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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2018 #40 **November 30, 2018**

INSIDE:

FDA Revising System for Medical Device Clearances

The U.S. Food and Drug Administration (FDA) announced changes to "modernize" the agency's 510(k) clearance pathway for low- to moderate-risk medical devices. The proposed framework will continue to prioritize safety for patients and devices, while embracing the rapid pace that technology changes.

"We believe that where appropriate, new medical devices that come to market under the 510(k) pathway should either account for advances in technology or demonstrate that they meet more modern safety and performance criteria," said FDA Commissioner Scott Gottlieb, MD and Center for Devices and Radiological Health Director (CDRH) Jeff Shuren, MD in a joint statement issued on November 26th. We want to make sure that new devices are evaluated against advances in technology that can improve patient safety and performance. In making these reviews, where appropriate, we want to rely on modern safety and performance criteria. At the same time, we're going to pursue additional actions that will allow the FDA to retire outdated predicates, especially in cases where we've seen safer or more effective technology emerge."

According to the *Wall Street Journal*, "[b]y early 2019, the FDA plans to issue a guidance to the industry that will alternatively allow certain well-understood types of devices 'to rely on objective safety and performance criteria' to get cleared onto the U.S. market… Some of the comparison products—known as 'predicate devices'—were approved soon after the agency began regulating medical devices in 1976. More than 80 percent of medical devices in the U.S. have since gained market entry under this standard."

The FDA recently faced criticism in a published article and blog posts from the International Consortium of Investigative Journalists (ICIJ) that questioned the safety of medical devices and the regulatory environment governing manufacturers worldwide. The article suggests that patients are subjected to injury and death due to medical devices that lack appropriate vetting in the form of human testing, even though they meet the current regulations of the governing bodies in charge of oversight.

"Governments in dozens of countries in Africa, Asia and South America don't regulate medical devices at all, instead placing their trust in European authorities or in the [FDA], which is generally considered to provide more robust oversight than any other health agency in the world," states the article. "Yet even that oversight is lacking, with complex devices approved too quickly by American authorities, and troublesome ones not pulled from hospital shelves fast enough, patient advocates

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FDA Revises System for Medical Device Clearances (continued from page 1)

and health experts say. The FDA is now exploring further loosening its rules in order to get some new devices onto the market with substantially less testing than before, a move seen as part of a broader effort to bolster the U.S. as a competitor to Europe, which offers manufacturers an even faster path to approval of new products."

Commissioner Gottlieb explained that FDA's new emphasis on modernizing the 510(k) pathway will not sacrifice safety or attempt to clear devices based on outdated standards. He sees the changes as a way of holding manufacturers accountable for continuing to innovate without compromising patient or product safety. "Our efforts at 510(k) modernization—and our efforts to promote reliance on more up-to-date predicates—will also include a closer examination of devices with documented safety issues that were cleared based on older predicates," said Commissioner Gottlieb in a statement released by the agency on November 27th. We want to push product developers to embrace newer predicates with improvements in technology so that patients and providers will continually have access to safer and more effective devices."

The Advanced Medical Technology Association (AdvaMed) issued a statement in response to ICIJ, "instead of a comprehensive look at both the challenges and the achievements of an industry that touches almost every human life, these stories counterfeit the life-changing and life-saving solutions delivered to billions of people worldwide. We should never discount any patient's experience. But by magnifying the stories of only a few individuals, we overlook the overwhelmingly positive experiences of millions of others. We take seriously all reports of patient impact, and though the medical community can never completely eliminate risk, we always strive to improve our technologies and care delivery." The complete AdvaMed statement is available here.

(Sources: *Wall Street Journal*, FDA Is Revamping Clearance Procedures for Medical Devices, 11/26/18; FDA & CDRH Joint Statement, 11/26/18; Scott Gottlieb, MD Statement, 11/27/18; ICIJ Implant Files, Medical devices harm patients worldwide as governments fail on safety, 11/25/18; AdvaMed Statement, 11/25/18)

Upcoming ABC Webinars – Don't Miss Out!

- **SMT Journal Club** – December 12th at 12 pm. EST. Additional details forthcoming!

