

ABCNEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2020 #34

September 25, 2020

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ABC Delivers Testimony to U.S. International Trade Commission

America's Blood Centers (ABC) Chief Executive Officer Kate Fry, MBA, CAE testified during a U.S. International Trade Commission hearing this week on the role of community blood centers in the nation's response to COVID-19. Ms. Fry noted that, "[a]cross the country, approximately 70 different independent blood centers and hospital-based blood collectors have quickly ramped up COVID-19 Convalescent Plasma (CCP) production, collecting nearly 200,000 doses of CCP and distributing over 160,000 doses to date, which has helped support patients fighting COVID-19. In addition, 4,500 doses have been sent to support The Armed Services Blood Program and many more doses have been provided to support randomized clinical trials, INDs, and research. Further, this amount only represents the nearly 80 percent of CCP collected by community-based or hospital-based blood centers. CCP collections are currently outpacing distributions, allowing blood centers to start building a national stockpile of 30,000 units and growing."

Ms. Fry also discussed the impact of the pandemic on community blood centers and the nation's blood supply. "During the course of this pandemic, our member blood centers have assumed two critical missions: to rapidly mobilize the collection of CCP and adapt operations to facilitate collections from volunteer donors, under new COVID safety protocols, in order to meet the constant need for blood components and services. The blood community continues to face challenges in charting this unprecedented situation...The U.S. blood supply faces serious operational challenges as thousands of blood drives have been and continue to be canceled as organizations and businesses temporarily close, move to a virtual environment, or limit the number of people on site. As a result, blood centers have had to quickly transition their operations to ensure a sufficient blood supply during the pandemic. While the need for blood remains, patient blood use temporarily decreased 30 to 40 percent on average while elective procedures were canceled due to the pandemic, with some communities experiencing far higher decreases."

She added that, "[t]he financial resources made available to blood centers to fully fund the activities necessary for the rapid production and distribution of this new product has been essential in identifying and recruiting potential donors and allowing blood centers to undertake operational changes such as staff and equipment redeployment, training, software modifications, re-engineering fixed site, and mobile drives to accommodate appropriate social distancing, and expanded hours to enable collections from substantially increasing numbers of CCP donors."

(continued on page 2)

ABC Statement to U.S. International Trade Commission (continued from page 1)

Ms. Fry explained supply chain considerations from the challenges that blood centers face in recruiting donors to:

- "the number of available suppliers [is continuing to dwindle] for key supply chain areas utilized by blood centers;
- various supplies are impacted as utilization increases for both blood centers and other healthcare providers;
- as hospitals and other health care providers scrambled to find the supplies they required, blood centers also fought to develop supply relationships to purchase these essential supplies; and
- while the availability of COVID-19 testing was an issue for the public at large, the delays in testing and receiving results was particularly problematic for blood centers that required fast and accurate results to ensure staff and donor safety without resorting to long quarantine periods."

The statement in its entirety is available on the ABC website.

(Source: ABC Statement, 9/23/20)

NIH CCP Clinical Trials Expand

The National Institutes of Health (NIH) announced this week that it is "expanding enrollment" in the clinical trials designed to "further evaluate" convalescent plasma from recovered COVID-19 patients as a potential therapy for hospitalized individuals battling the disease. "The evidence on convalescent plasma as a treatment for severe cases of COVID-19 is promising but incomplete. We need to carry out rigorous randomized control clinical trials to determine how this therapy can improve outcomes," said NIH Director Francis S. Collins, MD, PhD in an agency news release. "While the world waits for an effective vaccine, it is vital that we simultaneously expand the options for available treatments for those currently suffering from the worst effects of this disease."

