
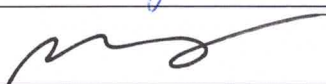




**Document Authorization:**

	Name	Date	Signature
Owner	Sijin Guo	11Dec2025	
Operation Management	Baozhong Zhao	11Dec2025	
Quality Assurance	Xibo Li	11Dec2025	

**Changes from previous version:**

Section	Summary of Changes	Change Control Number
ALL	1. New document	


	<p style="text-align: center;">STANDARD OPERATING PROCEDURE</p> <p style="text-align: center;">Employee Competency, Training and Awareness</p>	<p>Document: QUA007-1 Effective Date: 11Dec2025 Status: Effective Page 1 of 5</p>
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## 1. PURPOSE

The purpose of this procedure is to describe the process for performing and documenting training of employees.

## 2. SCOPE

This procedure applies to all employees.

## 3. INTERNAL REFERENCES

Document ID	Title

## 4. EXTERNAL REFERENCES

Document ID	Title

## 5. RESPONSIBILITIES

Job Function and/or Department	Responsibility
All Personnel	a. Maintaining their training records in a current state b. Attending required training sessions.

## 6. DEFINITION

Term	Definition
Qualified Trainer	A qualified trainer may be: a. Subject matter expert (SME) which can be an internal employee, contractor, or consultant b. The author or approver of a procedure c. An individual who has previously completed training and understands the process or system
Subject Matter Expert	An individual possessing in-depth knowledge of the particular subject based upon their education, training, and experience. Those individuals with specific expertise in a particular area or field.

## 7. PROCEDURE

### 7.1. General

7.1.1. Employees (includes temporary employees) must have the appropriate level of education, training, and experience to perform their job function. These requirements are satisfied by employee's CV and/or resume which are stored in employee profiles.

7.1.2. Contractors and consultants must have the appropriate level of education, training, and experience to perform their job function.

7.1.3. Contractors, Consultants and Temporary employees, will receive training on an as-needed basis, as determined by their job function and responsible manager.

7.1.3.1. Personnel hired on a temporary basis who perform routine, day-to-day responsibilities are considered contractors.

7.1.3.2. Contractors may have signature authority delegated to them.

7.1.3.3. Contractors are subject to the same level of training requirements as personnel based on their job function and responsibilities. Personnel hired on a temporary basis to provide advice or information are considered Consultants.

7.1.3.4. Consultants do not have signature authorization.

7.1.3.5. Consultants are subject only to the training requirements as defined by hiring supervisor or manager.

7.1.3.6. At a minimum, the hiring department will obtain a copy of a consultant's curriculum vitae (CV) or resume which will be maintained in Quality Assurance.

- 7.1.4. Training records are maintained electronically.
- 7.1.5. Employee's Job Descriptions are stored by Human Resources.
- 7.1.6. Job descriptions are updated upon promotions, internal transfers and change of job function and/or responsibilities.

NOTE: For contractors, the section of the employee's signed contract describing the scope of work (SOW) and services to be provided may be used as the job description.

## 7.2. Training Curriculum

7.2.1. The training curriculum is composed of core procedures and a list of required department and job specific SOPs as determined by the employee's job function.

7.2.2. The training curriculum is based on the employee's job function and responsibilities, listing the minimum training requirements. Example training matrix is shown below.

	ADM	EHS	INT	QUA	PRD	QUC	FIN	SUC
Production Management	x	x	x	x	x	x		
Production - Chemistry	x	x	x	x	x			
Production - Biology	x	x	x	x				
QC	x	x	x	x		x		
Supply Chain	x	x	x	x				x
Finance	x	x	x	x			x	

## 7.3. The Training Program Includes:

7.3.1. Job-specific procedure training (i.e., SOPs and work instructions)

7.3.1.1. Individual training curriculum based on job function

7.3.1.2. Individual one-on-one training with a qualified trainer.

7.3.1.3. Group training is led by a qualified trainer and captured on group training.

7.3.2. Externally led training (source is external from a qualified trainer contracted to teach a specific topic)

## 7.4. Subject Matter Expert (SME)

7.4.1. Prior experience

7.4.1.1. Documents showing evidence of prior experience (e.g., CV). This should be a brief description of previous jobs if they are pertinent to current employment.