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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the healthcare 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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Pathogen Reduction Technology Workshop Hosted by FDA

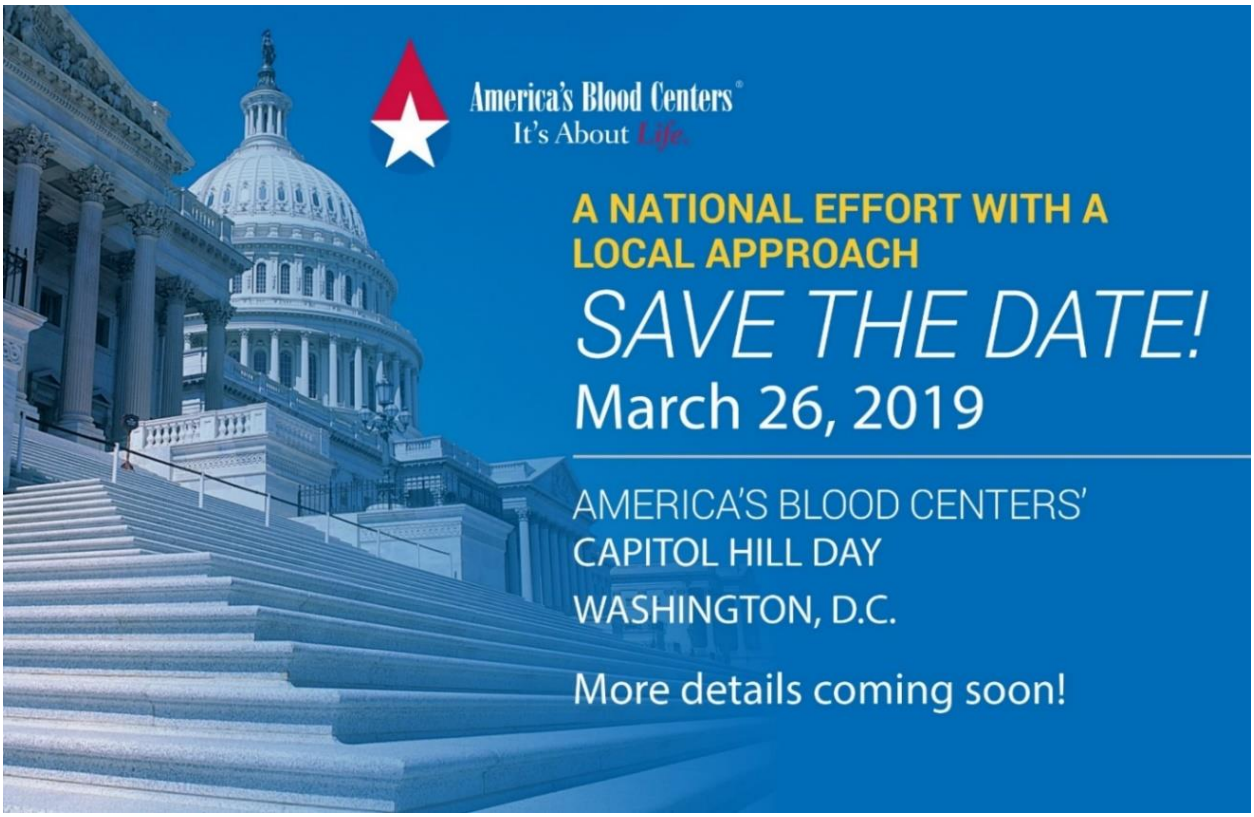
Pathogen reduction technologies (PRT) have long been viewed as a potential safety improvement for their ability to inactivate bacteria and viruses in blood products. Concerns remain over the costs associated with the implementation of PRT systems, reimbursement for blood products having undergone PRT, and whether such blood products meet regulatory safety requirements following pathogen reduction.

The U.S. Food and Drug Administration (FDA) held a public workshop entitled "Pathogen Reduction Technologies for Blood Safety" on November 29th – 30th. The workshop included regulatory, blood center, hospital, manufacturers, researchers, and academic stakeholders and afforded them the opportunity to discuss the past, present, and future states of PRT. "FDA is committed to moving pathogen reduction technology forward and moving the needle forward will require collaboration among everyone here," said Office of Blood Research and Review Director Nicole Verdun, MD as the workshop concluded. "This truly is a partnership. We do look forward to working with you. Come to us early and come to us often. We are here for you."