The randomized trials are being funded as a part of "Operation Warp Speed" and are expected to include hospitalized patients nationwide "at academic and community-based hospitals...outcomes will be compared with respect to clinical improvement measures and resource needs, such as ventilators. Both trials currently are enrolling participants and anticipate results as early as this fall." The National Center for Advancing Translational Sciences (NCATS) within NIH will "oversee grant awards" according to the news release. "The rapid expansion of these vital randomized, controlled convalescent plasma clinical trials demonstrates how nimbly the network of Clinical and Translational Science Awards (CTSA) Program hubs and the CSTA Trial Innovation Network (TIN) can respond to the nation's research needs and shorten the path from discovery to treatment," added NCATS Director Christopher P. Austin, MD in the news release. Two trials that have currently been underway since April led by New York University Langone Health and Vanderbilt University Medical Center respectively are increasing their enrollment to 1,000 participants. Additional information about this study and participation is available at ClinicalTrials.gov.

(Source: NIH News Release, 9/22/20) •

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.





September 25, 2020



REGULATORY NEWS

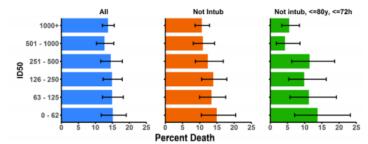
The U.S. Food and Drug Administration (FDA) published "updated evidence to support the emergency use of COVID-19 convalescent plasma." The document states that "four lines of evidence continue to support the emergency use of COVID-19 Convalescent Plasma at this time one month after initial issuance of the [emergency use authorization] (EUA):

- historical data regarding prior experience with the use of convalescent plasma in other outbreak settings;
- data from animal studies;
- data that continues to emerge in the published literature from clinical studies performed during the current outbreak, and
- results obtained from a large expanded access treatment protocol (National Expanded Program)."

	7-day			28-day		
	Overall (N=4330)	Not Intub (N=2488)	Not intub, ≤80 y, ≤72 h (N=932)	Overall (N=2817)	Not Intub (N=1238)	Not intub, ≤80 y, ≤72 h (N=485)
Deaths Lower Titer	14.97%	13.99%	11.29%	49.57%	49.43%	46.63%
Deaths Higher Titer	13.61%	11.00%	6.27%	46.21%	41.48%	33.23%
Absolute Improvement	1.36%	2.99%	5.02%	3.36%	7.95%	13.40%
Relative Improvement	9%	21%	44%	7%	16%	29%
Statistical Significance	Not	Significant	Significant	Not	Significant	Significant
	significant	p=0.03	p=0.008	significant	p=0.004	p=0.004

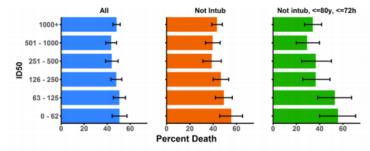
Table 1. 7- and 28-Day Deaths in Patients Treated with COVID-19 Convalescent Plasma





Lowest titers are at the bottom of the graphs, and the titers increase moving up (along the y-axis)s. Reduction in the percentage death at higher titers is noted in the not intubated and in the subset analysis of patients who were not intubated (Not Intub), were 80 years of age or less and were treated within 72 (Not intub <=80y, <=72h) hours of diagnosis.

Figure 2 - Percentage Death in Hospitalized Patients by Day 28



Lowest titers are at the bottom of the graphs, and the titers increase moving up (along the y-axis). Reduction in the percentage death at higher titers is noted in the not intubated and in the subset analysis of patients who were not intubated (Not Intub), were 80 years of age or less and were treated within 72 (Not intub <=80y, <=72h) hours of diagnosis.

Courtesy of FDA

<u>REGULATORY NEWS</u> (continued from page 3)

The agency states that it continues to find that COVID-19 Convalescent Plasma has met the "may be effective" standard for an EUA. However, because the efficacy analysis of the expanded access protocol (EAP) did not include an untreated group of patients for comparison who did not receive convalescent plasma, FDA strongly encourages the continuation of randomized controlled clinical trials to more definitively evaluate the potential benefits of this therapy."

