America's Blood Centers®
It's About Life.

ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

2019 #31 **September 13, 2019**

INSIDE:

DoD Announces FDA Variance for Use of Cold-stored Platelets

The U.S. Food and Drug Administration (FDA) granted an Exception and Alternative Procedure, or variance, to 21 CFR 606.65(e) and 610.53(c) to store apheresis platelet products at 1 to 6 °C for up to 14 days without agitation. The cold-stored platelet products will be used to treat actively bleeding patients when conventional platelet products are not available or using them is not practical.

The Department of Defense (DoD) announced the variance, which was requested by the U.S. Army Blood Program according to the news release, for use of cold-stored platelets "in theater" a term synonymous for an area of military operations. "The FDA granting of this platelet variance will directly increase survival of our service members on the battlefield," said Acting Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight in the Office of the Assistant Secretary of Defense for Health Affairs Terry Rauch, PhD, in the release. "The close working relationship between our DoD teams and the FDA was critical to providing this capability to the Department and we are grateful for the tremendous support we've received from the FDA."

The variance is the latest instance of collaboration between the FDA and DoD after the agencies agreed to a memorandum of understanding (MOU) in 2018 for development and assessment of medical products. "Issuance of this variance is a critical first step to deliver platelets to combat zones," said Principal Assistant for Acquisition, U.S. Army Medical Research and Development Command, Army Futures Command Dawn Rosarius in the news release. "Ultimately, wider availability of platelets will decrease the leading cause of preventable death on the battlefield—life-threatening bleeding due to trauma. In addition, during multi-domain operations of the future, cold-stored platelets could play a critical role in stabilizing casualties if evacuation is delayed. Our continuing work to develop a product for licensure is the crucial next step to achieve this goal."

The MOU was designed with both safety of blood products and military personnel in mind as the agencies worked closely together to advance the development and availability of lifesaving medical products. "Ensuring our Nation's warfighters have safe and effective medical products is a top priority for the agency," added FDA Deputy Commissioner for Policy, Legislation, and International Affairs Anna Abram. "This decision will support access to platelet products in the battlefield where their use is most needed. The FDA remains deeply committed to helping ensure that these potentially life-saving medical products are made available in the most expeditious, safe, and effective manner possible."

(continued on page 2)

DoD Announces FDA Variance (continued from page 1)

Currently, DoD medical personnel treat severely wounded soldiers with platelets stored at room temperature, whose 5- to 7-day shelf life constrains their use in theater.

(Source: DoD News Release, 8/29/19)

GLOBAL NEWS

The Irish Blood Transfusion Service (IBTS) is removing the lifetime blood donation deferral, that had been in place due to concerns over Variant Creutzfeldt Jakob disease (vCJD), of individuals who have resided in the United Kingdom (UK) for one or more years from January 1980 through December 1996. "The permanent deferral for one-year residency in the UK was introduced in November 2004," said Chief Executive Officer Andy Kelly in the IBTS news release. "This resulted in the loss of approximately 10,000 donors and has been a source of annoyance to those donors that they have not been able to donate since that date. The IBTS has to protect the patient who receives blood and this step was necessary at that time. The evidence now available allows the IBTS to overturn this deferral and reinstate those donors. The IBTS would like to welcome back donors who were previously ineligible to donate because of a risk of vCJD. Before attending a blood donation clinic, we recommend that you visit the FAQ page on www.giveblood.ie to view our current eligibility criteria."

According to IBTS Medical and Scientific Director Professor Stephen Field, there have been four cases of transfusion transmitted vCJD in the UK. He stated in the news release, "[t]he blood transfused to the four patients who developed vCJD was not leucodepleted. i.e. the white cells had not been removed prior to transfusion. The removal of white cells from blood before transfusion to a patient was a measure introduced by the IBTS in 1999 to reduce the risk of transmitting vCJD by blood transfusion. No cases of transfusion transmitted vCJD have occurred worldwide with blood that was leucodepleted. Blood transfusion cannot be guaranteed to be 100 percent safe, there will always be some risk associated with transfusion, but the risk of transmitting vCJD by blood transfusion is now considered to be remote."

