Name of Supplier:_____

Address:_____

City, State, Zip Code:_____

Company Represenative:_____

Title:_____

Audit Standards:_____

Product(s) Perchased:_____

Purpose of Audit:_____

Date Audit Conducted:_____

Auditor's Name	Signature	Title	Date

GENERAL INFORMATION
1. Company Organization
2. Is the facility FDA registered?
3. Is the facility certified to any Quality System Standards?
4. Total Number of employees:
5. Are there other facilities of the company that manufacture the same product?
6. Date of the last FDA inspection:
Comments:

ORGANIZATION/PERSONNEL/FACILITY
1. Is a Quality Manual or plan in place and approved by Management?
2. Is responsibility and authority for product quality assigned to personnel that are independent of manufacturing? (An organization chart will be useful)
3. Is there a designated individual responsible for the QA Program?
4. Are resources adequate in areas such as management, operations, verification and internal audits?
5. Is there a written audit procedure?
6. Are internal quality audits conducted regularly?
7. Does management review the audits?
8. Does Quality Assurance review new/revised drawings and specifications?
9. Are current work instructions, drawings, etc. readily available at each operation or work station?
10. Is there a formal deviation procedure?
11. Are personnel familiar with work instructions adequately trained or certified?
12. Is the training formally documented?
13. Are there proper dress requirements to reduce product contamination?
14. Are there procedures for contamination control for equipment and product? Examples include trash, sewage, byproducts, and pest control.
15. Are buildings of suitable design and contain sufficient space to perform necessary operations, prevent mix-ups and assure orderly handling? For: Production Warehousing Packaging/Labeling Inspection/Measuring
16. Is there a maintenance schedule posted on process or inspection equipment for adjustment/calibration and cleaning?

17. Are there calibration procedures and records along with frequency of calibration?
18. Are automated data processes used as part of process or the quality system?
19. If used, is the computer software validated for its intended use with a protocol?
Comments:

DOCUMENT CONTROL
1. Is there control of accuracy and usage of current version of documents and the removal of obsolete documents?
2. Is there a system for tracking/monitoring document changes?
3. Does it include a record describing the change, signature of approving individuals, approval and effective date?
4. Are the changes communicated to affected personnel in a timely manner?
Comments:

DESIGN CONTROL
1. Is there a system to control the design of products? (design input, output, review, verification, validation, transfer, changes, and design history file)
Comments:

PURCHASING CONTROLS
1. Is there a formal program for supplier survey and evaluation?
2. Are specified requirements for materials/service maintained?
3. Are agreements in place with suppliers to notify the manufacturer of changes?
Comments:

IDENTIFICATION AND TRACEABILITY
1. Is there a system to prevent product mix-ups during all stages of receipt, production and distribution?
2. Does traceability exist with each lot/batch with use of control numbers or other system that provides an identifier?
Comments:

PRODUCTION AND PROCESS CONTROLS
1. Are there procedures for process controls? Is the following information recorded during process: Components used Equipment Dates Operation Test Results
2. Do they include documented instructions, standard operating procedures and methods that define and control the manner of production?
3. Is there monitoring and control of process parameters during production?
4. Is there compliance with reference standards or codes?
5. Are there procedures to document changes to a specification, method, process or procedure?
6. If environmental conditions could potentially have an effect on product quality, are procedures in place to adequately control and monitor the conditions?
7. Have all production processes been verified through validation studies which include activities, results, approval of validation and major equipment validated?
Comments:

ACCEPTANCE ACTIVITIES
1. Are there procedures for acceptance activities for receiving, in-process and finished goods acceptance?
2. Are the results of acceptance activities documented?
3. Is identification of acceptance status maintained throughout manufacturing, packaging, labeling, and installation to ensure that only products which have passed the required acceptance activities are distributed or used?
4. Reserve samples of each lot are retained for_____
Comments:

NONCONFORMING PRODUCT
1. Is there a system in place to ensure that product that does not conform to specified requirements is prevented from unintended use?
2. Does the system address identification, documentation, evaluation, segregation, disposition of nonconforming product?
3. Is responsibility defined for review and disposition of nonconforming product?
4. Are there procedures for reprocessing?
Comments:

CORRECTIVE AND PREVENTITIVE ACTION
1. Is there a system for handling corrective and preventive actions?
2. Do the procedures cover internal observations such as inspection and test records, internal audits?
3. Do the procedures cover external observations such as customer complaints and service records?
Comments:

LABELING AND PACKAGING
1. Are there procedures to control labeling activities?
2. Do they include integrity, inspection, storage, and operations?
3. Is packaging designed to protect the material from damage?
Comments:

HANDLING, STORAGE, DISTRIBUTION
1. Are there procedures to ensure mix-ups, damage, deterioration or contamination of product do not occur during handling?
2. Are materials used to facilitate stock rotation?
3. Are there adequate distribution records?
Comments:

RECORDS
1. How long are records retained?
2. Are records stored to prevent deterioration and loss?
3. Are records stored to prevent deterioration and loss?
4. Is there a system for Device Master Records?
5. Is there a system for Device History Records?
6. Are complaint files maintained?
7. Who handles the complaints?
Comments:

STATISTICAL TECHNIQUES
1. What statistical techniques are utilized for process capability or product characteristics – Statistical Process Control (SPC) or Statistical Quality Control (SQC)?
Comments:

SUMMARY
1. Was the supplier cooperative during the audit?
2. Does the supplier have a good understanding of GMP?
3. List areas that need improvement:
Comments:

SURVEY RESULTS
Reviewed By:
Signature/Date:
Approved: Yes_____ No_____ If not approved, state why and list corrections necessary in Section 3 under “Summary”. Indicate timing of actions if it is known.