The U.S. Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) has <u>published</u> the recordings of its August public meeting. A complete listing of the recordings from each day is available below:

- Day 1, Part I
- Day 1, Part II
- Day 2, Part I
- Day 2, Part II
- Day 2, Part III
- Day 2, Part IV

(Source: ACBTSA Recordings, 9/8/20) •

BRIEFLY NOTED

Reuters reports that the CoVIg-19 Plasma Alliance, a coalition which includes Takeda, Biotest AG, CSL Behring, and Octapharma Plasma in addition to other organizations, clinical trial for a hyperimmune globulin therapy candidate is scheduled to begin soon. The delayed trial was initially slated to begin earlier this summer (July). It will "[seek] to compare outcomes from the plasma product to those from the drug Remdesivir and a placebo." The National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) is sponsoring the study in the U.S. The trial hopes to recruit" 500 participants from the United States, Britain, Argentina, and Denmark."

(Source: Reuters, Takeda-led COVID-19 plasma product to begin trial this month, 9/17/20)

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 <u>calendar of events</u> 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!

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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.

America's Blood Centers

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September 25, 2020







It's time to get ready for the new FDA guidelines* issued to control bacterial risk in platelets. The first step is creating SOPs that include your large-volume delayed sampling (LVDS) strategy.

To help you prepare for a seamless transition, we have 20-mL SampLok® sampling kits as a stand-alone accessory for use with the Trima Accel® Automated Blood Collection System. Trima Accel disposable sets with these same samplers pre-attached to each platelet bag will be available soon.

Let's get started. Contact your Terumo Blood and Cell Technologies representative today.



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PEOPLE

Richard Gammon, MD a medical director at OneBlood and assistant professor of Pathology at the University of Central Florida College of Medicine is <u>receiving</u> one of the 2020 President's Awards from AABB. The distinction "recognizes the extraordinary public service and contributions of an individual or an organization in the health care arena. The recipient's work furthers AABB's goals and missions." Dr. Gammon is being honored specifically for his "dedicated leadership of AABB's Blood Banks and Transfusion Service Standards Program Unit, as well as AABB's Transfusion Safety/Patient Blood Management Subsection and other committee work."



(Source: AABB Announcement, 9/22/20)



Retired Army Col. Glen Michael Fitzpatrick, PhD, currently the president of Cellphire, Inc. will be the 2020 recipient of the Armed Services Blood Program's (ASBP) Lifetime Achievement Award. "With four decades of outstanding leadership as a blood banking expert matched only by his commitment to the warfighter, we are honored to present the 2020 ASBP Lifetime Achievement Award to Col. Fitzpatrick," said Army Col. Audra L. Taylor, division chief at ASBP in a news release. "His career is truly great in scope and accomplishment." Dr. Fitzpatrick added in the release, "It's a privilege

and an honor to receive the ASBP Lifetime Achievement Award. I want to thank those who nominated me and the committee that selected me as the recipient of this award. It was an honor to serve my country and support troops globally. Now as a civilian working at Cellphire, I hope to continue my work in supporting our troops and civilians by ultimately bringing next generation blood products, including freeze-dried platelets, to both battlefield and civilian medicine." He served in the U.S. Army for 29 years before retiring in 2003 including a stint as the director of ASBP from 1999-2003.

(Source: Cellphire Inc. News Release, 9/23/20) ♦

MEMBER NEWS

Oklahoma Blood Institute (OBI) and Oklahoma University (OU) Medicine, and the OU Health Sciences Center are collaborating on a study to "determine the prevalence of Oklahoma healthcare workers who have previously been infected with COVID-19." According to the study's researchers, they seek to determine "whether antibodies made by previously infected individuals have the ability to neutralize the virus," said OU Health Sciences Center Virologist James Papin, PhD in a news release. "While we have some evidence that individuals who have recovered from COVID-19 possess antibodies that can protect from re-infection, what we do not know is how long those antibodies persist or if antibodies produced during asymptomatic infection can protect against re-infection. As part of the testing, we will determine the highest dilution of antibodies that can block the virus from infecting cells, as a higher dilution indicates a stronger response and thus greater chance of protection from re-infection." Earlier this week, KFOR Oklahoma's News 4 reported that "around 7 percent" of all healthcare workers in the state have antibodies for COVID-19. "That's all healthcare workers, it's not just frontline workers," said OBI President and Chief Executive Officer John Armitage, MD to the news organization in an interview. "It's folks who might work in the cafeteria at the hospital or work in an office setting in the hospital." He also indicated that OBI has seen the presence of antibodies in donors rise from around 2 percent previously to above 6 percent in the past few weeks.

