

Quality Control Processes in the Preparation of Blood Products

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The first part of the talk consisted of an overview of a basic Quality Control Program.

The efficient and consistent attainment of acceptable product quality can be accomplished through the performance of a thorough Quality Control Program. The program is designed to assure that the critical control points associated with the manufacturing of blood and blood products are monitored for acceptability and to identify unacceptable trends in product quality.

Through the use of quality control procedures, products, processes and those things that can affect product quality are periodically inspected at critical control points to verify conformance to requirements. Defects and deficiencies are addressed immediately. The mechanisms employed provide immediate feedback to the staff member so production of further defects can be avoided.

Activities and documentation for the program are integrated into the manufacturing operations as tightly as possible to prevent errors and disruptions. The manufacturing operation includes the receipt of materials and supplies, the determination of donor suitability and continues through the distribution of product. Functional, cross-functional, and continuous improvement requirements and their associated structures have been defined to present an integrated, total quality control system.

The second part of the talk discussed Acceptability requirements for Products including examples of corrective action steps to be taken in the event of a QC failure.

Red blood cell , platelet (random and pheresis), and leukoreduction QC parameters were reviewed. The frequency and number of components to test was also discussed. It was noted that the trending and monitoring of this finished product QC aids in the continual improvement process within the QC program.