7.4.2. Current experience

7.4.2.1. This information should be available through previous job descriptions / role profiles. Update the CV to include for example promotions, or a move to a different section. It is not possible or sensible to cover all aspects of work by the certificate of competence system, therefore these records should become particularly important when more senior positions are held within the Company.

## 7.5. Training Timelines for New Hires

7.5.1. The direct supervisor creates and assigns the training curriculum based on job function and responsibilities with the assistance of QA.

7.5.2. Training on the procedures listed in the training curriculum should be completed prior to engaging in the activities defined in the core procedures.


7.5.3. All training shall be verified by an employee's supervisor or Quality Assurance.

## 7.6. Training on Job Specific Procedures and Work Instructions

7.6.1. No more than 10 SOP training is allowed per day to maintain training outcome.

7.6.2. Supervisors or Quality Assurance will verify completed training.

7.6.3. Authors and approvers of a new or revised procedure are considered trained by virtue of the document

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review and approval process.

#### 7.7. On-The-Job Training

7.7.1. The training is focussed on competence in processes and equipment use. When competence has been demonstrated in a certain process or piece of equipment, through sign off of certificates or on-the-job training, the individual is considered competent to work on all pieces of work employing these processes and equipment. Until a training module or on-the-job training is completed, the person can only work on the process or instrument in question under supervision.

7.7.2. Training with a qualified trainer starts with the read and understand of the procedure and the review of the procedure with the trainee.

7.7.3. Trainee observes the qualified trainer performing or demonstrating the procedure.

7.7.4. Trainee performs the procedure with the qualified trainer's assistance.

7.7.5. Trainee performs the procedure independently with qualified trainer's verification.

#### 7.8. Retraining

7.8.1. Employees will be retrained when changes occur in policies, procedures, processes, and methods or instruments.

7.8.2. If the trainee's job skill competency is deemed satisfactory, the trainer will sign and date the training document to acknowledge that the trainee has completed the training successfully and demonstrated the ability to perform the tasks independently.

7.8.3. If the trainee's job skill competency is deemed unsatisfactory, the trainer will document the assessment in the training document. The trainer will notify trainee's supervisor that the trainee is not qualified for performing the tasks independently. Management discretion/decision is needed to proceed.

#### 7.9. Group Training

7.9.1. Training on procedures or specific topics may be conducted in a group setting by a qualified trainer.

7.9.1.1. Group training is documented on Group Training Form.

7.9.2. Group Training Record Archival

7.9.2.1. Following the training, the trainer will sign and date the form. The form is then submitted to Quality Assurance for approval and document retention.

#### 7.10. GMP Training

7.10.1. GMP training is conducted on an ongoing basis to ensure individuals engaged in GMP activities have up-to-date knowledge of current regulatory requirements.

7.10.2. Training requirements are based on the employee's job function.

7.10.3. Personnel engaged in GMP activities are required to receive GMP training at least once per calendar year.

7.10.4. Annual GMP training is coordinated by Quality Assurance.

7.10.4.1. Departmental training, where approved by Quality Assurance may fulfil the annual GMP training requirement.

7.10.4.2. An appropriate off-site conference, class, or seminar may be used to meet the requirement for annual GMP training.


7.10.4.3. Participation in customer or regulatory inspections, where approved by Quality Assurance may fulfil the annual GMP training requirement.

7.10.5. GMP training documentation is filed in the employee's training file.

#### 7.11. Externally Led Training

7.11.1. Externally led or off-site training includes appropriate conferences, classes and seminars relevant to the employee's current job function or in preparation for increased and/or change of responsibilities.

7.11.2. The certificate for attendance at off-site training courses is considered the equivalent of Group Training Form.

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7.12. Maintenance of Training

7.12.1. Employee training records are subject to Quality Assurance Internal Audits.

7.12.2. Supervisors and/or managers are responsible for timely approval of training records. Supervisors/managers are also responsible for ensuring employee profiles are current. The following training record review activities are performed to ensure the most current employee information is available:

7.12.2.1. The job description is confirmed to reflect the current job held, including transfers, change of responsibilities, and/or promotions.

7.12.2.2. The CV and/or resume is present.

7.12.2.3. The training curriculum is confirmed as current, including changes to the procedure list where required by promotions, transfers, new/applicable procedures, or other changes are warranted by departmental or job changes.

7.12.2.4. SOP and work instruction training is confirmed as current.