Permanent deferrals will remain in place for some individuals including those:

- with a family history of Creutzfeldt Jakob disease (CJD);
- who received intravenous immunoglobulin in the UK after January 1st, 1980;
- that underwent a plasma exchange procedure in or out of the Republic of Ireland;
- that received a blood transfusion outside of the Republic of Ireland; or
- that received a blood transfusion in the Republic of Ireland on or after January 1st, 1980.

(Source: IBTS News Release, 9/9/19)

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail.

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.

America's Blood Centers
Chief Executive Officer: Kate Fry
Chief Medical Officer: Rita Reik
Editor: Mack Benton
Subscriptions Manager: Leslie Maundy
Annual Subscription Rate: $390

Send subscription queries to
lmaundy@americasblood.org
America's Blood Centers
1717 K St. NW, Suite 900, Washington, DC 20006
Phone: (202) 393-5725
Send news tips to newsletter@americasblood.org.

Immune Thrombocytopenia and Appropriate Use of Intravenous Immunoglobulin

Contributed by Richard Gammon, MD, Medical Director at OneBlood

Please note: America's Blood Centers welcomes regular contributions or briefs from guest authors for scientific/medical peer-reviewed published papers. The views/comments expressed in submitted articles from external parties are those of the author(s) and are not to be interpreted as the viewpoint of America's Blood Centers. If you are interested in contributing an article for potential publication please contact us here.

Immune thrombocytopenia (ITP) is an autoimmune disease characterized by isolated thrombocytopenia. Patients may be asymptomatic or present with mild mucocutaneous to life-threatening bleeding. Only five percent of patients with ITP present with severe bleeding. Close to 15 percent of patients develop bleeding leading to hospital admission within five years after diagnosis.

ITP can be a primary condition or caused by other diseases. Its incidence ranges from two to four cases per 100,000 person-years, with two peaks: one between 20 and 30 years of age with a slight female predominance and another larger one after 60 years of age with equal sex distribution. Chronic ITP develops in up to 70 percent of adults with this condition.

The pathophysiology of ITP is complex and is not completely understood. The traditional concept is that antibody-coated platelets are prematurely destroyed in the spleen, liver, or both. Autoantibodies can also induce destruction of platelets as well as inhibit megakaryocyte function. However, antiplatelet antibodies are not detected in up to 50 percent of patients which raises the possibility of alternative mechanisms of platelet destruction.

ITP is defined as a platelet count below 100,000/uL in patients where other causes of thrombocytopenia have been ruled out. A clinical history, including assessment of the use of drugs, physical examination, and complete blood count, is important to rule out other causes of thrombocytopenia and to evaluate for secondary causes. Examination of the peripheral-blood smear shows reduced numbers of platelets. No diagnostic test for ITP exists.

The current goals of treatment are to stop active bleeding, while reducing the risk of future bleeding. Specific measures include the withdrawal of anticoagulant and antiplatelet agents and treatment with platelet transfusions, glucocorticoids, intravenous immunoglobulin (IVIG), or all of these measures. Data from randomized trials are lacking, and the use of these treatments is supported generally by small observational studies. Platelet transfusions can help to limit bleeding, but they have only short-term transient effects (for a few hours), and therefore the patient may need to undergo infusions repeatedly. They should not be used alone but rather in combination with IVIG and glucocorticoids.

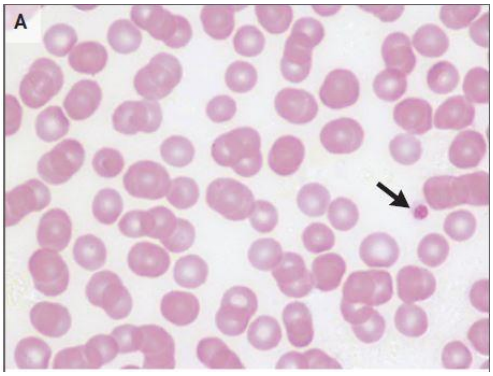

Photo courtesy of the New England Journal of Medicine: Thrombocytopenia (only one platelet- arrow) and normal erythrocytes in a peripheral-blood smear.

