

November. 17-20. **American Society for Clinical Pathology (ASCP) and Canadian Association of Pathologists- Association Canadienne des Pathologistes (CAP-ACP) Joint Annual Meeting. Montreal, QC.** Registration is open. More information available here.

December 15. **NHTSA Office of EMS Prehospital Blood Transfusion: Tracking Success & Improvement Webinar (Virtual).** Registration is open. More information is available here.

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CALENDAR (continued from page 12)

2027

March 8-11. **2027 ABC Annual Meeting. Atlanta, Ga.** More information is coming soon.

May 11-13. **2027 ADRP: The Association for Blood Donor Professionals Annual Conference Columbus, Ohio.** 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

Reference Lab Supervisor. OneBlood is currently recruiting for a Lab Supervisor in our AABB-Accredited Immunohematology Reference Laboratory in Ft. Lauderdale, FL. This position provides leadership and technical expertise, coordinates workflow and staff scheduling, and performs training and quality activities for the staff responsible for performing basic through advanced testing procedures on patient and/or donor samples. Applicants must have a bachelor's degree in medical technology, biological science or related scientific field from an accredited college or university. Three or more years in a clinical laboratory, preferably blood banking environment, or an equivalent combination of education, certification, training, and/or experience. Applicants must have a valid and current Florida Clinical Laboratory Technologist license in Immunohematology or Blood Banking; Florida Supervisor license and SBB certification preferred. To apply and view a complete Job Description of this position, go to www.oneblood.org and click on the Careers tab. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

Director of Operations (Lifeline Blood Services – Jackson, TN). Lifeline Blood Services is seeking an experienced **Director of Operations** to provide strategic leadership for Administrative Services, including Human Resources, Information Technology, Finance, Purchasing, and Fleet & Facilities. Working closely with the CEO, this executive leadership role ensures operational excellence, regulatory compliance, and organizational success. **Qualifications:** Bachelor's degree required; Master's preferred. Minimum of five (5) years of operations management experience. Strong leadership, financial, organizational, and communication skills. Experience with budgeting, contracts, vendor management, and regulatory compliance preferred. **Schedule:** Full-time, Monday-Friday, 8:00 a.m.-5:00 p.m., on-call as needed, with up to 25 percent travel. At Lifeline Blood Services, our mission is to serve our communities with the safest lifesaving transfusion medicine possible. If you are a collaborative leader who is passionate about operational excellence and making a meaningful impact, we encourage you to apply. **Click here to view the full job description and apply.**

Chief Operations Officer. We are hiring for Chief Operations Officer: **Purpose:** To effectively deploy and manage the operations resources (physical, human, and financial), drives oversight, compliance with all outside regulatory and accrediting services, and oversee operational performance of We Are Blood to achieve its mission and goals. **Responsibilities:** Oversee the operations processes of We Are Blood, including blood donor screening, collections, clinical services, components preparation, donor testing, reference laboratory, inventory management, distribution, and supply chain. Participate in developing and implementing the organization's strategic plan. Provide leadership in establishing and accomplishing operational goals and objectives. In conjunction with Executives and VPs, develop business plans and monitor the execution of each plan. Responsible for the oversight of the operational planning/budgeting and compliance for meeting budgets, goals, and objectives. Prepare and present operational reports and metrics as directed by the CEO. Provide leadership and direction for reporting staff in evaluating, coaching, and counseling employees. Ensure timely and effective training, feedback, and constructive guidance to improve employees' job performance and to expand their knowledge, skills, and techniques. **Skills, Education, & Experience:** College degree with RN, MT (ASCP), SBB, or related field preferred. Minimum of seven to10 years of leadership management and/or supervisory experience in a blood center required. Relevant experience in a highly regulated environment may

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POSITIONS (continued from page 13)

substitute for formal education. Excellent communication skills, both verbal and written, as well as presentation skills. Must have the ability to handle difficult situations and deal with sensitive and highly confidential information. Requires strong interpersonal, organizational experience, and demonstrated success in project and time management. Prefer management-level budget experience. Apply here.

