1. Purpose

This document defines the company's policies and procedures for completing and documenting corrective and preventive actions. These policies and procedures include CAPA inputs, problem identification, severity categorization, activity plan, closure, and information awareness.

2. Scope

This procedure applies to all corrective and preventive actions initiated. Issues regarding products that have not been released to commercialization are exempt from the CAPA process.

3. General

3.1. Definitions

- **Corrective Action** – Action taken to eliminate the cause of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence
- **Nonconformity** – Non-fulfillment of a specified requirement
- **Preventive Action** – Action taken to eliminate the cause of a potential nonconformity, defect, or other undesirable situation in order to prevent occurrence

3.2. Responsibilities

Quality Management – Quality Management is responsible for the implementation and continued compliance with the procedures specified in this document and by the regulatory authorities.

3.3. Equipment and Materials – N/A

3.4. Safety Precautions – N/A

3.5. Training Requirement – Quality Assurance personnel shall be trained to the procedures specified in this document.

3.6. Record Management – All CAPA documentation are managed and maintained by the Quality Department.

3.7. Reference Documents and Materials

21 CFR 820 – FDA Quality System Regulations

SOR/98-282 – Canadian Medical Device Regulations

MDD 93/42/EEC – Medical Device Directive

ISO 13485 – Medical Device Quality Management Systems

ISO 14971 – Medical Devices – Application of Risk Management to Medical Devices

QF-0012-1 – Corrective and Preventive Action (CAPA) Form

QP-0011 – Customer Complaints and Advisory Notices

4. Corrective and Preventive Action (CAPA) Procedure

The Corrective and Preventive Action (CAPA) process is a systemic approach to eliminating the cause of an existing or potential nonconformity, defect, or other undesirable situation in order to prevent the occurrence. The actions taken to eliminate the root causes of actual nonconformance(s) shall be to a degree appropriate to the magnitude of problems and consistent with the associated risks. The problem solving methodology utilized contains elements from PDCA, DMAIC, and 8D principles.

4.1. CAPA Inputs

Inputs for the CAPA process include, but are not limited to data analysis and management review of the following:

- Process Monitoring
- Complaint Files
- Nonconforming Product
- Acceptance Activities
- Servicing
- Audits
- Medical Device Reporting and Recalls

Not all complaints and nonconforming products are CAPA's, it is dependent on items such as risk and type of error (systematic vs. random).

4.2. Problem Identification

Effort shall be taken to clearly and completely describe the problem associated with the CAPA. The problem statement shall define an achievable scope and contain as many pertinent facts as are available. Ambiguous information, feelings, opinions, etc shall not be included in the problem statement.

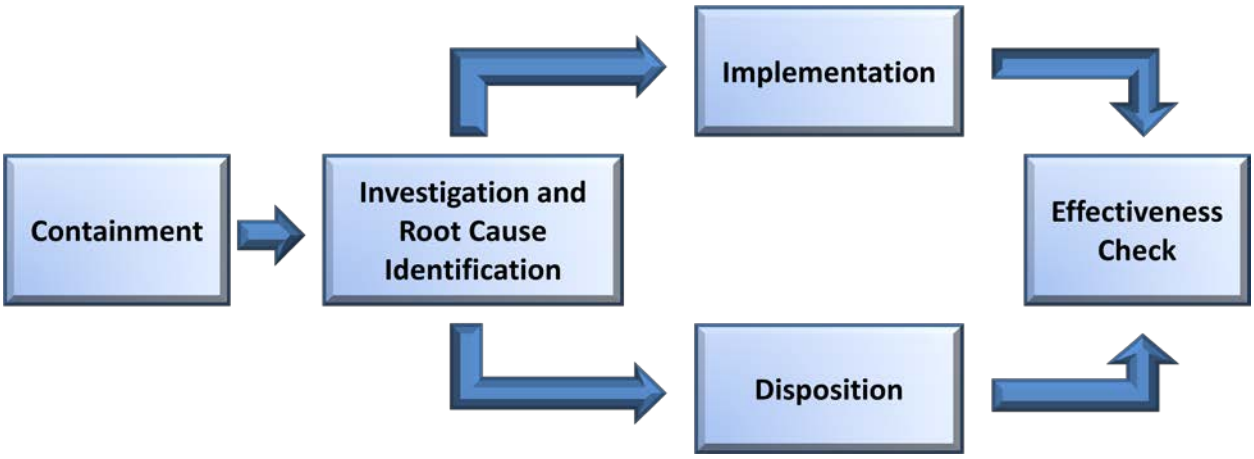
4.3. Severity Categorization

The severity of a CAPA is determined utilizing the methodology described in ISO 14971. Each CAPA shall be classified as Minor, Moderate, or Major based on the associated risk to the end user and the business. The severity of the CAPA drives priority levels, company awareness, and the degree of the actions taken in the Action Plan. Tables in Appendix A shall be utilized to determine associated risk.