The workshop featured six sessions addressing:

- blood-borne infectious agents and their impact on blood safety;
- implementation of PRT for blood products;
- PRT for whole blood and red blood cells
- emerging innovations relevant to PRT
- funding opportunities for future pathogen technology research; and
- summary presentations.

The *ABC Newsletter* will have more coverage on the workshop in next week's issue.



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INSIDE ABC

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

ABC *Awards of Excellence* Call for Nominations Deadline Extended

ABC members are encouraged to nominate blood donation sponsors, corporations, and advocates for the 22nd Annual *Awards of Excellence*. This year's ceremony on Monday, March 25th will be in Washington, D.C. during ABC's 57th Annual Meeting at the Ritz-Carlton (Pentagon City). Nominations are currently open until Wednesday, December 12th. Additional details are available in MCN 18-044. The online submission form is available here. ABC members are permitted to submit up to three nominations per category. The following awards will be presented during the awards ceremony and are currently open for nominations:

- ABC Outstanding Blood Drive of the Year
- Outstanding Public Relations Campaign
- Corporation of the Year Award
- Larry Frederick Award (jointly presented by ABC and ADRP)
- William Coenen President's Award
- Blood Community Advocate of the Year Award
- Thomas F. Zuck Lifetime Achievement Award

A complete description of each award is available here. Please direct any questions about nominations or the awards ceremony to Leslie Maundy.

(Source: MCN 18-044)

December SMT Journal Club Webinar Articles Announced

The ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar on December 12th at noon eastern will feature three articles:

- The effect of red-blood-cell transfusion on fatigue in hospitalized patients with anaemia (*Vox Sanguinis*);

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- Impact of changes to donor hemoglobin criteria on the rate of donor deferral (*Transfusion*); and
- Vox Sanguinis International Forum on the use of prehospital blood products and pharmaceuticals in the treatment of patients with traumatic haemorrhage (*Vox Sanguinis*).

Additional details including registration information is forthcoming.

RESEARCH IN BRIEF

Costs for immunoglobulin vs. apheresis treatment of Guillain-Barre syndrome (GBS). The first line therapy for GBS can be either intravenous immunoglobulin (IgIV) or therapeutic plasma exchange (TPE), with both efficacy and safety believed to be comparable. IgIV has often been chosen because it is logistically simpler, and less invasive. Indian investigators have analyzed the relative costs of the two approaches and find that TPE is less expensive. "Out of pocket" costs for IgIV therapy were $4,298 compared to $2,040.50 for TPE. Whether this relationship holds in the U.S. is not clear, but a similar study from 2011 found a similar ratio of direct costs ($10,329.85 vs. $4,238.16).

Citations: Maheshwari, A., Sharma, R.R., Prinja, S. *et al*. Cost-minimization analysis in the Indian subcontinent for treating Guillain Barre Syndrome patients with therapeutic plasma exchange as compared to intravenous immunoglobulin. *J. Clin. Apheresis*. 2018.

Winters, J.L., Brown, D., Hazard, E. *et al*. Cost-minimization analysis of the direct costs of TPE and IVIg in the treatment of Guillain-Barré syndrome. *BMC Health Services Res*. 2018.

Can we predict the transmissibility of emerging viral zoonoses? In the past century, more than 200 viruses from more than 20 families have been recognized as definite or possible human pathogens. Zoonotic organisms have animal reservoirs that can spill over into human populations to cause epidemics that are associated with morbidity, mortality, and resource consumption. West Nile, chikungunya, Zika, and SARS are zoonotic viruses that have recently impacted transfusion medicine and HIV is the paradigm. Predicting which viruses will bridge from their reservoir(s) into humans would allow a more proactive approach to public health broadly and by the blood community as well. University of Georgia investigators have used statistical analysis of the characteristics of 224 suspected human viruses applied to viruses of undocumented spillover capacity to predict human transmissibility. For example, they find that infection of non-human primates, lack of a viral lipid envelope and detection in the human respiratory or central nervous system, predict human transmissibility. Using machine learning to apply these findings, the investigators suggest they will be able to prioritize viruses for preparedness activities. They do not provide any analysis of the potential for blood-borne spread of these agents.