Hospital Services Director of Operations (LifeServe Blood Center). Lead a mission-driven team where your decisions directly support patients, donors, and clinical partners across the region. In this role, you'll oversee blood manufacturing, product management, distribution, and advanced immunohematology reference laboratory testing—critical operations that ensure safe, reliable blood products for more than 175 hospitals across Iowa, Nebraska, South Dakota, and Illinois. You'll guide daily operations, uphold rigorous regulatory and quality standards, manage financial performance, and develop leaders at every level. This position directs staffing, equipment allocation, laboratory procedures, and productivity outcomes while fostering a culture of continuous improvement and exceptional customer service. You'll supervise testing personnel, validate results, support policy development, and ensure compliance with SOPs, quality programs, and federal regulations. Ideal candidates excel in complex operational environments, bring strong leadership experience, and thrive in roles where precision, accountability, and collaboration matter. Occasional evening or weekend availability may be required. Join one of the nation's largest community-based blood centers and make an impact that truly saves lives. Please click here to view the full job description and apply.

Transfusion Medicine Quality Program Manager. ARUP Laboratories is seeking a Transfusion Medicine Quality Program Manager to lead and support quality, regulatory, and continuous improvement initiatives across ARUP's transfusion medicine programs, including Blood Donor Services, the hospital-based blood bank, and the Immunohematology Reference Laboratory. In partnership with medical directors, laboratory leadership, and corporate quality teams, this role is responsible for developing and maintaining a comprehensive quality management framework aligned with ARUP's Quality Management System. The Manager will oversee regulatory compliance, audit readiness, risk management, CAPA processes, and data-driven quality improvement efforts in a highly regulated environment. This position serves as a key liaison between ARUP Laboratories and University of Utah Health clinical partners and provides expert guidance on transfusion medicine quality, regulatory interpretation, and best practices. The role also supports standardization, change management, training, and quality-related reporting to leadership. Qualified candidates will have a bachelor's degree in Medical Laboratory Science, Clinical Laboratory Science, or a related scientific field; at least seven years of experience in transfusion medicine, blood banking, and/or donor services; and at least five years of experience in quality systems, regulatory compliance, and audit management. Knowledge of FDA, AABB, CAP, CLIA, ISO, and related standards is required. A master's degree and relevant certifications are preferred. Please click here to review the full job description and apply.

Business Development Manager. Gulf Coast Blood is seeking a dynamic Business Development Manager to help expand our impact across advanced therapies, research programs, and clinical services. In this role, you will drive business growth by identifying new opportunities, building strategic partnerships, and expanding relationships with hospitals, pharmaceutical companies, biotech firms, and research organizations. You will manage the full business development lifecycle—from prospecting and solution development to deal closure and ongoing account growth—while supporting innovative programs that help save and sustain lives. **Qualifications:** We are looking for a results-driven professional with experience in business development, sales, account management, or healthcare-related industries. **Advanced therapies or biotechnology background are strongly preferred!** The ideal candidate will have strong relationship-building, communication, and strategic thinking skills, with the ability to navigate complex client environments and identify growth opportunities. **Why join us?** We offer competitive compensation and benefits, career growth opportunities, and the chance to contribute to innovative therapies and services that make a meaningful difference in patient care throughout our community. If you're passionate about building partnerships and driving innovation, apply today!

Blood Bank Medical Laboratory Specialist (MLS/MLT). Gulf Coast Blood is seeking a dedicated Blood Bank Medical Laboratory Specialist (MLS/MLT) to join our East Texas team and support our lifesaving mission. In this role, you will perform specialized immunohematology and transfusion medicine testing, ensure accurate blood product processing and distribution, maintain regulatory compliance, and contribute to providing safe, high-quality blood products to patients throughout the region. You will work collaboratively with healthcare professionals while upholding AABB, FDA, and internal quality standards. **Qualifications:** We are seeking candidates with a current **MLS or MLT certification (ASCP or equivalent)** and experience in a clinical laboratory setting. Blood banking experience is preferred but not required. Strong attention to detail, critical thinking skills, and a commitment to quality

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POSITIONS (continued from page 14)

patient outcomes are essential. **Why join us?** We offer competitive compensation and benefits, opportunities for professional growth, and the chance to make a meaningful impact in the communities we serve. If you're passionate about laboratory science and helping save lives, we encourage you to apply today.