4.4. CAPA Action Plan

The following planned activities shall be completed as necessary to carry out an effective CAPA. Containment and Disposition activities may not be required for preventive actions or actions that do not involve product. Each activity shall be documented in the CAPA file and the CAPA will remain open until each activity has been completed and approved by Department and Quality Management.

The activity plans shall be initiated upon the opening of a CAPA by the Quality Department and identification of the problem or issue. All reasonable efforts shall be made to complete and close CAPA plans in a timely manner without undue delay.



4.4.1. Containment

The objective of the containment phase is to prevent the distribution or propagation of the identified defect or issue. This is done immediately upon identification of the problem to minimize risk and actions taken should error on the side on conservatism. Once the root cause has been determined in subsequent phases, the containment activities can be re-evaluated to release items that are unnecessarily being held. Examples of containment activities include: QC Hold, Product Quarantine, and Production Shutdown.

4.4.2. Investigation

The objective of the investigation activity is to gather and analyze as much information/data as necessary to determine the root cause of the issue (if possible) and an effective solution to prevent its reoccurrence. Common tools utilized in root cause analysis include:

- Fault-tree Analysis
- 5 “whys”
- Fishbone Diagrams
- Pareto Charts
- Scatter Diagrams

If during the investigation information is uncovered that should be reported to customers, the advisory notice procedure defined in Doc QP-0011 shall be utilized.

4.4.3. Implementation Plan and Execution

The implementation is a four part activity; PDCA. The first is developing the implementation plan. the second is the execution of that plan, the third is verification or validation that activities were effective and do not adversely affect the medical device, and the fourth and final step is to fully implement the corrective or preventive actions. The actions taken shall be optimized to the magnitude of the problem and associated risk. As part of the implementation plan, consider the effectiveness check and the criteria for acceptance.

4.4.4. Disposition

The disposition of affected product may proceed at any point following the completion of the investigation. All associated product shall be dispositioned prior to closure of the CAPA. The following are examples of acceptable dispositions:

- No impact to product, acceptable for distribution
- Rework
- Scrap
- Use As Is with justification

4.4.5. Effectiveness Check

The effectiveness check shall verify or validate that the corrective and preventive action had the intended results and did not adversely affect the quality of finished product. The effectiveness check shall provide confidence that the risk of reoccurrence has been appropriately mitigated.

4.5. CAPA Closure and Information Awareness

Corrective and Preventive Actions shall remain open until all action items are completed and documented. Once complete, the documentation shall be reviewed and approved by the responsible department management and the quality department. The responsible department management shall ensure that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems.

Upon opening a CAPA, the expected closure date is set to 60 days. In the event additional time is necessary to complete all applicable sections, an extension shall be submitted and approved by Quality Management. Granted extensions shall be noted on the CAPA Log.

5. Revision History

Rev #	Doc #	Effective Date	CHO	Description of Change
01	QP-0012			Initial implementation of the Corrective and Preventive Action Process

6. Appendix A – Risk Assessment

The following risk assessment methodology has been developed utilizing principles from ISO 14971.

6.1. Severity Assessment

Severity Index	Severity Category	Description of Severity
S1	None	No safety concerns and minimal to no impact on quality of product or service
S2	Minor	Customer annoyed, isolated event
S3	Moderate	Systematic issues. Potential for minor safety issue
S4	Serious	Significant to major safety issue and/or loss of efficacy
S5	Critical	Major Safety issue / loss of regulatory compliance

6.2. Probability of Occurrence Assessment

Probability Index	Rate of Failure
P1	< 0.01 %
P2	0.01 % - 0.10 %
P3	0.11 % - 1.00 %
P4	1.01 % - 10.00 %
P5	> 10.00 %

6.3. Risk Assessment

Risk Index R = S x P	Severity Category
R1 to R6	Minor
R8 to R10	Moderate
R12 to R25	Major