**ASEPTIC FILLING**

**Blood Collection Process**

1. **Proper environment of closed system**
   - Yes
   - No → Perform required upgrades or repairs to filling environment

2. **Area property cleared of material (line clearance)**
   - Yes
   - No → Clear area of inappropriate materials and institute procedures for the clearance

3. **Equipment properly cleaned and sterilised and/or new disposibles installed**
   - Yes
   - No → Clean and sterilise and/or install new disposable systems

4. **Filtering and filling as per procedures and specifications**
   - Yes
   - No → Reconcile product, correct deficiencies and reprocess if possible

5. **Product, packaging and label reconciliation acceptable inclusive of mass balance**
   - Yes
   - No → Investigate deficiencies and implement corrective actions

6. **Samples taken, labelled and recorded including retains**
   - Yes
   - No → Acquire necessary samples and document deviation report may be required
   - Yes → Quarantined product to freezer