IVIG raises the platelet count within one to four days in 80 percent of patients, but effects last only one to two weeks. IVIG is indicated in patients with serious bleeding and with very low platelet counts (<10,000/uL), who are at increased risk for serious bleeding. Concomitant use of glucocorticoids with IVIG can be associated with a more sustained response.

A recent Canadian audit of IVIG requests found a lack of compliance with provincial requirements and

(continued on page 4)

Immune Thrombocytopenia (continued from page 3)

inadequate documentation of efficacy which led the auditor to conclude that its use was broadly inappropriate for all treated diseases. In response, a retrospective review of patients with ITP who received IVIG at a single institution over a one-year period took place. Forty patients received IVIG for ITP for a total of 76 infusions, 22 (55 percent) of patients were female. The most common indications for IVIG within currently accepted guidelines were: active bleeding 13 (17 percent), pre-operative or antepartum care 22 (29 percent), contraindication to corticosteroids 8 (11 percent), and requirement for antithrombotic or myelosuppressive therapy 5 (7 percent). Five patients (8 percent) fell outside of guidelines and included use of IVIG as a diagnostic challenge where the etiology of thrombocytopenia was unclear. The authors conclude that at their institution, use of IVIG for ITP was generally appropriate and carefully considered even in cases that did not meet provincial recommendations. They also note that detailed utilization/knowledge data inquiries were required to develop tools and policies to enhance appropriate IVIG use.

Second-line therapies include thrombopoietin-receptor agonists and immunomodulators. In the absence of randomized trials directly comparing these therapies or of biomarkers to guide the choice of medication, treatment decisions are based on clinical judgement. Splenectomy is usually limited to patients who are refractory to other treatments and in whom at least a year has passed since diagnosis.

Guidelines for the treatment of patients with ITP were published by an international consensus group in 2010 and by the American Society of Hematology in 2011. However, both sets of guidelines antedated many of the current studies that are currently under revision.

Citations: Cooper, N., Ghanima, W. Immune Thrombocytopenia. *N Engl J Med.* 2019. Doi: 10.1056/NEJMcp1810479.

Liu, J., Pavenski, K., Sholzberg, M. Appropriateness of intravenous immunoglobulin use in immune thrombocytopenia (ITP): A Canadian centre deep dive audit. *Transfusion and Apheresis Science*. 2019.

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) held a Patient Engagement Advisory Committee meeting on September 10th that addressed and made recommendations regarding cybersecurity in medical devices. The public meeting included a presentation from Acting FDA Commissioner Norman Sharpless, MD and roundtable discussions on theoretical scenarios of cybersecurity safety concerns that are facing the medical device industry. According to a summary report published by CDRH, "[o]verall, the committee generally believes that there is not a blanket approach that would work for all patients. However, they highlighted three strategic elements that FDA and industry should consider in conveying cybersecurity risks to patients when the probability of exploitation is not known:

- explaining the unknown factor;
- FDA and industry understanding the fear of the potential unknown and having those concerns addressed and factored in well in advance of the preapproval process is important to patients and consumers; and
- a balanced discussion between risk and benefits, highlighting the benefits especially if it is a life-saving device. The committee also suggested that there is a need to use all mediums of communication as it pertains to communicating cybersecurity risk and the 'particulars' matter regarding certain audiences or devices.

(continued on page 5)

REGULATORY NEWS (continued from page 4)

The Committee believes medical device cybersecurity is a matter of homeland and national security." A complete meeting report is available along with meeting materials.