Medical Apheresis LVN. Gulf Coast Blood is seeking a dedicated **Medical Apheresis LVN** to support our mission of providing safe, high-quality blood components to hospitals and patients across the Texas Gulf Coast region. As an Apheresis Nurse, you will provide donor and patient care through apheresis and leukapheresis procedures. This role includes phlebotomy, peripheral IV and central line care, medication administration and monitoring the donors receiving mobilizing agents. The nurse will monitor patients throughout the procedure. The nurse ensures documentation meets regulatory standards and maintains compliance with AABB, FDA, FACT, and internal policies. **Qualifications:** We're looking for someone who has graduated from an accredited vocational or nursing program with a current LVN license. Request at least four (4) years of recent direct patient care experience, preferably in acute care with strong peripheral IV skills. Apheresis or dialysis experience is strongly preferred. Must hold BLS or ACLS certification and have reliable transportation for travel to donor and group sites. **Why join us?** We offer a **competitive compensation and benefits package**, free parking at the Texas Medical Center, opportunities for career growth, and a supportive workplace focused on excellence and mission. Apply Today!

HR Director. At Stanford Blood Center (SBC), how we treat our people is just as important as the lifesaving work we do. We're looking for an **HR Director** who shares that belief — and brings the experience, courage, and heart to help us live it every day. This is a strategic partnership. You'll work closely with our VP and senior leadership to advance SBC's people agenda, navigate a mission-driven organization within a large health system, and be a trusted resource for managers and staff alike. You bring the same resourcefulness to HR that SBC brings to its mission: finding a way forward. What we're looking for: A leader with presence and warmth in equal measure — someone people at every level feel comfortable approaching. A strategic thinker who brings an HR lens to organizational conversations, not just day-to-day problem solving. Someone who has navigated tough situations and comes out with relationships and trust intact. Solid experience with California employment law and labor/union relations. Background in high volume, people-intensive environments: healthcare, retail, or similar. Ten to 15 years of progressive HR experience with a track record of follow-through. Requirements: Bachelor's degree in Human Resources, Business Administration, or relevant field. Minimum 10 years of progressive HR experience with increasing responsibility. We're a close-knit team doing work that saves lives. If you're energized by meaningful work and want an HR role where you can make a genuine difference, we'd love to hear from you. Click here to apply. Questions? Contact Miriam Garrido, Talent Acquisition Consultant Miriam1@stanford.edu.

Regional Director (Tallahassee, FL). OneBlood is seeking an experienced Regional Director to oversee donor blood collection operations and lead regional teams in support of its lifesaving mission in the Panhandle. This leadership role is responsible for driving operational excellence, ensuring compliance with regulatory and accreditation standards, and achieving donor recruitment and collection goals across the region. Candidates should possess strong leadership, analytical, communication, and team management skills, along with the ability to build collaborative relationships and improve operational performance. A bachelor's degree and significant management experience in healthcare, blood banking, or a related field are preferred. Travel within the region may be required. This position is based in Tallahassee, Florida, and offers the opportunity to join a mission-based organization dedicated to maintaining a safe and reliable blood supply for local communities. Competitive compensation and a comprehensive benefits package offered. Apply at **OneBlood Careers**.

Director of Mobile Operations (Austin, TX). Oversee the management of all mobile and support operations, which includes but is not limited to medical history, donor eligibility, automated component collection and whole blood collection processes, as well as staff scheduling, quality control, and education and training in conjunction with the Director, Fixed Site Operations. Establish and maintain quality practices while continually seeking to improve and expand upon performance and knowledge for self and staff. A minimum of five (5) years management experience, including strategic planning, or a minimum of three (3) years blood center senior management experience is required; blood center or relevant industry-related experience may be substituted for some management experience. Blood center experience in donor collection operations management strongly preferred, particularly experience with FDA/ AABB and/ or Industry audits. College degree and/or RN license preferred. Either of these may substitute up to two (2) years management experience. Must be at least 21 years old, possess a valid driver's license, and be able to provide a copy of an acceptable driving record and proof of liability insurance. Ability to maintain a flexible schedule, including travel, evenings, weekends, and on-call responsibilities. Click here to apply.