Citation: Walker, J.W., Han, B.A., Ott, I.M., Drake, J.M. Transmissibility of emerging viral zoonoses. *PLoS One*. 2018.

Restrictive vs. liberal red blood cell (RBC) transfusion in pediatric burn patients. Many subgroups of patients are poorly represented in the major trials assessing the relative clinical values of varying triggers for RBC transfusion. In an observational, before and after study of a change in transfusion triggers from 10 g/dL hemoglobin to 7 among pediatric burn victims, transfusion rates and volumes were decreased, and mortality lowered at the lower threshold. Sepsis rates were unaffected. The authors conclude that "more restrictive transfusion protocols are safe and efficacious in pediatric burn patients. The associated reduction of transfused blood may lessen medical risks of blood transfusion and lower economic burden."

Citation: Voigt, C.D., Hundeshagen, G., Malagaris, I. *et al*. Effects of a restrictive blood transfusion protocol on acute pediatric burn care: Transfusion threshold in pediatric burns. *J. Trauma and Acute Care Surg*. 2018. Doi:10.1097/TA.0000000000002068.

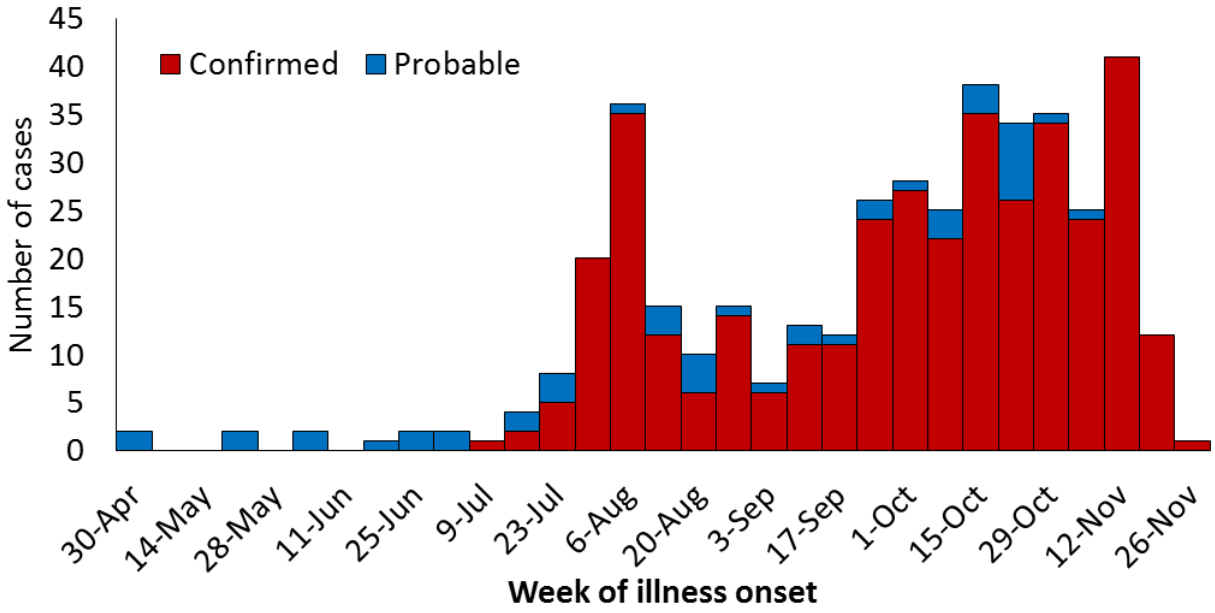
INFECTIOUS DISEASE UPDATES

EBOLA

The Ebola outbreak in the Democratic Republic of Congo (DRC) is ongoing. The World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) have not classified the affected areas as having "widespread transmission of Ebola virus," which would trigger donor interventions in the U.S. The U.S. Food and Drug Administration (FDA) guidance requires that "in the event that one or more countries is classified by CDC as having widespread transmission of Ebola virus, your donor history questionnaire (DHQ), including your full-length and abbreviated DHQ, and accompanying materials, must incorporate elements to assess prospective donors for symptoms of recent or current illness with Ebola virus infection or disease, and travel to, or residence in, an area endemic for Ebola virus in accordance with 21 CFR 630.10(e)(2)."

