FDA Regulatory References List

Current Applicable FDA Guidance Documents

Processes must be compliant with …
Memorandum to Registered Blood Establishments: “Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products”, May 29, 1996.

Quality Control Sheet Requirements

QC must be compliant with documentation …
21 CFR part 211.
21 CFR part 600.
21 CFR part 606.

21 CFR part 606.60(a) - Device Specific Information (Operators Manual, other directions for use)

Must address the following topics with documentation …
Product specifications (i.e., volume, concentration, counts, comparison to targets).
Informed consent/adverse events.
Product profile (i.e., container equilibration, directions for potential failed LR, filtration directions).
Miscellaneous (default values).
Calculations.
Donor profile.
RBC/plasma loss.
Maintenance.
Sampling.
Validation/QC.

Failure Investigations

Process/Procedure must be compliant with …
Written procedures for failure investigations that are in compliance with 21 CFR part 211.100 and 21 CFR part 606.100.
Production Record Review – 21 CFR part 211.192: ‘Any unexplained discrepancy…shall be thoroughly investigated…written record made and include conclusions and follow-up’.
Production and Process Controls – 21 CFR part 606.100( c): ‘All records reviewed…thorough investigation including conclusion and follow-up of any unexplained discrepancy or failure’.