(Sources: KFOR Oklahoma's News 4, <u>OBI reports positivity rates of COVID-19 antibody tests</u>, 9/21/20; OU Medicine News, <u>COVID-19 Antibodies Examined in Healthcare Workers</u>, 7/8/20) **♦**





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.

ADRP Annual Conference Goes Virtual

Register today for the ADRP Annual Conference, now a virtual event. The dates may have changed, but the content has not! Please plan to join us November 16th-18th. Over the course of three days, individuals will have access to abstract presentations, roundtables, and a virtual exhibit hall. As an attendee, you will be able to use the virtual conference platform for one year and have the opportunity to experience all of the sessions that you may not have been able to participate in at an in-person conference, an increase of 11.5 education hours! This event will benefit blood center staff in multiple disciplines including donor recruitment, collections, marketing, and communications. We encourage staff from all levels to attend, to enhance the collaboration within their individual donor center. Group discount rates are available for ADRP subscribers. More information is available here. The full conference program can be viewed here.

Charting the Course to Excellence ADRP Annual Conference Nov. 16-18, 2020 | Wherever You Are!

ADRP Digital Marketing Solutions Virtual Master Class Underway

Registration is still open for the ongoing Digital Marketing Solutions Virtual Master Class. This series of three single-day events, with the first having taken place on September 16th followed by a subsequent session on September 23rd, will continue next week (September 30th). It has been designed to move beyond the basics and build upon the skills needed to excel at your job while providing participants with the latest tools and trends to incorporate into their current business plans.



Not convinced? Watch ADRP President Lisa Entrikin explain why this event is essential and like no other in the industry. Recordings of the presentations will be available to attendees up to one year.



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GLOBAL NEWS

The European Medicines Agency (EMA) has designated a CRISPR/Cas9 gene-edited therapy with "Priority Medicines" (PRIME) status to treat severe sickle cell disease based on "clinical data from an ongoing phase I/II trial. The therapy (CTX001) is a joint collaboration between CRISPR Therapeutics and Vertex Pharmaceuticals, Inc. According to the announcement, "PRIME is a regulatory mechanism that provides early and proactive support to developers of promising medicines, to optimize development plans and speed up evaluations so these medicines can reach patients faster. The goal of PRIME is to help patients benefit as early as possible from innovative new therapies that have demonstrated the potential to significantly address an unmet medical need." The investigational therapy is designed to take an individual's "hematopoietic stem cells [and engineer them] to produce high levels of fetal hemoglobin (HbF; hemoglobin F) in red blood cells."

(Source: CRISPR Therapeutics and Vertex Pharmaceuticals, Inc. Joint News Release, 9/22/20)

COMPANY NEWS

A recent announcement from **Roche** introduced the <u>launch</u> of a quantitative SARS-CoV-2 antibody test for European countries that accept the CE mark. The company is also seeking emergency use authorization (EUA) for the Elecsys Anti-SARS-CoV-2 S which "quantitatively measure[s] antibodies" in individuals exposed to SARS-CoV-2. "As the possibility of an effective SARS-CoV-2 vaccine becomes a reality, quantitative measurement of antibodies will be crucial in the evaluation of any potential vaccine," said Roche Diagnostics Chief Executive Officer Thomas Schinecker in a news release. "The new quantitative Elecsys antibody test can play a pivotal role in vaccine clinical trials as well as helping clinicians assess patients' immune response. This will be instrumental in protecting people most vulnerable to the virus, as well as in overcoming COVID-19 for society in general. This new test, the twelfth in the Roche SARS-CoV-2 testing portfolio, is another essential addition to support healthcare systems and patients as we jointly fight COVID-19."

