

BloodNews

United Blood Services



News & Information
for our Hospital Customers

September 2007

Is Your Facility 'On Q'?

Are your regulatory affairs in order? Does your Quality Department live by the concepts of Total Quality Management? Do you have a Validation Plan? Can you recite the US FDA's Good Tissue Practices forwards and backwards? Is your facility 'On Q'?

On Q – The Source for Quality Training is an exciting training opportunity offered by Quality Source and Blood Systems, the parent organization of United Blood Services. It provides practical information and knowledge of the quality and regulatory concepts necessary to succeed in today's complex blood banking environment. The programs include classroom instruction,

guest speakers, case studies and exercises designed to hone quality management and operational skills for staff in labs and hospital blood banks. *On Q* is PACE® accredited and was designed by quality professionals with many years of experience in blood banking and transfusion service.

Currently, the *On Q* training program is offered in three different sessions as well as a separate Transfusion Services class. *On Q–Session 1* includes information regarding audits, document control, validation, deviation management and regulatory affairs. *Session 2*

covers change control, materials management, process improvement, quality monitoring, risk management, registration and licensure. The objectives for *Session 3* include but are not limited to information for HCT/PS, Clinical Trials, 21 CFR Part 11, advanced auditing and investigations, European Union requirements and Six Sigma White Belt tools. *On Q for Transfusion Services* covers topics such as document control, equipment, process controls and improvement, regulatory requirements and internal assessments.

On Q was initiated in 2006 when three different sessions were held for blood center customer attendees. In 2007, *Sessions 1, 2 & 3* have been completed, as well

as eight *Transfusion Services* classes, many of the sessions receiving rave reviews from attendees. "[The *On Q* training session] was very important information for people like me who are in small labs and do not have much opportunity for networking or for classes," said Sue Anderson of Kittson Memorial Hospital in Hallock, MN. "I will be taking some of the information to our monthly risk management meeting and I do plan to implement some of it in our lab. It was also nice to see that we are doing some things right!"

On Q–Session 3, the last session of 2007, will be held September 24-28 in Scottsdale, AZ. There are more *Transfusion Services* sessions scheduled through the end of the year at various United Blood Services centers throughout the country. To schedule attendance, contact Montana Crosby at (480) 675-5871 or mcrosby@bloodsystems.org. For more information regarding the *On Q* training sessions, visit the Quality Source website at www.QualitySource.org.

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–Sue Anderson

Kittson Memorial Hospital

Hallock, MN

Market Withdrawals and Recalls To Be Delivered By E-Mail

United Blood Services will begin using e-mail as the primary method to notify our customers of Blood Product Recalls and Blood Product Market Withdrawals. The date for this change has not been confirmed but we expect it to occur before the end of 2007. We are making this change to get this information to and from our customers in the quickest manner possible. If follow-up or reminder notices are required, we will send those letters by fax, or USPS certified mail, return receipt requested. Customers without access to e-mail will still receive letters via USPS first class mail. In early September we sent customers a request for e-mail contacts. If your facility has not responded, please get in touch with your United Blood Services Customer Account Manager.



BloodNews is published by United Blood Services for the hospitals we serve. Media inquiries can be made to Barb Kain at (480) 675-5664. The United Blood Services network is one of the nation's oldest and largest non-profit blood service organizations, and is a founding member of America's Blood Centers and the AABB.

New BUI Number Printers Debut in September

On September 24, 2007, United Blood Services will begin using new Blood Unit Identification (BUI) number printers to ensure that blood components released to hospitals have enough labels for each hospital's use.

The new printers came about as a result of key customer service requests. Hospitals were reporting that there were not always enough Donation Identification Numbers (DIN) on the blood products they received, requiring that they manually record the numbers on their internal records. This both interrupted and increased their work flow and they requested that we make more labels.

As a result, United Blood Services created a pilot program to evaluate a new DIN replicator system to print additional number labels for each component bag. The testing was structured to identify the appropriate mix of eye-readable and barcode-readable numbers so we

could configure the appropriate number of labels for each bag. Modifications were made along the way to include our blood center ID on each label. The blood center ID is only eye-readable and not part of the replicated barcode. Software, printers and labels were evaluated at three of our blood center locations and, after input from hospital customers, were approved for release to the rest of our centers. The printers and barcode readers are compatible with our current Codabar system as well as future ISBT 128 numbers.

At the time of labeling and distribution, Red Blood Cells will have at least three eye-readable labels and two barcodes and Platelets will have at least two eye-readable labels and one barcode. If the component has fewer labels, the label replicator system will be used to print and apply additional labels for each component. Internal quality checks have been created to ensure the appropriate label is applied to the appropriate product.

New Date Finalized for ISBT 128

Preparing for the switch to ISBT 128 labeling has been a complicated process for hospitals and blood centers, and approximately one-third of the hospitals served by United Blood Services have expressed doubts about whether or not they will be prepared for the new labeling by our planned November transition. In order to better serve all of our customers, we have decided to move the transition date to Monday, April 28, 2008. It is our policy to implement all new changes on Mondays.

Please note that this date is firm, as the AABB's proposed standard 5.1.5.3.1, which will be the new standard, will be in effect as of May 1, 2008. This standard states:

Labeling of blood and component containers shall be in conformance with the most recent version of the United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components using ISBT 128. Units conforming to 1985 FDA Uniform labeling Guidelines are acceptable if collected and labeled before May 1, 2008.

If you have questions regarding the implementation date, please contact your United Blood Services representative or the ISBT Conversion Team at ISBTCore.MB@bloodsystems.org.



Inaugural Blood Bank Technology Class Graduates

The first class accepted into Blood Systems' Blood Bank Technology Program graduated last month. The graduating students completed the intense 2-year Web-based Blood Bank Technology (BBT) curriculum presented by Blood Systems Laboratories in conjunction with the University of Texas Southwestern. They were awarded a continuing education certificate and are now eligible to take the certification examination for Specialist in Blood Bank technology (SBB) administered by the Board of Registry of the American Society of Clinical Pathologists.

As a leader in blood banking, United Blood Services provides and supports excellence in transfusion medicine education. The BBT curriculum provides intensive professional study in both theoretical and applied educational areas. The theory portion includes didactic online courses. The clinical education experience is provided in a blood center or transfusion service setting. The program is accredited by the AABB in collaboration with the Committee on Accreditation of Allied Health Education Programs (CAAHEP).

Applications for the next class will be available in the spring.