SOP Categories

**Cleaning Procedures:**
- Cleaning Procedures for the GMP Cell Processing Facility
- Changeover Procedure between Cellular Therapy Products
- Facility Cleaning and Waste Disposal

**Deviation Management:**
- Variance and Incident Reports
- Deviation from Written Procedures

**Environmental Monitoring:**
- Environmental Monitoring
- Gowning for Controlled Environment Areas
- Decontamination of Material and Equipment

**Personnel Training:**
- Cell Therapy Training
- Personnel Training
- Retrospective Documentation of Training

**Quality Assurance/Quality Control**
- Corrective and Preventative Action Investigations and Reports
- Investigation of Out of Specification and Aberrant Results
- General On-Site Vendor Audits
- Physician Notification of Final Product Sterility Failure
- Quality Assurance Review

**Quality Management:**
- Cell Therapy Facility Documentation System
- Document Change Control
- Documentation System
- GMP-GTP Facilities Quality Management Plan
- Product Quality Assurance Program and Release and Return of Clinical GMP/GTP Products
- Transport and Storage of Hematopoietic Progenitor Cell Products
- Transportation of Cryopreserved Cells

**Regulatory/Clinical**
- Investigational New Drug (IND) Annual Report Preparation
- Preparation of an Investigational New Drug (IND) Application
- Preparation of an Investigator’s Brochure (IB)

**Standard Operating Procedures (SOP): Development & Management:**
- Generation and Management of Standard Operating Procedures
- Standard Operating Procedures

**Validation Processes:**
- Equipment Qualification
- Validation of Procedures and Equipment
- Validation
- Vendor Qualification Process