(Source: Roche News Release, 9/18/20)

Eli Lilly has announced "proof of concept data from an interim analysis" of its monoclonal antibody therapy to treat COVID-19. "These interim data from the BLAZE-1 trial suggest that LY-CoV555, an antibody specifically directed against SARS-CoV-2, has a direct antiviral effect and may reduce COVID-related hospitalizations," said Daniel Skovronsky, MD, PhD in a news release, chief scientific officer and president of Eli Lilly Research Laboratories. "The results reinforce our conviction that neutralizing antibodies can help in the fight against COVID-19." The randomized phase II trial reported a "[r]ate of hospitalizations and [emergency room] visits was 1.7 percent (5/302) for the antibody therapy versus 6 percent (9/150) for placebo—a 72 percent risk reduction in this limited population." The results of the interim analysis will be "publish[ed]" in a peer-reviewed journal in the coming weeks according to Eli Lilly. "We are grateful to the patients, physicians, and staff that have participated in this trial," added Dr. Skovronsky. "We look forward to continued data generation as this trial proceeds."

(Source" Eli Lilly News Release, 9/16/20)

CALENDAR

Note to subscribers: Submissions for a free listing in this calendar (published weekly) are welcome. Send information to <u>newsletter@americasblood.org</u> or by fax to (202) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)

Sept. 30. ADRP Digital Marketing Solutions Virtual Master Class. More details available here.





CALENDAR (continued on page 8)

Oct. 3-5. **2020 AABB Annual Meeting (Virtual).** More information available here.

Oct. 27. Biomedical Advanced Research and Development Authority (BARDA) Industry Day 2020 (Virtual). More information available here.

Nov. 16-18. 2020 ADRP Conference (Virtual). More details available here.

Nov. 17. FDA Public Meeting – Communications About the Safety of Medical Devices (Virtual). More details available here.

2021

Mar 8-10. **ABC Annual Meeting, Washington, D.C.** More details coming soon.

June 25-26. 64th Annual California Blood Bank Society Annual Meeting, Santa Clara, Calif. More details coming soon.

May. 11-13. 2021 ADRP Conference, Kansas City, Mo. More details coming soon.

Sept. 15-17. 4th European Conference on Donor Health and Management, Hamburg, Germany. 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, e-mail: newsletter@americasblood.org

POSITIONS

Med Techs (Schedule: Monday – Thursday, 12p noon - 10:30pm, with on-call rotation). We need YOUR laboratory knowledge to help save lives! Kentucky Blood Center is seeking a qualified medical technologist to perform and interpret serological procedures on specimens submitted for compatibility testing. This position also acts as an expert problem solver, and will resolve issues related to antibodies, blood typing, and cross-matching. The role regularly interacts with hospital laboratories, helping them find answers, and communicating findings. Qualifications: MT, MLS, CLS (4-year degree) with a minimum two years recent blood bank experience, required; ASCP is a plus. Must have strong verbal and written communication skills, and be proficient with MS Office, with the ability to navigate web applications, and custom systems. Reference Laboratory employees must exhibit great teamwork, a positive attitude, and a "Do What It Takes" work ethic, with the goal of helping our hospital customers and patients. Proof of education must be provided during the interview process. Benefits: Health/Dental/Vision/Life/Short Term Disability/Long Term Disability/Cancer Insurance/Accident Insurance/Flexible Spending Accounts/Health Savings Accounts/Paid Time Off/Paid Holidays/Employee Assistance Program/Retirement Savings Plan. For more info, and to apply, go to: https://kybloodcenter.org/aboutus/careers/.

Director of Information Technology (Fresno, CA). Central California Blood Center is seeking an experienced Director of IT. For over six decades, the Central California Blood Center provided blood and blood products to California's Central Valley. We are dedicated to advancing transfusion medicine and excellence in customer service through innovative thought leadership, technology and research. We are seeking an IT Director who is passionate about our vision, who will be an integral part of our dynamic team. Primary Duties: Participates in strategic and operational decision-making as a member of the Senior Management Team; Leads IT strategic and operational planning; Develops and maintains IT organizational structure; Strives to lower IT overhead and costs; Establishes, monitors and upgrades informational security, threat detection, mitigation and disaster recovery processes. Establishes goals, objectives and operating procedures consistent with regulatory requirements and strategic plans; Identifies opportunities for cost-effective investment of financial resources; Develops, tracks and controls operating and capital budgets; Oversees vendor agreements and monitors systems' performance; Collaborates on hardware, software, maintenance and cloud contracts; Develops RFPs to assure best acquisitions and fair purchasing practices.



