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	Revision No.:	01
	Effective Date:	<date>

Training and Competency Procedure

Document Approval

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Document Preparation Notes: (To Be Reviewed Before Issue)

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1. Purpose

To define how training and competency are identified, delivered, assessed, recorded, and maintained to ensure personnel are qualified to perform assigned activities that may impact quality, safety, data integrity, or compliance.

2. Scope

Applies to all personnel performing activities that may affect:

- product or service quality
- patient / user safety
- data integrity
- regulatory compliance

Includes employees, contractors, and temporary staff where applicable.

3. Definitions

Training

The process of providing knowledge or instruction to enable personnel to understand requirements, procedures, or tasks.

Competency

Demonstrated ability to apply knowledge and skills effectively and consistently to perform assigned tasks.

Training Record

Documented evidence that training was completed.

Competency Assessment

A documented evaluation confirming that a person can perform a task as intended.

4. Roles & Responsibilities

Update as applicable

Role	Responsibility
Management / Quality Executive	• Defines training and competency requirements • Approves training and competency requirements for roles

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Line Manager / Supervisor	- Identifies role specific training and competency needs - Ensures personnel complete required training - Confirms competency where required
Trainer / Assessor	- Delivers training - Performs or supports competency assessments
Personnel	- Complete required training - Apply training in practice - Participate in assessment assessments

5. Identification of Training and Competency Training Requirements

5.1 Role Based Requirements

Training and competency requirements shall be determined based on:

- role and responsibilities
- task complexity and criticality
- regulatory and organizational requirements

These requirements shall be documented and assessed in the Training Matrix / Register (QMSP-TC-001).

5.2 Triggers for Training

Training shall be required at a minimum:

- on induction / onboarding
- when procedures, systems, or processes change
- following scenarios, LOPA, or audit findings where training is identified as a contributing factor
- periodically based on defined refreshment intervals

Each instance of training completion shall be recorded using the Training Record Form (QMSP-TC-001).

6. Training Delivery and Documentation

6.1 Training Methods

Training may be delivered through:

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- controlled document version (e.g. SOPs, WIs)
- classroom or online instruction
- on-the-job or practical training

The selected method shall be appropriate to the task and risk.

6.2 Training Records

For each training event, a **Training Record Form (QMSP-TC-001)** shall be completed as document:

- trainee identity and role
- training topic and document reference
- training type (initial, refresher, change driven)
- training date and duration
- trainer identity
- assessment method (where applicable)

Completion of a training record confirms attendance only, not competency.

7. Competency Assessment

7.1 When Competency Assessment is Required

Competency assessment shall be required when:

- tasks are complex or high-risk
- errors could impact quality, safety, or compliance
- required by regulation or external policy
- following significant change or repeated error

7.2 Competency Assessment Records

Where competency assessment is required, it shall be documented using the **Competency Assessment Record (QMSP-TC-002)**.

The assessment record shall document:

- task or activity assessed

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- assessment method (e.g. observation, demonstration, test)
- assessment criteria
- assessment outcomes
- assessor identity and approval

Competency shall not be assessed based on training completion alone.

8. Training Matrix / Register

The Training Matrix / Register (QMSP-TC-002) shall be used to:

- define required training and competency per role
- track completion status
- identify gaps in training
- support audit and management review activities

The register provides oversight and planning and does not replace individual training or competency records.

9. Effectiveness and Review

Training and competency effectiveness shall be evaluated through:

- performance monitoring
- deviation and CAPA analysis
- audit outcomes
- management review

Where training or competency deficiencies are identified, retraining or reassessment shall be initiated and documented using the applicable forms.