[COMPANY X] STANDARD OPERATING PROCEDURE	PROCEDURE NUMBER SOP-AAA-004	
DEPARTMENT: GENERAL ADMINISTRATION	EFFECTIVE DATE:	
SOP TITLE: FDA INSPECTION	SUPERSEDES: SOP-AAA-003	PAGE: 1 OF 3

I. OBJECTIVE

1.0 To define the guidelines to be followed when handling a Food and Drug Administration (FDA) inspection.

II. SCOPE

1.0 The scope of this SOP applies to all departments. The Quality Assurance Manager or designee will act as the company escort and be responsible for informing the FDA of the contents of this SOP prior to the start of the inspection.

III. REFERENCES

1.0 ISO 13485 Medical Devices – Quality Management Systems
2.0 MDSAP Medical Device Single Audit Program
3.0 21 CFR Part 11 Pharma Manufacturing

IV. DEFINITIONS

1.0 FDA Form 482 – a formal notice issued to the owner, operator, or agent in charge of a facility at the time of an inspection. It serves as the official notification that the FDA is exercising its authority to inspect the premises under Section 704(a) of the Food, Drug, and Cosmetic Act.
2.0 FDA Form 483 – issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that, in their judgment, may constitute violations of the Food, Drug, and Cosmetic (FD&C) Act and related Acts.
3.0 FDA Form 484 – a document issued by the investigator to the firm to acknowledge the collection of samples during an inspection. It lists the description and quantity of the samples taken.

V. ATTACHMENTS

1.0 N/A

VI. PROCEDURE

1.0 Upon arrival, the receptionist will request that all present FDA investigators identify themselves by presenting the appropriate photo ID and signing in. The receptionist will immediately call the Manager of Quality Assurance or designee to inform them about the FDA's arrival.
2.0 The Manager of Quality Assurance or designee will immediately notify the appropriate Department Managers that the FDA is on site.
3.0 The Manager of Quality Assurance or designee will go to the reception area and escort the FDA investigator(s) to the Conference Room or appropriate Manager's office.
4.0 The Manager of Quality Assurance or designee will request the purpose of the visit and written notice of the inspection (FDA Form 482) in order to verify that the company, location, and date of the inspection apply to this site and are correctly incorporated on the FDA Form 482.

5.0 Prior to starting the inspection, the Manager of Quality Assurance or designee must inform the FDA that cameras, tape recorders, or any similar recording devices are not allowed on the premises.

6.0 The Manager of Quality Assurance or designee will accompany the FDA investigator(s) at all times during the inspection. If more than one investigator is present, additional escorts will be appointed by the Manager of Quality Assurance or designee to accompany each investigator, should they decide to look at different areas simultaneously.

7.0 The Manager of Quality Assurance or designee will inform the FDA investigator(s) that all communications/questions must be directed at the official [COMPANY X] escort(s) and/or Department Manager(s) only and not to the plant line workers. If the escort(s) and/or Department manager(s) cannot answer the question(s), the escort(s) must relay the question(s) to the appropriate company personnel for resolution.

8.0 The Manager of Quality Assurance or designee is responsible for making and retaining a duplicate copy of any and all documents supplied to the FDA investigator(s). Each page of every document provided to the FDA investigator(s) must be stamped "CONFIDENTIAL".

9.0 The Manager of Quality Assurance or designee must retain a duplicate of any and all samples given to the FDA investigator(s). Obtain a receipt (FDA Form 484) for all samples given.

10.0 The Manager of Quality Assurance or designee shall hold a brief meeting with the FDA investigator(s) at the completion of the inspection so the company escort(s) can be informed of the FDA's observation and/or written report (FDA Form 483).

11.0 The company will not permit the signing or review of any documents, such as affidavits, by any company personnel.

12.0 After the completion of the inspection, it is the responsibility of Quality Assurance and/or Regulatory Affairs to respond, in writing, to the FDA on any observations stated on the FDA Form 483.

VII. RESPONSIBILITY

1.0 It is the responsibility of the Quality Assurance Manager or designee to ensure that this procedure is adhered to.

VIII. IMPLEMENTATION

1.0 This procedure shall be implemented on or before the effective date appearing on this document.

IX. REASON FOR REVISION

(08/04)

1.0 Changed all references from [COMPANY Y] to [COMPANY X]

(10/05)

2.0 Procedure reviewed. No changes needed.

(09/07)

3.0 Procedure reviewed. No changes needed.

(04/09)

4.0 Procedure reviewed. No changes needed.

(09/10)

5.0 Procedure reviewed. No changes needed.

(02/16)

6.0 Procedure reviewed. No changes needed.

(03/21)

7.0 Updated format.

8.0 Inclusion of definitions for FDA Form 482, FDA Form 483, and FDA Form 484.

9.0 The following references were added to Section IV: ISO 13485, MDSAP, and 21 CFR Part II.

(03/26)

10.0 Revised format.

11.0 Corrected Department Title to “General Administration”