September 25, 2020



POSITIONS (continued from page 9)

Monitors trends in IT and blood industries; Oversees relationships between internal and external IT resources; Supervises recruitment, development, and retention of staff. Bachelor's Degree and/or five years' experience in related technologies. Five years' experience managing and/or directing an IT operation. Master's Degree preferred. Offering up to \$4K relocation benefit. To apply and view the complete job description, click here.

Medical & Laboratory Director (Denver, CO). Do you want to be a part of a lifesaving organization? Since 1948, Vitalant has proudly served as a leader in the blood banking industry. Under minimal direction, this position provides field medical director oversight for the patients, donors, center staff, and healthcare professionals in assigned areas. Requirements: MD or DO or equivalent degree. Knowledge of federal, state, and local regulations for assigned areas. Two years Fellowship/Post-Doc in Histocompatibility or equivalent. Active applicable state licenses and/or certificates within first 6 months. Board certification in Clinical Pathology, Internal Medicine, Pediatrics, or other clinical specialty. Board certification in Transfusion Medicine OR Hematology or eligibility followed by certification within two years of employment. American Society of Histocompatibility and Immunoge-Histocompatibility Director certification. Fellowship training or equivalent experience in blood banking/transfusion medicine. Experience at a blood center and/or hospital transfusion service including provision of education, clinical consultations, and some combination of therapeutic apheresis, cell therapy, laboratory, immunohematology, etc. experience. Eligible to serve as FACT Laboratory Director within two years of employment. Living and Deceased Solid Organ Transplantation, Transfusion Support, Related and Unrelated HSC/BM Transplantation, and Histocompatibility testing for other clinical purposes. Click here to apply. EEO

Assistant/Associate Director Blood Transfusion Service (Massachusetts General Hospital, Harvard Medical School). The Blood Transfusion Service at the Massachusetts General Hospital seeks a full-time, early or mid-career, academically oriented transfusion medicine physician. The successful candidate will combine clinical and teaching activities with a research program in a field relevant to transfusion medicine, hematology or hemostasis. Our service encompasses an FDA-licensed donor center, therapeutic apheresis, an outpatient transfusion/infusion clinic, a transfusion service, and progenitor cell collection and processing. We collaborate closely with clinical colleagues in bone marrow and solid organ transplantation, CAR-T cell therapy, cardiac surgery, trauma and critical care, neurology, and pediatrics. Service and teaching responsibilities will be shared with three other full and part-time staff physicians. Candidates must be BC/BE in Transfusion Medicine, with primary training in either Pathology or Hematology/Oncology (adult or pediatrics). Academic rank and salary will be based on experience and accomplishments. Please send a curriculum vitae and a description of interest to: Robert Makar, MD, PhD, GRJ148, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114-2696; or email to rmakar@mgh.harvard.edu. The Massachusetts General Hospital is an equal opportunity/affirmative action employer.

Information Systems Compliance Specialist – Req.: 201038 (Scottsdale, AZ). Do you want to be a part of a lifesaving organization? Since 1948, Vitalant has proudly served as a leader in the blood banking industry. Primary Purpose: Under minimal supervision, this position is responsible for reviewing quality systems and compliance in all areas of computerized medical devices and computer applications for Blood Systems and business units. This position serves as a resource to department and operations on computer-related quality and regulatory issues. Requirements: Bachelor's degree required. Knowledge of computer environments, standards development, and system life cycle methodology required. Knowledge of regulations as they relate to the blood industry quality and IT activities preferred. IT related certifications (i.e., ITIL, COBIT, CISA, CSQE, etc.) preferred. Four years of related experience in a regulated industry required. To include: Two years of experience in IT quality, regulatory, and/or auditing. Please apply here. EO/Minorities/Females/Disabled/Veterans