| FACT CT Inspection Agenda Example | | |
| --- | --- | --- |
| FACT Renewal Inspection  Hospital and Medical Center  Washington DC, USA | | |
|  | | |
| DAY/TIME | Meeting Topic | Attendees (name and role) |
| **DAY 0** December 31, 2021 | | |
| TBD | Inspection Team Pre-Inspection Meeting | All inspectors |
|  | | |
| **DAY 1** January 1, 2022 | | |
| 08:00 | Introductory Meeting | All inspectors,  Program Director,  Director/Med Director – Clinical, Apheresis, Cell Processing  Quality Managers, Managers, Supervisors  Other leadership |
| 08:45 | Clinical Inspection Tour with Interviews:  Inpatient/Outpatient clinics, Pharmacy, Radiology, ICU, ER, OR (if collecting marrow) | Clinical inspector  Clinical coordinator for inspection |
| Apheresis Inspection Tour with Interviews | Apheresis inspector  Clinical coordinator for inspection |
| Cell Processing Inspection Tour with Interviews | Processing inspector  Clinical coordinator for inspection |
| 09:30 | Individual Sections:  Quality Review | Clinical inspector  Clinical coordinator for inspection |
| Apheresis inspector  Clinical coordinator for inspection |
| Processing inspector  Clinical coordinator for inspection |
| 10:30 | Break (as needed) | |
| 10:45 | Resume individual inspections:  Quality Review | Clinical inspector  Clinical coordinator for inspection |
| Apheresis inspector  Clinical coordinator for inspection |
| Processing inspector  Clinical coordinator for inspection |
| 12:00 | Lunch break:  Inspectors’ closed meeting | All inspectors |
| 12:45 | Resume individual inspections:  Patient or Product Record Review | Clinical inspector  Clinical coordinator for inspection |
| Apheresis inspector  Clinical coordinator for inspection |
| Processing inspector  Clinical coordinator for inspection |
| 14:15 | BREAK (as needed) | |
| 14:30 | Resume individual inspections (Data Management, Clinical Outcomes, Marrow, Off-site storage as needed) | Clinical inspector  Clinical coordinator for inspection |
| Apheresis inspector  Clinical coordinator for inspection |
| Processing inspector  Clinical coordinator for inspection |
| 16:00 | Inspectors’ closed meeting | All Inspectors |
| 16:30 | EXIT INTERVIEW | All inspectors  Program Director,  Director/Med Director – Clinical, Apheresis, Cell Processing  Quality Managers, Managers, Supervisors  Other leadership |

|  |  |  |
| --- | --- | --- |
| Contact Information | | |
| **ROLE** | **NAME** | **CELL PHONE NUMBER** |
| Team Leader |  |  |
| Clinical Inspector – Adult |  |  |
| Clinical Inspector – Pediatric |  |  |
| Apheresis Inspector |  |  |
|  |  |  |
| Cell Processing Inspector |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| Program Director |  |  |
| Clinical Program Quality Manager |  |  |
| Marrow Collection Facility Medical Director |  |  |
| Apheresis Medical Director |  |  |
| Apheresis Quality Manager |  |  |
| Cell Processing Director |  |  |
| Cell Processing Medical Director |  |  |
| Cell Processing Quality Manager |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| FACT Coordinator |  |  |