As of November 27th, there were 422 reports (375 confirmed and 47 probable) in the DRC provinces of North Kivu and Ituri.

Confirmed and probable Ebola virus disease cases by week of illness onset, data as of November 27th



**Data in recent weeks are subject to delays in case confirmation and reporting, as well as ongoing data cleaning. Trends during this period should be interpreted cautiously.*

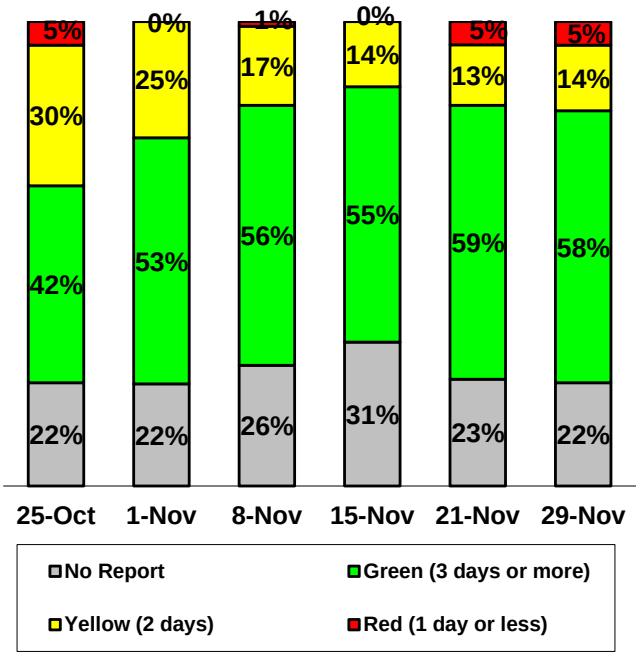
(Ebola virus disease – Democratic Republic of the Congo, 11/29/18)

ABC Calendar of Events

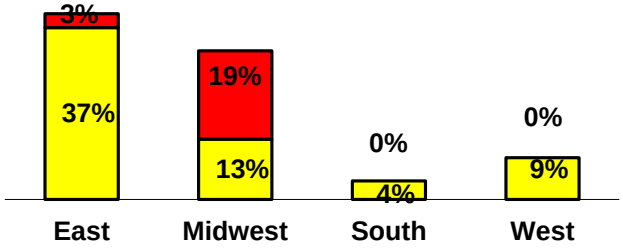
ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The calendar of events includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!

STOPLIGHT®: Status of America's Blood Centers' Blood Supply

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, November 29, 2018



Percent of Total ABC Blood Supply Contributed by Each Region
East: 20%; Midwest: 25%; South: 24%; West: 31%

Daily updates are available at:
www.AmericasBlood.org

WORD IN WASHINGTON

Sen. Chuck Grassley (R-Iowa) chair of the Senate Judiciary Committee sent a letter to the U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb, MD expressing concern over the Department of Health and Human Services (HHS) Office of the Inspector General's (OIG) Report revealing potential vulnerabilities in medical device cybersecurity. "Cyber risks to the health care sector are real, ongoing, and all reasonable efforts must be taken to combat them to protect patients," wrote Sen. Grassley in the letter. "While I applaud the proactive steps the FDA took during the course of the drafting of the report to improve medical device cybersecurity, I am writing to ensure that this progress continues and that any remaining deficiencies are fixed. The report highlighted some very important issues where the FDA has room for improvement. Specifically, the OIG stated that the FDA's 'plans and processes were deficient in addressing medical device cybersecurity compromises.'" The letter asked the agency to provide written response addressing the following:

- How the FDA implemented fixes sufficient to close the recommendations;
- Has the FDA assessed whether foreign governments or other entities are threats to post market medical device cybersecurity? If so, which governments or entities has FDA identified?
- Explain how the FDA is using MDR data. Is this data being used to improve cybersecurity for medical devices? Can the MDR system be utilized to report cybersecurity concerns?

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WORD IN WASHINGTON (continued from page 7)

- Provide a briefing to my Committee staff regarding cyber security threats to medical devices and the steps FDA is taking to combat them.

