



INSPECTION AGENDA – STEM CELL

Inspection Activity

Opening Meeting

- Introduction from FDA Lead Inspector
- Discussion of Scope, Inspection Plan and GMP Standard
- Timetable
- Attendance Sheet
- Company Introduction and Overview

Design and Lay-out Review prior to Site Inspection

- (Storage Area, Production Areas, Utilities, Quality Control Laboratory)

Site Inspection

- **Storage Area**
 - Storage of cells (*cryogenic vessels*)
 - Cell bank system (*if applicable*)
 - Cryopreservation
 - Temperature and Nitrogen level monitoring
 - Preventive Maintenance of cryogenic vessels
 - Alarm system of cryogenic vessels
 - Backup system in case of power failure
 - Contingency plan in case of equipment break down
- **Processing Area**
 - Gowning and Handwashing Procedures
 - Receiving of cells
 - Cell Culture Area
 - Contamination control measures
 - In-process checks
 - Handling of cultured cells



- Labeling of finished product
- Waste Disposal
- **Quality Control Laboratory**
 - Donor Testing
 - Handling of Reagents and Media
 - Sterility Room Qualification
 - Quality Control checks *but not limited to: (specifications and records)*
 - Cell Characterization
 - Cell Count and Viability
 - Endotoxin
 - Sterility Test
 - Microbial Contamination Testing
 - Mycoplasma
 - Out of Specification Procedure

Documentation

- **Quality System**
 - Quality Risk Management
 - Release Procedure
 - Change Control
 - Deviation
 - CAPA
 - Supplier Qualification
 - Handling of reject cells
- **Qualification and Validation**
 - Air Handling Unit System
 - Cleanroom Qualification
 - Biosafety cabinet
 - Biosafety level
 - Quality Control Instruments
 - Water System *(if applicable)*
 - Computer System *(if applicable)*
- **Patient Record**



- Source of cells (*autologous or allogenic*)
- Unique numbering system
- Donor Selection
- Donor Screening
- Patient Monitoring Sheets
- Release controls prior to administration of product to patient
- **Other relevant documents**
 - Collection of cells from donor (*procedure*)
 - Freezing and thawing of cells (*procedure*)
 - Handling of Product Complaint, ADR/ADE
 - Clinical Protocol
 - Outsourced Activities
 - Self-Inspection

Report Writing

Discussion of audit findings