

Cellular Therapy Liaison Meeting
10 September 2009
BECS

M. Allene Carr-Greer, MT(ASCP)SBB
Director, Regulatory Affairs
AABB

Definition from October 2007 draft guidance – BECS Validation In the User's Facility

- A Blood Establishment Computer System (also referred to as "system") includes: computer hardware, computer software, peripheral devices, personnel, and documentation, e.g., User's Manuals, Standard Operating Procedures (SOPs).
- The computer software used in a Blood Establishment Computer *System* includes BECS (blood establishment computer *software*), which is a medical device.
- FDA considers a Blood Establishment Computer System to be equipment under Title 21 Code of Federal Regulations (CFR) 606.60, and automated or electronic equipment under 21 CFR 211.68.

Disclaimer

- Presentation is intended to be about BECS in general
- However, some features / options may not be found in all software products
- Many features / options exist that are not mentioned in this presentation

General Comments

- Systematically designed to operate in a secure environment
- Generally encompass all aspects of blood banking within one fully integrated package
- Grouping processes allows management / QA unit to declare the rules by which the data is managed and the users are allowed to operate under cGMP
- Reports for supervisory review are readily available (automatic and on-demand)
- Widespread use of touch screens, tablets, other mobile devices, real-time wireless connections, printers for on-demand labels

Blood Collection Services (registration / medical history / collection)

- Electronic review of historical eligibility status and 'days to next donation' for various product types
- Extensive checks on demographic files to ensure donor has only one record in system
- Self administered questionnaires
 - Appropriate follow-up questions built in
 - Automatic deferrals based upon question responses
 - Inventory attributes assigned based on responses
- Recording of vitals, initial and retest
 - Automatic deferrals based upon vitals
- Real-time draw information
- Inventory attributes based on question responses

Inventory Control (product processing and tracking)

- Document creation of new products (donated or imported)
- Tables control the further processing steps (what products are allowed to be made or what processes can be performed on the products) and expiration dates
- Products can be created with required processes / tests to be performed
- Products/inventory can be defined, managed and tracked differently based on the type of inventory (blood, platelet, HPC, shelf life, use, etc.)
- Inquiry and reporting function (unit number, product type, inventory status and/or location, expiration dates)

Laboratory interfaces

- Results from an outsourced testing facility, existing Lab Interface System (LIS) or directly from testing equipment
- Interfaces are configurable through centralized interface utilities

Laboratory testing

- Control tables - testing can be flexible and dependent upon the type of inventory (platelets get bacterial cultures)
- Creation/evaluation of donor testing records is performed automatically
 - based on management defined profiles (a repeatedly reactive result will automatically create an open record for a confirmatory test, etc)
- Donor / product results and interpretations
- Evaluate the posted results, process quarantined inventory, and activate donor deferrals based on laboratory testing

Shipping & Receiving

- Handling and distribution of transfusable products, products for further manufacture, Rhogam, supplies, etc
- Maintains complete history of shipping as products move around - readily available if there is a need to recall or if a manufacturer / vendor has initiated a recall
- Creation of stock orders, distribution of orders

Reference laboratory

- Record and maintain antigen and antibody history for donors, patients, and purchased inventory for both red cell antigen groups and HLA antigen groups
- Processing and testing requirements for patients may be recorded
- Search functions allow for fast reporting of available inventory, or for emergency recruiting of eligible donors when no active inventory is available

Transfusion services

- Create/maintain patient demographic records
- Create/maintain orders for transfusable products, including testing and processing requirements
- Control tables to define what is acceptable for data entry
- Recorded patient reference testing is available for review and processing upon receipt of a patient order
- Orders are processed within the rules established by management / control tables

Quality assurance

- Provide QA Departments with the ability to review activity within the system, possible user errors and allow correction, within SOPs
- Provide general audit functionality