(Source: Senate Judiciary Committee Letter 11/9/18)

MEMBER NEWS

Northern California Community Blood Bank CEO Kate Witthaus recently traveled to Paradise, Calif. to aid in the search and recovery efforts following the aftermath of the Camp Fire. She and fellow members of the Humboldt County Sherriff's Posse Search and Rescue Team spent most of Thanksgiving week clearing hazards and searching through burned structures. *ABC Newsletter* Issue #39 on November 16th covered the impact of the fire on ABC members in California and how individuals can contribute to relief efforts.

Kate Witthaus marks a vehicle clear. Photo courtesy of Mark McKenna.

Kate Witthaus points to an area inside of a house that both burned and was damage by a falling tree. Photo courtesy of Mark McKenna.

(Source: Northern California Community Blood Bank News Release, 11/28/18)

LifeStream and OneLegacy announced a partnership this week to raise awareness of both blood and organ donation. "Our partnership with OneLegacy allows LifeStream to highlight the need for blood donation to support the large amount of blood used during organ transplantation," said Rick Axelrod, MD, president and CEO of LifeStream in a joint news release. "We are excited about the opportunity to partner with OneLegacy to create new blood drives in the Southern California community and increase the number of blood donations provided to LifeStream Blood Bank to support our mission for saving lives." OneLegacy is the biggest organ, eye, and tissue recovery organization in the U.S. As part of the agreement, LifeStream will receive a three-year grant from OneLegacy and each organization will support the other through co-branding and co-marketing efforts. "Central to our community-outreach and public-education commitment is engaging local communities and securing meaningful partnerships where everyone wins," said One-Legacy CEO Thomas Mone in the news release. "To fulfill patient need, LifeStream must collect 500 blood donations daily. At the same time, more than 22,000 California residents are waiting to receive lifesaving hearts, livers, lungs, kidneys and other organs; but there are simply not enough donors to meet the growing need. Now LifeStream and OneLegacy will partner together to enhance the blood donor registration process

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MEMBER NEWS (continued from page 8)

so that each time someone gives blood they also have the opportunity to register as an organ, eye and tissue donor."

(Source: LifeStream and OneLegacy Joint News Release, 11/29/18)

New York Blood Center (NYBC) is partnering with ERYTECH to provide red blood cells (RBC) for ERYTECH's development of innovative cancer therapies according to a recent news release. "NYBC's blood collection and processing scale in the Northeast United States will strengthen our RBC supply to be utilized at our New Jersey manufacturing site which is currently under construction," said ERYTECH CEO Gil Beyen in the news release. "We also look forward to working with NYBC to advance our preclinical platform based on our proprietary ERYCAPS® technology." The partnership will further ERYTECH's preclinical activities in the U.S. "We are excited to partner with ERYTECH to advance the development of vital and novel cancer treatments," said NYBC Chief Medical and Scientific Officer Beth Shaz, MD in the news release. "Our state-of-the-art infrastructure and expertise in blood services and research make us uniquely suited to support clinical and preclinical activities with both products and laboratory services."

(Source: ERYTECH News Release 11/15/18)

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail (lmaundy@americasblood.org) or by fax to (202) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2018

Dec. 6. **FDA's Oncology Center of Excellence Product Development in Hemophilia Public Workshop, Silver Spring, Md.** More details available here.

2019

Feb. 4-5. **15th Annual FDA and the Changing Paradigm for HCT/P Regulation, Washington, D.C.** More details available here.

March 6-7. **IPFA 4th Asia Workshop on Plasma Quality and Supply, Hanoi, Vietnam.** More details available here.

March 22. **2019 International Blood Safety Forum, Washington, D.C.** More details coming soon.

March 23-26. **2019 ABC Annual Meeting, Washington, D.C.** More details coming soon.

May 14-16. **ADRP Annual Conference, Indianapolis, Ind.** More details available here.

May 22-23. **IPFA/PEI 26th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens", Krakow, Poland.** More details available here.

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 899-2621; e-mail: lmaundy@americasblood.org.

