1. **Purpose**

This document defines the policies and procedures for ensuring the competence of personnel performing work associated with the Quality Management System. These policies and procedures define how requirements are established, fulfilled, recorded, and evaluated for effectiveness.

1. **Scope**

This document applies to employees and job functions that are associated with the Quality Management System. Departments and job functions not associated with the Quality Management System are exempt from this process.

1. **General** 
   1. **Definitions** – N/A
   2. **Responsibilities**

**Department Management** – Department Managers are responsible for ensuring each employee receives the necessary training and is competent to complete the assigned job functions. Department Managers are responsible for establishing and maintaining the training and competency requirements for each position.

**Human Resources Management** – Human Resources is responsible for maintaining records and documentation associated with Personnel Qualifications.

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

* 1. **Equipment and Materials** – N/A
  2. **Safety Precautions** – N/A
  3. **Training Requirements** – Department managers and employees working within the Quality Management System shall be trained to this procedure and the training documented.
  4. **Reference Documents and Materials**

**21 CFR 820** – FDA Quality System Regulations

**SOR/98-282** – Canadian Medical Device Regulations

**MDR 2017/745** – EU Medical Device Regulation

**MDD 93/42/EEC** – EU Medical Device Directive

**ISO 13485** – Medical Device Quality Management Systems

**QP-0003** – Document Control Process

**QF-0004-1** – Training Record

**QF-0004-2** – Competency Record

1. **Training and Competency Assessment Procedure**

The company utilizes two mechanisms to ensure employees are competent and have been effectively trained to perform the required job functions: Personnel Qualifications and Quality System Training. Personnel Qualifications is managed and documented by Human Resources and is a compilation of education, experience, certifications, etc. Quality System Training is managed by department managers and includes the skills and training directly associated with internal policies and procedures.

The company determines management positions to be considered competent to perform required job duties based on Personnel Qualifications. Management does not require Quality System Training unless job function involves direct interaction with product and/or service quality.

* 1. **Personnel Qualifications**

The Personnel Qualifications are determined by department management and defined within a job description that is maintained by Human Resources. The job description is specific to the position and is comprised of information such as position title, location, description of responsibilities, and education/skill requirements.

Documented evidence of Personnel Qualifications is maintained within each employee’s personnel files. The type of documented evidence is determined by Human Resources and is dependent on the requirements defined within the job description. Examples include job applications, resumes, certifications, etc.

* 1. **Quality System Training**

The Quality System Training requirements are established and maintained by department management. The training requirements are specific to the job function(s) being performed by the employee. These requirements may change as the needs of the company change. Department managers are responsible for providing the necessary training for employees to complete assigned tasks. Training shall include any identified defects or errors that are associated with job performance or function.

Quality System Training is documented on Training Record and records maintained by department managers. A document approver that has reviewed and approved a document is considered to have read and understood the document and any associated Quality System Training requirement is fulfilled. A signed Document Change Order (CHO) shall serve as documented evidence of a fulfilled requirement for document approvers.

Department management is responsible for ensuring the completion of this training. Training records are maintained by the Quality Department.

* 1. **Training and Competency Evaluation**

The competency of non-product association employees and effectiveness of training is evaluated during employee evaluations. This review is completed annually by designated management and a documented record is maintained within each employee’s personnel file.

The competency of product association employees and effectiveness of training is evaluated documented on the Competence Record (QF-0004-2). This assessment is completed by an experienced employee once the training period is completed, as determined by management. A documented record is maintained within QMS training records.

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0004 |  |  | Initial implementation of the Training and Competency Process |