(Source: CDRH Announcement, 9/11/19)

U.S. Secretary of the Department of Health and Human Services (HHS) Alex Azar will soon visit the Democratic Republic of the Congo, Rwanda, and Uganda with a delegation of members of the Administration. They will meet with members of the World Health Organization to assess and show America's commitment to continue assisting with the ongoing Ebola outbreak, currently the second deadliest ever recorded according to a HHS news release. The delegation will include:

- Robert Redfield, MD, Director of the Centers for Disease Control and Prevention (CDC);
- Anthony S. Fauci, MD, Director of the National Institute of Allergy and Infectious Diseases (NIAID);
- Garrett Grigsby, Director of the HHS Office of Global Affairs;
- Tim Ziemer, Senior Deputy Assistant Administrator of United States Agency for International Development (USAID); and
- staff from the President's National Security Council.

The U.S. recently announced that it would:

- fund another year of Ebola vaccine manufacturing;
- send CDC staff to impacted areas; and
- continue to support ongoing clinical trials.

(Source: HHS News Release, 9/9/19)

BRIEFLY NOTED

A circuit court judge recently ruled that CSL Plasma, Inc. must permit donors suffering from severe anxiety to bring their service dogs with them to donate. Judge Thomas Ambro indicated that the plasma center's policy that prohibited service dogs in some instances violated the Americans with Disability Act, after the center prevented George Matheis and his service dog Odin from donating due to the potential for individuals with extreme anxiety to pose a safety risk or cause a disturbance. The latest circuit court decision comes after Tenth Circuit Court ruled that plasma centers are service establishments that are subject to the ADA statute, while the Fifth Circuit Court ruled that plasma centers are not subject to the statute. Prior to the latest ruling, CSL Plasma told Mr. Matheis that he could not bring Odin to donate, nor donate without him unless a doctor signed off on him donating alone.

(Source: *Bloomberg,* Plasma Center Must Let Donor With PTSD Bring in Service Dog, 8/30/19)

(continued on page 6)

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste and published after editorial review. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 899-2621. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

BRIEFLY NOTED (continued from page 5)

The Biomedical Excellence for Safer Transfusion (BEST) Collaborative announced that Sean R. Stowell, MD, PhD is the recipient of the 23rd Scott Murphy Memorial Award Lectureship. Dr. Stowell will deliver a lecture on "The Development and Consequences of Red Blood Cell Alloimmunization" during the 58th Meeting of BEST in San Antonio, Texas October-16th-17th. He is an assistant professor at the Emory University School of Medicine in the department of Pathology and Laboratory Medicine, Center for Transfusion Medicine and Cellular Therapies. The lectureship "was established in 2007 by the BEST Collaborative in recognition of the tremendous contribution of the late Dr. Scott Murphy, a past chair of the BEST Collaborative, had made to the field of transfusion medicine and to the science of platelet storage. The BEST Collaborative encourages junior faculty involved in the broadly understood field of transfusion medicine to apply for this unique award."

(Source: Best News Release, 8/28/19)

MEMBER NEWS

New York Blood Center held more than 100 blood drives this week honoring the memory of the victims of the September 11th attacks from 2001. Several drives have been hosted by first responders including the New York Police Department. "When tragedy struck our city 18 years ago, New Yorkers rallied around each other and stepped up to help those in need", said Andrea Cefarelli, senior executive director of Donor Recruitment at New York Blood Center in the announcement. "This September, we are calling on New Yorkers to continue giving back by helping to shore up the region's blood supply. It is the blood that is already on the shelves that saves lives, so we are urging everyone who can to donate blood to ensure that every patient and hospital has access to the life-saving blood they need."

(Source: New York Blood Center Announcement, 9/9/19)

WORD IN WASHINGTON

Rep. Ted Deutch (D-Fla.) and members of his staff visited and donated at OneBlood during a recent trip back to his home district. The preplanned trip also coincided with the center's preparations for Hurricane Dorian as Rep. Deutch, a longtime donor, toured the facilities and encouraged other members of Congress to follow his example by taking the opportunity to donate at their local community blood centers with their staff when visiting their home district. He also stressed the importance of being a regular donor in an interview with OneBlood, "It's the blood that's already available that is used immediately. So, people shouldn't wait for a tragedy. They should just make [blood donation] a part of what they do."

