

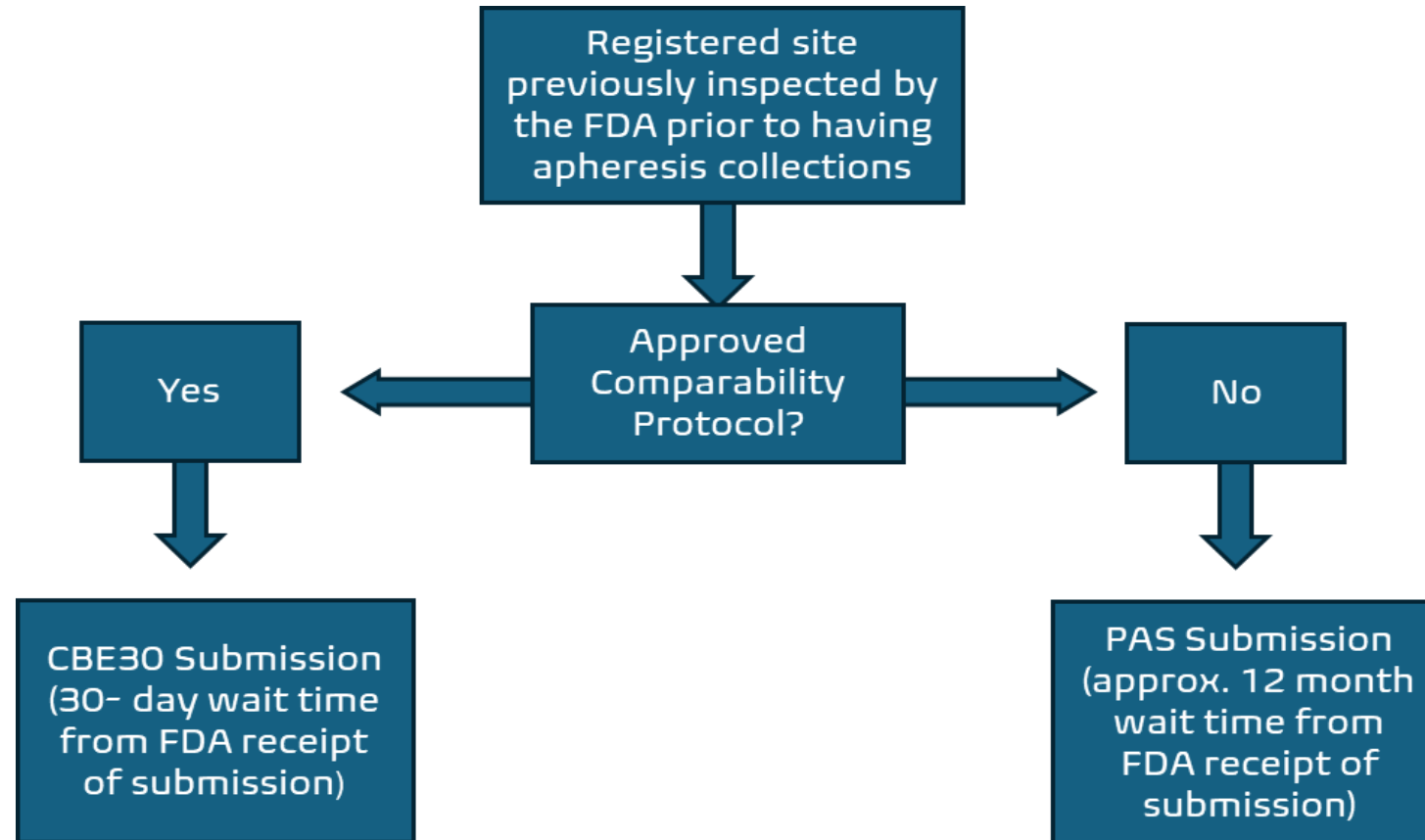
Flowcharts- Apheresis Collections Licensure Routes & Validation Data

September 2024

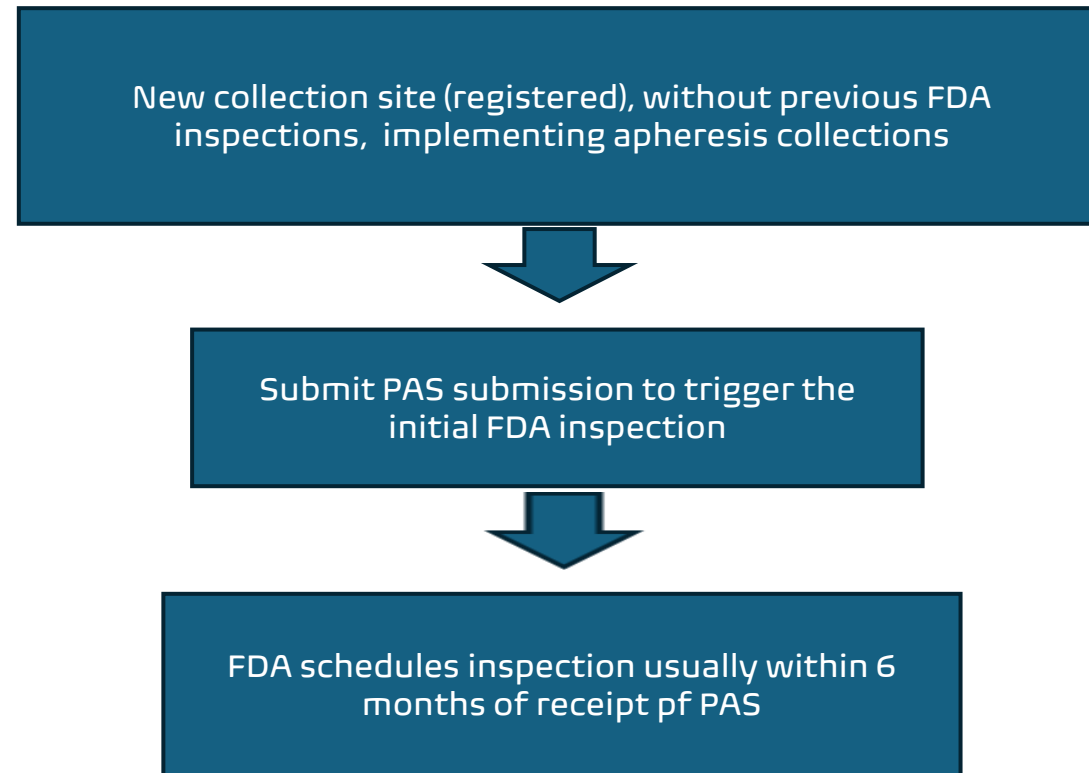


America's Blood Centers[®]
It's About *Life.*

New Collection Site for Apheresis – Registered and Previously Inspected by FDA



New Collection Site for Apheresis-Registered but Not Inspected by FDA



QC Validation Data: Apheresis Collection – Platelets

Develop a predetermined statistically valid plan based on the binomial distribution (e.g., testing 60 components from consecutive collections with no failures)

Example 1:
20 singles
20 doubles
20 triples

Example 2:
30 singles
30 doubles

Example 3:
60 doubles

QC Validation Data: Apheresis Collection – Red Blood Cells

