1. **Purpose**

This document defines the policies and procedures for managing FDA inspections conducted at company facilities. All employees shall cooperate with the FDA to the fullest extent required by law and as established in relevant FDA regulations.

1. **Scope**

This procedure applies to all employees, subcontractors, and others who manage and otherwise participate in FDA inspections

1. **General** 
   1. **Definitions** – N/A
   2. **Responsibilities**

**Quality** – Quality is responsible for leading the FDA inspection and ensuring informational requests fulfilled with the appropriate documentation and records. Quality is responsible for maintaining any FDA inspection records and any follow-up activities

**All Employees** – All employees are responsible for participating and cooperating with a FDA inspection to the extent specified in this procedure.

* 1. **Equipment and Materials** – N/A
  2. **Safety Precautions** – N/A
  3. **Training Requirement** – All employees associated with medical devices shall be trained to this procedure.
  4. **Record Management** – All inspection records, FDA Establishment Inspection Reports (EIR), and FDA Form 483 are maintained by the Quality Department.
  5. **Reference Documents and Materials**

**21 CFR 820** – FDA Quality System Regulations

**FDA Inspection Guides** – Guide to Inspections of Medical Device Manufacturers

1. **Procedure**

Although regulation allows for unscheduled FDA inspections, inspections are generally scheduled to ensure appropriate records and staff are available. The Quality Management Representative will lead FDA Audit activities. In the event the Management Representative is unavailable; the Deputy Management Representative will be substituted.

* 1. **Audit Preparation**

In preparation for a FDA inspection, the following activities shall be completed:

* Review Quality Systems and Procedures
* Review any previous FDA Form 483’s.
* Assign responsibilities to the team and ensure each individual understands their role (i.e. greeter, notetaker, runner, etc.)
* General overview of code of conduct, room assignments, etc.
  1. **During the Audit**

During the FDA Inspection, all employees shall cooperate with the FDA to the fullest extent required by law and as established in relevant FDA regulations. Upon arrival, the FDA Inspector shall be politely asked to show his/her credentials and to disclose the intent of their visit. Once credentials are verified, the inspector shall be escorted to a conference room. FDA Inspector questions and inquiries will be directed to the employee with the appropriate expertise. Answers shall be as short and direct as possible to satisfy only the question asked by the inspector. Employees are directed to be honest and readily admit if they do not know the answer, do not ramble or go on tangents.

Employees should never sign any FDA documents without knowledge of Management Representative and/or General Council. This is to protect the employee from unknowingly signing documents that can subject them or the company to liability.

* + 1. **Excluded Documentation and Records**

Documents that the FDA may not inspect, unless voluntarily provided to the FDA include:

* Internal and Supplier Quality Audits (only records necessary to demonstrate activities are completed)
* Management Review (only records necessary to demonstrate activities are completed)
* Financial Data
* Sales, Pricing, and Customer Data (other than traceability records)
* Personnel Data (other than records necessary to demonstrate competency and qualifications)
  + 1. **Record Requests**

All records and procedures requested by the FDA inspector shall be provide as physical documents. These shall be printed in duplicate from a workstation removed from the auditor. One copy shall be provided to the FDA inspector; the second copy shall be provided to the notetaker or Management Rep.

* 1. **Audit Completion**

Following the FDA Inspection, the Management Representative shall correspond with the FDA as necessary to obtain an Establishment Inspection Report and resolve any 483’s that were reported.

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0020 |  |  | Initial release of the procedure for managing FDA Audits. |