Photo courtesy of Rep. Deutch

(Source: OneBlood Announcement, 9/6/19)

America's Blood Centers®
It's About *Life.*

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 Seeks BPAC Nominations and Feedback on Committee Structure

America's Blood Centers (ABC) is seeking member input on the U.S. Food and Drug Administration's Blood Products Advisory Committee (BPAC). Specifically, we are looking for member suggestions on both the committee structure as well as the names of individuals you believe ABC should consider nominating for both the industry representative(s) and general committee positions. Please send any feedback by September 18th to ABC CEO Kate Fry, MBA. Additional details are available to ABC members in MCN 19-059.

(Source: MCN 19-059, 8/22/19)

August SMT Journal Club Webinar Recording Available

A recording of the ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar from August 19th is available to ABC members. The webinar explored:

- Financial impact of alternative approaches to reduce bacterial contamination of platelet transfusions (*Transfusion*);
- Response to random apheresis platelets versus HLA-selected platelets versus pooled platelets in HLA-sensitized patients (*Transfusion*); and
- Platelets stored in whole blood at 4 C: in vivo posttransfusion platelet recoveries and survivals and in vitro hemostatic function (*Transfusion*).

Additional details including the presentations and a playback of the webinar are available to ABC members in MCN 19-060.

(Source: MCN 19-060, 8/26/19)

ABC 2020 Meetings & Workshops

Meeting/Workshop	Dates	Location	Hotel	Registration Dates & Fees
2020 ABC Annual Meeting	March 9th-11th	Washington, D.C.	Ritz-Carlton (Pentagon City)	More details coming soon!
ADRP 2020 Conference	May 19th-21st	Phoenix, Ariz.	Hyatt Regency	More details coming soon!

Notes:

For the most up-to-date information on all events, members of ABC may check the calendar on ABC's Member Site.

Non-members may attend all events; information will be updated on ABC's Public Site.

COMPANY NEWS

The Roche cobas® Babesia test received a recommendation to be licensed by the U.S. Food and Drug Administration (FDA) from a regulatory review committee. More details including the August 27th recommendation are available on the FDA website. The cobas® Babesia test is nucleic acid screening test for direct detection of Babesia DNA and RNA designed for use on the cobas 6800 and 8800 systems in whole blood and blood component samples as well as organ and tissue donations obtained from living donors.

(Source: FDA Announcement, 9/6/19)

Be The Match® has and the Sickle Cell Transplant Advocacy & Research Alliance (STAR) have partnered to provide free support services to sickle cell disease patients and their families. The organizations announced the partnership as part of National Sickle Disease Awareness Month**.** "At Be The Match® we are committed to ensuring patients from all communities understand their treatment options and are given the tools they need to make the best decisions for their health," said Be The Match® Health Equity Program Manager in a news release. "Our Patient Support Center is available to help patients navigate their disease and find the best treatment so they can thrive. We are excited to be able to offer sickle cell patients the chance to receive support from other sickle cell survivors through our Peer Connect program, in partnership with STAR." The program also hopes to increase the number of black donors in the Be The Match® Registry. "STAR's goal is to serve as a connecting point for organizations to share information regarding both bone marrow transplants and gene therapy as potential cures for sickle cell disease and help promote the need for bone marrow donors, fundraising and participation in clinical research," added Lisa Logan Smith, executive director of STAR in the release. "It is through this emerging network that STAR has been able to sustain itself while also managing the relationships it continues to build with hospitals and pharmaceutical companies to help make these treatments a possibility for more patients affected by sickle cell disease with the hope to eventually cure the disease."

