



**Fenwal Automated Devices:
FDA Licensing Workshop
August 2007**

Agenda

- ALYX
 - Double LR RBCs
 - LR RBCs/Plasma
 - Non-LR Double RBCs (limited launch)
 - Plasma (not in distribution)
- AMICUS
 - Single needle platelets with optional RBCs, plasma
 - Double needle platelets with optional plasma
 - 5-day platelet storage; 7-day platelet storage with BactAlert
- CS-3000:
 - Automated and manual platelets, plasma, leukocytes, therapeutics
- Auto-C
 - Plasmapheresis

Donor Eligibility

- Follow FDA regulation or guidance
 - May follow AABB standards
- Additional Fenwal criteria
 - ALYX Double RBCs
 - Double RBCs: by sex, height, weight, minimum Hgb or Hct to determine RBC target volume
 - ALYX RBC/Plasma
 - RBC/Plasma: by Hgb or Hct range, weight to determine RBC target and plasma volume

Validation, Quality Control and Acceptance Criteria

- FDA regulations and/or guidance
 - Per FDA regulation:
 - Scientifically sound and appropriate sampling plans required in Laboratory Controls: 21 CFR 211.160(b); 606.140(a)
 - Changes to an Approved Application; Biologics Licensing requires validation: 21 CFR 601.12(b)(3)(iv-vi); 601.12(c)(3)
- AABB standards

Product Validation

- ALYX
 - Double RBCs: volume vs target; hemoglobin or total RBC volume
 - RBCs LR: residual WBCs; % recovery
 - V1.5: Displayed on screen
 - V2.1: Manual calculation
 - V3.0: Re-institute on screen value
- No additional Fenwal specific requirements for any devices

Quality Control

- No additional Fenwal specific requirements or recommendations
 - RBCs LR: residual WBCs; % recovery
 - V1.5: Displayed on screen for 100%
 - V2.1: Manual calculation for 1%
 - V3.0: Re-institute on screen value

ALYX RBCs

- Specifications
 - Target vs actual volumes: RBC volume \pm 10% of target RBC volume
 - LR:
 - $< 5.0 \times 10^6$ residual WBCs with 99% confidence, 99% of time
 - 85% recovery of LR RBCs
- Note: Non-LR RBCs from LR collection are not cleared

ALYX PLASMA

- Specifications
 - None

AMICUS Platelets

- Specifications
 - Will collect $\geq 3.0 \times 10^{11}$ platelets
 - Maximum 4.7×10^{11} per storage container
 - Standard storage volume collected by device default
 - Lower validated volumes
 - Cleared for 600/700mL per storage container
 - Residual WBC count
 - $< 5.0 \times 10^6$ (99% confidence, 99% of time)
 - Single, doubles cleared per collection
 - Triples cleared per component

AMICUS RBCs

- Specifications
 - No specifics, generally:
 - Hematocrit range of 80-85%
 - Volume range of 220-240 mL

AMICUS PLASMA

- Specifications
 - Total plasma volume should be within 20 mL or $\pm 10\%$ (whichever is greater), of target plasma volume

Auto-C

- Specifications
 - Plasma for transfusion must be transfused or processed as FFP within 6 hours of collection
 - Source Plasma

Location of Information

- Operators Manual (OM) and kit disposable Directions for Use
- Clearance
 - Described in separate chapters in OM
- Donor eligibility
 - ALYX: OM Appendix contains nomograms
- Specifications
 - ALYX
 - OM Ch. 1 – Introduction
 - AMICUS:
 - OM Ch. 2 – Before Using the AMICUS Separator
 - OM Ch. 4 – Procedures

continued

- Validation
 - ALYX:
 - Guidelines and Suggestions for Implementation; Core Documents
 - Installation checklist
 - Operational Validation checklist
 - Product validation flowchart
 - Sample validation plan
 - Validation Data Sheet
 - Validation Flowchart

continued

- AMICUS:
 - OM Ch. 10 – Operational Qualification for different software versions
 - Implementation Plan for the Amicus Separator
 - Installation Qualification checklist
 - Operational Qualification sample protocol
 - Product Quality Validation – refer to FDA requirements and recommendations; AABB standards

continued

- Calibration/Maintenance
 - ALYX: OM Ch. 6
 - AMICUS: OM Ch. 6
- Failure investigations: factors that can affect performance and product quality
 - ALYX:
 - OM Ch. 1 - Introduction
 - AMICUS
 - OM Ch. 2 – Before Using the AMICUS
 - Operators Workbook – Session 5 – Common Mistakes and Consequences

continued

- Product mixing
 - AMICUS
 - OM Ch 4 – Procedures
 - RBCs: Operators Workbook, Session 6
 - Platelets: Operators Workbook, Session 4
- Sampling
 - ALYX
 - Core documents
 - SOP for sampling final product
 - AMICUS
 - OM Ch 4 - Procedures

continued

- Additional risks to include in Informed Consent
 - ALYX: OM Ch. 1. - Introduction
 - AMICUS: OM Ch. 2 - Before Using the AMICUS Separator
- Residual RBCs/Plasma for collection/annual loss calculations
 - OM Appendix: for all Fenwal devices

Services Provided by Fenwal

- Training/training documents
 - Train the trainer
- Validation document support
- Draft SOPs
- Regulatory support
 - Registered only use
 - Preparation of FDA licensing applications
 - Additional information requests from FDA
 - Post-inspection questions

Contact for Regulatory Support

Sharyn Orton, MT(ASCP)(SBB), PhD
Director, Regulatory Affairs
Fenwal, Inc.

847-270-4632