POSITIONS

Director of Quality Assurance. Kentucky Blood Center (Lexington, Kentucky), is seeking a Director of Quality Assurance to support the oversight of our compliance program. This critical management position reports to the VP, Quality and Regulatory Affairs, and provides supervision of the QA department. Responsibilities include: Adherence to regulatory and accrediting organization standards; Compliance with applicable AABB, FDA, CLIA, State, OSHA, EU, Short-Supply Agreement requirements; Working to maintain a safe blood supply, and ensuring the safety of KBC stakeholders; Standard Operating Procedures (SOP's); Auditing – development and execution of methods and systems; Occurrence management; Regulatory investigations; Training documentation; Team leadership and process management; Strong communication and guidance at all organizational levels. Requirements: MT (ASCP), with five years' experience in related quality assurance management background. Microsoft Office skills; knowledge of general compliance and regulatory practices, with occasional travel. Supervisory experience in coaching and leading teams is preferred. Blood banking knowledge highly desired. Competitive salary, benefits including health/dental/vision/life/disability; PTO/holidays, EAP, 401(k) plan. Relocation provided. For more information or to apply online, visit www.kybloodcenter.org. Drug-free and EOE/AAP.

Technical Director. Located in the heart of the magnificent coastal redwoods of Northern California, The Northern California Community Blood Bank is a non-profit blood bank serving Humboldt and Del Norte Counties. The Northern California Community Blood Bank has an immediate opening for a Technical Director. Under the direction of the Administrator and Medical Director, the Technical Director has overall 24-hour responsibility for the Laboratory and all activities related to processing, testing, storage, transportation, and other handling of blood and blood products. The Technical Director oversees component production, inventory, product distribution, reference immunohematological testing, and compliance with regulatory and standard-setting agencies. Experience, Education and Licensure: Four-year degree from an accredited college or university in science, medical technology or a related field. Valid current CA license as a Clinical Laboratory Scientist. Experience as a technologist performing high complexity testing in a clinical laboratory and familiarity with standard laboratory methods and techniques. Demonstrated ability to perform standardized routine testing, specialized testing in blood donor processing, and immunohematology is preferred. Must meet the CLIA defined General supervisor qualifications (42 CFR 493.1461). To Apply: Contact Kate Witthaus, Northern California Community Blood Bank, 2524 Harrison Avenue, Eureka, CA 95501, (707) 443-8004.

Director, Donor Recruitment. LifeStream (San Bernardino, CA) located 60 miles east of Los Angeles and 50 miles west of Palm Springs seeks qualified applicants for its Director, Donor Recruitment position. This position is responsible for developing and directing the blood center's donor recruitment department/plans to achieve collection goals. Scope of responsibilities includes oversight of all mobile and fixed site recruitment. Requires the ability to oversee the daily operations, as well as strategically work toward the long-term goals. Must be able to facilitate all operational activities related to recruitment of donors and management of recruitment staff within the expected budget guidelines. Must be an effective leader and have the ability to adapt to change. Excellent salary (with bonus program) and benefits including relocation package. Bachelor's degree required. Demonstrated experience in sales/territory management skills, strong leadership and team building skills, excellent verbal and written communication and public speaking skills and computer literacy. Prior blood center experience preferred. Minimum three years management experience. Successful candidate must demonstrate ability to work closely with Marketing and Collections Managers/Directors to facilitate efficient and effective blood drives. This position reports to the Vice President/Operations. LifeStream is an Equal Opportunity Employer, M/F/D/V. Apply online at: https://www.lstream.org/careers/

Vice President of Biologics & Supply Chain. OneBlood, a not-for-profit community asset responsible for providing safe, available and affordable blood to more than 200 hospital partners and their patients, is currently searching for a strong leader to join the organization as Vice President of Biologics & Supply Chain in the St. Petersburg, Florida area. This position will provide operational and technical leadership for Biologics Operations by working with the management team to develop opportunities and implement short and long-range goals and strategies, plans and policies. Qualified candidates will possess a bachelor's degree from an accredited university with a master's degree preferred. A minimum of fifteen (15) years of progressively responsible experience in various operational, management and leadership roles including a minimum of five (5) years supply chain experience and a minimum of eight (8) to ten (10) years of progressively responsible management experience or an equivalent combination of education, certification, training and/or experience. A State of Florida Supervisor license in Immunohematology or Blood Banking and Black Belt Certification are preferred. Consider bringing your leadership, vision and expertise to OneBlood and join our mission to save lives. Interested candidates should apply online at www.oneblood.org/careers.