(Source: Be The Match News Release, 9/1/19)

Global Blood Therapeutics, Inc. recently announced acceptance of their new drug application (NDA) for a sickle cell disease treatment, voxelotor, that seeks accelerated approval from the FDA. The agency has granted Voxelotor with FDA Breakthrough Therapy, Fast Track, and Rare Pediatric Disease designations. Findings from a randomized, double-blind, placebo-controlled trial published in the *New England Journal of Medicine* in August suggested that voxelotor increased hemoglobin and decreased hemolysis in sickle cell disease patients. "The FDA's acceptance of our NDA for voxelotor under Priority Review is a major milestone in the development of this investigational therapy and further illustrates the significance the [FDA] places on getting important and innovative treatments to individuals living with [sickle cell disease] as quickly as possible," said Ted W. Love, MD, president and chief executive officer of Global Blood Therapeutics in a news release. "We look forward to working with the FDA during this process, with the goal of potentially changing the treatment paradigm for [sickle cell disease]."

(Source: Global Blood Therapeutics News Release, 9/5/19) ♦

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!

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) 393-1282. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2019

Sept. 19. **National Institutes of Health Clinical Center Immunohematology and Blood Transfusion 38th Annual Symposium, Bethesda, Md.** More details available here.

Sept. 20. **Red Cell Genotyping 2019: Patients First, Bethesda, Md.** This 9th annual symposium will review the laboratory aspects and clinical benefits of red cell genotyping in patients and blood donors. More details available here.

Sept. 23-25. **The MedTech Conference, powered by AdvaMed, Boston, Mass.** More details available here.

Oct. 15-16. **Biomedical Advanced Research and Development Authority Industry Day 2019, Washington, D.C.** More details available here.

Nov. 12-14. **U.S. Food and Drug Administration Center for Drug Evaluation and Research Small Business and Industry Assistance Clinical Investigator Training Course, College Park, Md.** More details available here.

2020

Jan. 14-15. **IPFA/EBA Workshop on Plasma Collection, Location to be announced.** More details available here.

Mar. 9-11. **2020 ABC Annual Meeting, Washington, D.C.** More details coming soon.

Mar. 25-26. **IPFA 5th Asia Workshop on Plasma Quality and Supply, Thailand.** More details available here.

May 13-14. **IPFA/PEI 27th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens, Porto, Portugal.** More details available here.

May 19-21. **2020 ADRP Conference, Phoenix, Ariz.** More details coming soon.

CLASSIFIED ADVERTISING

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

POSITIONS

Senior Director of Donor Services. MEDIC Regional Blood Center, Knoxville, Tennessee, is seeking to fill the position of Senior Director of Donor Services. The ideal candidate would be a highly motivated individual with exceptional customer service skills and able to work independently while managing multiple priorities. Must possess excellent written and verbal communication skills, be organized and creative, and have the ability to effectively evaluate and solve critical problems. This position reports directly to the Chief Executive Officer and is responsible for defining the strategy, goals and objectives, and operational structure of Donor Services; provides management, supervision, and coordination of all day-to-day operations of fixed-site and mobile donor collections; key responsibilities include donor registration, eligibility screening, and phlebotomy for whole blood and apheresis donations. Specific duties consist of defining staffing needs, establishing hours of operation, monitoring of operational productivity, allocation of resources, ensuring the adherence to organization and departmental policies and procedures, and coordinating with other areas of operations. Qualifications: BSN required; (RN license in state of Tennessee); ten years of progressively responsible management experience and

(continued on page 10)

POSITIONS (continued from page 9)

demonstrated ability to effectively manage multiple initiatives. Experience in blood banking preferred. For complete job description and to apply, send resumes to hr@medicblood.org.

Assistant Director Technical Services. Stanford Blood Center, a subsidiary of Stanford Health Care, is focused on connecting our communities to provide hope for healing. We lead the fields of transfusion and transplantation medicine by advancing science and technology. For more information, visit http://bloodcenter.stanford.edu/. We are seeking a Technical Services Assistant Director. Under the direction of the Sr. Operations Director and the Medical Director, the Technical Services Assistant Director will set the strategy, goals, objectives and structure of Technical Services. Core Duties: Manage, supervise and coordinate the day-to-day operations and TS organizational structure which consists of five leaders and approximately 42 team members, and three distinct functions; Component manufacturing and distribution, Processing laboratory, and Product QC laboratory. In partnership with SBC Leaders, coordinate activities and goals of departments within the Blood Center. Manage implementation of policies and procedures, and ensure that employees understand and adhere to established policies and procedures. Qualifications: Four-year college degree and four years laboratory experience required. Four years of progressively responsible management experience and demonstrated ability to effectively supervise varied activities or functions required. Medical Technology (ASCP) license required. Must hold or qualify for California Clinical Laboratory Scientist (MTA) license. For complete job description and to apply, visit https://www.stanfordhealthcarecareers.com/ and reference job #53404.

