Training Management Policy

Role	Position/Department	Name	Date
Author			
Reviewer			
Approver			

[Company Name], Inc.

Table of Contents

1. Purpose

The purpose of this policy is to establish requirements for training all personnel at [Company Name], Inc. (hereinafter referred to as “the Company”) whose activities affect product quality or the operation of the Quality Management System (QMS), ensuring they possess the necessary knowledge and skills to perform their duties, thereby improving product quality and operational effectiveness.

2. Scope

This policy applies to the training of all employees engaged in medical device operations at the Company.

3. Normative References

21 CFR Part 820 - Quality Management System Regulation (QMSR)

ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes

4. Definitions

Term	Definition
Quality Management System (QMS)	Management system to direct and control an organization with regard to quality. (ISO 13485:2016, clause 3.10)
Competence	Ability to apply knowledge and skills to achieve intended results. (ISO 13485:2016, clause 3.3)
Training	Process to provide and develop knowledge, skills, and behaviors to meet requirements.
Verification	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. (ISO 13485:2016, clause 3.43)
Validation	Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. (ISO 13485:2016, clause 3.42)
QMSR	Quality Management System Regulation as codified in 21 CFR Part 820.

5. Training Objectives

The Company shall ensure that all personnel recognize the relevance and importance of their activities and how they contribute to the achievement of quality objectives through the following training objectives:

a) Ensure all personnel understand how their activities contribute to achieving quality objectives and recognize the significance and importance of their work.

b) Provide or maintain the competence necessary for personnel performing work affecting product quality to carry out their assigned tasks.

c) Ensure all personnel recognize what defects may occur in medical devices when specified work is performed improperly.

d) Ensure personnel performing verification and validation activities recognize defects or errors that may be encountered through their work.

6. Training Administrator

The Training Administrator shall be designated by the Head of Medical Device Operations and shall have the following responsibilities:

a) Identify the competence necessary for personnel performing work affecting product quality.

b) Provide training or take other actions to satisfy competence needs.

c) Evaluate the effectiveness of the training or other actions taken.

d) Develop and implement training plans in a systematic manner and maintain records.

e) Report training implementation status in writing to the Domestic Quality Operations Manager.

f) The Training Administrator may designate qualified Training Instructors to ensure reliable execution of practical aspects of training and provide instructions regarding practical training matters.

7. Training Instructors

7.1 Qualification

a) Personnel who primarily conduct training shall possess competence appropriate for trainers.

b) When a Training Instructor other than the Training Administrator is appointed, the Training Administrator shall select and qualify the instructor from qualified personnel.

7.2 Competence

a) Training Instructors must hold a competence evaluation rating of “A” for the work subject to training.

b) In addition to the competence evaluation, a minimum number of years of experience may be established if deemed necessary.

c) If specific qualifications are required for Training Instructors separate from internal competence evaluations (e.g., soldering certification), such qualifications must be held.

8. Training Content

Training shall include periodic training and introductory training for newly hired employees, mid-career hires, and transfers from other departments, covering the following content. For introductory training, training time may be shortened or omitted based on work experience or qualifications.

a) QMSR (21 CFR Part 820)

b) ISO 13485:2016

c) Product overview (including Product Master Files)

d) Federal Food, Drug, and Cosmetic Act, relevant regulations, and FDA guidance documents

e) Training on management work procedures and other necessary procedures

f) Ad-hoc training shall be conducted on matters deemed necessary.

g) On-the-job training (OJT) necessary for acquiring competence to perform work shall be conducted as needed.