Regulatory Agency Interactions

1. PURPOSE

Describe how the Company will react to correspondence and/or audits by regulatory agencies.

2. SCOPE

This procedure applies to all correspondence and inspections/audits by regulatory agencies such as but not limited to FDA. The scope includes activities that are compliance/quality related as well as activities that are related to regulatory registrations and applications.

3. REFERENCES

3.1 US FDA 21 CFR PART 11 Electronic Records
3.2 US FDA 21 CFR PART 801 Labeling
3.3 US FDA 21 CFR PART 803 Medical Device Reporting
3.4 US FDA 21 CFR PART 806 Medical Devices; Reports of Corrections and Removals
3.5 US FDA 21 CFR PART 807 Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices
3.6 US FDA 21 CFR PART 820 Quality System Regulation
3.7 US FDA 21 CFR PART 888 Orthopedic Devices
3.8 SOP-01-00009: Quality Auditing Procedure

4. DEFINITIONS AND ACRONYMS

FDA: Food and Drug Administration
CFR: Code of Federal Regulations

5. RESPONSIBILITIES

5.1 Quality function
- Responsible for composing and maintaining this procedure.
- Responsible for reviewing, approving and following this procedure.
- Responsible for oversight and control of this procedure.

5.2 All Personnel performing activities described in this procedure
- Responsible for understanding and complying with this procedure.

6. PROCEDURE

6.1 Correspondence with regulatory agencies
6.1.1 All correspondence received from regulatory agencies (email, letters, voicemail) will be directed to the President as applicable.
6.1.2 Any correspondence requiring a reply or follow-up will be addressed by the President/ as applicable.
6.2 Audits/Inspections by regulatory agencies

6.2.1 Upon arrival at the Company facility, any person identifying themselves as being from a regulatory agency should be made comfortable and seated. Ask the person's name and the agency/company that they represent.

6.2.2 Ask the Operations Manager or the President to meet the individual. One of these people will accompany the auditor/inspector for the entire visit.

6.2.3 The person meeting the visitor will confirm their credentials and purpose of visit. A Form FDA 482 should be issued by the FDA inspector. A conference room will be reserved in advance if the visit is pre-announced. A conference room will be arranged at the time if the visit was not pre-announced.

6.2.4 During the audit/inspection, someone will be designated to capture notes. The notes will be compiled and distributed to the file and personnel who were present during the inspection. The notes may be used to construct a response to any FDA Form 483 that may be issued.

6.2.5 Any 483's that may be issued will be addressed by the Operations Manager and/or the President as applicable.

6.2.6 If a FDA inspector requests to see audit records (i.e. Internal Audits, Third Party Audits, or Management reviews) certifications of the audits are to be supplied and not the actual audit records.

6.2.7 If a FDA inspector requests to take photographs or make audio recordings while on site, the inspector should be informed that it is against Company policy to allow these types of recordings as per this procedure.

6.2.8 If an auditor/inspector from any regulatory agency requests to have copies of documents that are being reviewed, the copies will be provided and marked as confidential

6.3 Records

6.3.1 A staging area will be designated to review all records requested by the inspector/auditor prior to the records being provided to the inspector/auditor. The file/record will be quickly reviewed to ensure the complete requested file/record has been selected and to ensure that extraneous materials have not inadvertently become part of the file/record. Any computer system generated records will be reviewed to make sure that the entire record is legible and complete prior to sharing with the inspector/auditor.

6.3.2 All interactions and correspondence with members of regulatory agencies will be documented and retained. The exception to this is when the Company may seek unofficial guidance or advice from regulatory agencies.

6.3.3 The President or the Operations Manager or their designee will provide any official response that may be required following an inspection by a regulatory agency.

6.3.4 The Quality function will assure the proper maintenance of all records.

END OF PROCEDURE.