Outside Sales Representative/Event Planner (Oklahoma City, Okla.). Account Consultants must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. Visit http://obi.org/careers/ **to apply.**

Director, Marketing and Public Relations. Blood Assurance is currently seeking a Director of Marketing and Public Relations. As a member of the operations team, this role is responsible for strategically planning, communicating and executing Blood Assurance marketing and public relations efforts in multiple markets. Develops organizational strategies and executes departmental management plans that support all efforts of the organization as it pertains to marketing and communication needs. Prepares and manages marketing budgets, represents BA leadership internally and externally, and partners with all management levels to meet organizational Key Performance Indicators. Advanced leadership and management skills; advanced decision-making, judgment, negotiation and communications skills with ability to effectively collaborate, develop productive teams, manage complex responsibilities, plan and execute strategic operational initiatives and impact organizational KPI results/success; requires flexibility, customer/client service focus, analytical, budgeting, reporting, computer and organizational skills. Bachelor's degree required; master's degree preferred in business field. At least five to 10 years prior related sales, marketing, or public relations experience required. Qualified candidates are encouraged to submit an online employment application for consideration at www.bloodassurance.org. Blood Assurance is an Equal Opportunity Employer and a Tobacco Free Workplace.

Quality & Regulatory Affairs Specialist. The Stanford Blood Center is seeking a Quality & Regulatory Affairs Specialist. Under the general supervision of the Director of Quality and Regulatory Affairs, this position will perform the quality and regulatory affairs duties and responsibilities by reviewing department procedures, forms, training documents, product and equipment quality control (QC), change control processes, validations, and assist with development, as necessary. Develop, perform and report departmental, system audits, and safety inspections. Perform Good Manufacturing Practice (GMP) and safety training, trend analysis of events and quality indicators, root cause analysis, process improvement, corrective and preventive actions; maintain compliance by enforcing applicable regulations and standards set by regulatory agencies and submit appropriate reports, when required. Core Duties include: Review validation plans, procedures, training documents, PDIF

(continued on page 11)

POSITIONS (continued from page 10)

records, product and equipment QC for regulatory compliance and assist with development and training as necessary. Develop, perform and generate departmental reports and system audits. Develop, revise, institutional QRA SOPs and training. Perform GMP, QRA and safety training. Perform trend analysis of events, complaints, and quality indicators with subsequent performance of root cause analysis, and process improvement. For complete job description and to apply, visit: www.stanfordhealthcarecareers.com and reference job # 51343.

Medical Director. If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of blood banking, transfusion medicine, immunohematology reference laboratories, therapeutic apheresis, cellular therapy and research, consider joining OneBlood as a Medical Director. Qualified candidates should possess a minimum of three years' experience and a M.D. or D.O. degree with board certification in Clinical Pathology, Internal Medicine or Hematology and subspecialty board certified in Blood Banking/Transfusion Medicine by a Board Registry recognized by the American Board of Medical Specialties. Appropriate state licenses will be required as needed. Must meet the eligibility requirements to obtain appointments at hospitals served by OneBlood. This position includes the option of free medical coverage with a competitive benefit package, 403(b) retirement plan with company contribution PLUS a company match, company vehicle lease/allowance, paid holidays, and much more. This position will be based out of the Ft. Lauderdale, Florida area, with some of the most gorgeous beaches in the nation! If you want to join our life saving mission and team of dedicated employees, visit our *Careers* page at www.oneblood.org to learn more. OneBlood, Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability.