**Title: Competence, Awareness, and Training**

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# Purpose:

The purpose of the competence, awareness and training processes is to ensure that personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

# Scope:

This procedure applies to all employees at LSI SOLUTIONS® with the exception of seasonal, temporary, or non-production employees and the President. Seasonal and temporary non production employees will be added to the proper tiers and trained in procedures and work instructions as required by the area they will be assigned to.

# Definitions & Acronyms:

For Additional Definitions & Acronyms see D000089, *Definitions and Acronyms*.

**Classroom Training** **–** Instructor-led training by LSI personnel.

**Domain –** Functional area; useful for stratification of training requirements.

**External Training –** Training provided by non-LSI personnel, such as external coursework, webinars, on-line seminars, conference related trainings, etc.

**Evidence of Competency –** Proof via records that you can apply skills and knowledge to achieve intended results.

**Essential Function –** Tasks critical to the job.

**General Training Items** – Training not associated with controlled documents (confidentiality agreements, meeting guidelines).

**Job Description** – A tool that outlines the essential functions and responsibilities; physical demands and work environment; as well as the requirements for education, experience, knowledge, skills and abilities for a position. It details qualifications required to perform a specific type of work and what tasks are to be completed.

**Knowledge, Skills & Abilities (KSAs) –** Capabilities, expertise, and characteristics that an individual must possess to perform the job duties.

**NHO** – New Hire Orientation

**On the Job Training** – Training where demonstration of competency can be provided through various means, such as hands-on skill / task completion, quiz, completion of checklist of items, or verbal explanation.

**Periodic Review of Training Profiles** – Regular process to ensure accuracy of content with respect to job responsibilities and assignment of profile to individuals.

**Read and Understand** – Self-directed learning. Reading a document for awareness or understanding purposes.

**Role** – Specialized job function within a Job Description.

**Skill-Based –** A profile that is tailored to a specialized function that requires competency.

**Soft Skills –** A combination of people skills, social skills, communication skills, character or personality traits, attitudes, career attributes, social intelligence and emotional intelligence quotients, among others, that enable people to navigate their environment, work well with others, perform well, and achieve their goals.

**Subject Matter Expert (SME)** – A person who has specialized skills or knowledge on a particular job or topic, based on education and/or experience. An SME is qualified to make a judgement on the qualifications of other personnel for that given area.

**Task-Based –** A profile that is tailored to a specific function.

**Trainer –** An employee who is responsible for teaching new or revised skills and knowledge to other employees.

**Training Awareness –** Knowledge that a process exists; ISO 9001: attained when people understand their responsibilities and how their actions contribute to the achievement of organizations goals.

**Training Effectiveness –** Criteria to determine if completed training was effective and achieved results. Evident effectiveness includes, but is not limited to quizzes, group questions, visual confirmation, skill assessment, or social ownership.

**Training Evidence File –** Additional supporting documentation in the form of certificates, or forms attached to a training record.

**Training History –** A list of training records for an individual or document.

**Training Item –** Document or general item that will be assigned to a user as part of their training requirements.

**Training Tier –** Categories of training or “tiers” based on the specificity of the training and the domains or individual employees that are required to train on them. Tier 1 requirements are the most general and required for the entire company, while Tier 4 and Tier 5 requirements are the most specific and therefore are only required for a limited number of employees performing a specific job function. See Figure 1.

**Training Understanding** – The ability to explain a process accurately to someone.

**Training Within Industry (TWI) –** A type of on-the-job training used in Production environments. Interactive job instruction training methodology wherein a trainee can be considered competent upon demonstration of successful completion of the work.

# References:

## Procedures

* + D000343, *Control of Documents*
  + D000344, *Controls of Records*
  + D000356, *Control of Production Processes*
  + D000374, *Sales and Marketing Training Procedures*

## Work Instructions

* + D000507, *Good Documentation Practices*
  + D000824, *Completing and Reviewing Training in GAS*
  + D000866, *Defining and Designating Training Profiles in GAS*
  + D003717, *Recruiting, Transfers & Promotions Procedure*
  + D005147, *HIPAA Work Instruction*
  + D007352, *Protocol Training Documentation Guidelines and Training to New Equipment*

## Forms and Templates

* + D000227, *Employee Training Record*
  + D000281, *Job Description Template*
  + D001091, *Employee Training Effectiveness Record*
  + D004472, *Periodic Review of Training Profiles Template*

## Other

* + D000089, *Definitions and Acronyms*
  + D001146, *Safety Manual*

# Responsibilities

## The Quality Assurance Department is responsible for:

* + Maintaining the accuracy of the content of this document.
  + Maintaining the accuracy and completeness of the Tier 1 training requirements.

## Managers are responsible for:

* + Creating new tier 3 and tier 4 training profiles for their employees based on job descriptions.
  + Maintaining the accuracy and completeness of the tier 3 and tier 4 training requirements for their employees.
  + Ensuring their employees complete their assigned training by their due dates and follow up on overdue training tasks to ensure completion.
  + Completing periodic reviews of their department’s training profile(s).
  + Working with SMEs to assign training requirements for Tier 5 profile(s).

## The Quality Assurance Manager/Training Specialist or designee is responsible for:

* + Assisting the managers, directors, and SMEs with the accuracy and completeness of the Tier 1, Tier 2, Tier 3, Tier 4, and Tier 5 training requirements.
  + Assigning training tasks (in GAS) to appropriate employees. Tiers 1, 2 and 3 will be assigned based on job role. Tier 4 and 5 will be assigned per request.
  + Following up on overdue training tasks to ensure completion.
  + Managing and conducting periodic reviews of training profiles.
  + Implementation, enforcement, maintenance, and enhancement of the Training Management processes.

## Environmental Health and Safety is responsible for:

* + Ensuring all employees receive the required general Health and Safety training based on D001146, *SAFETY MANUAL*, and, where applicable, job specific training is required.
  + Submitting EHS training records to the Quality Assurance Manager/Training Specialist or designee.
  + Conducting Safety training as needed.

## Sales and Marketing is responsible for:

* + Conducting training of sales and marketing personnel per D000374, *Sales and Marketing Training Procedures*.
  + Submitting sales and marketing training records to the Quality Assurance Manager/Training Specialist or designee.

## All Employees are responsible for:

* + Completing their required training by the due date specified in GAS.
  + Ensuring that they have completed the appropriate training prior to executing work.

## Human Resources is responsible for:

* + - Coordinating New Hire Orientation.
    - Communicating any changes made to employees’ status e.g. transferring, leaving or promotion.

## Directors are responsible for:

* + Creating new tier 2 training profiles based on their domain(s).
  + Maintaining the accuracy of the tier 2 training requirements for their domain(s).

## SMEs are responsible for:

* + Working with managers to build their Tier 5 profiles for non-SMEs.
  + Approving competency completion for their Tier 5 profiles for non-SMEs.
  + Performing periodic reviews of their Tier 5 profiles.
  + Working with managers to identify employees who belong in their Tier 5 profiles and communicating to managers the time commitment involved in being assigned their Tier 5 profiles.
  + Staying current or up to date within their field of expertise.

# Procedures:







## Education, Background, Training, and Experience

To ensure all potential candidates have the required education, background, training, and experience, Job Descriptions are developed by area supervisors and Human Resources, using D000281, *Job Description Template*. The Recruiter ensures employment offers are extended to qualified candidates using D003717, *Recruiting, Transfers & Promotions Procedure.* Upon hire, Human Resources maintains a copy of the employee’s resume and credentials in employee personnel files*.* Upon hire or any position change, the manager and Quality Assurance Manager/Training Specialist or designee will add any training or development plans to an employee’s training requirements to fill any gaps identified between their qualifications and the requirements of the job description as described in D003717, *Recruiting, Transfers & Promotions Procedure*.

Anyone performing work affecting product quality must be trained prior to work being completed or else performed under the supervision of a trainer or SME. Any personnel handling or producing product must be trained in the appropriate procedures as required by D000356, *Control of Production Processes.*

## Structure of Training Requirements

Training requirements are separated into five categories or “tiers” based on the specificity of the training and employees that are required to train on them. Tier 1 requirements are the most general and required for the entire company. Tier 2 requirements are based on domains. Tier 3 requirements are based on the job description, while Tier 4 and Tier 5 requirements are the most specific and therefore are only required for a limited number of employees performing a specific task or role. Certain employees may not be required to train on all five (5) tiers. The owners, described in the section below, will determine which employees will be trained on each tier.



### Tier 1: Quality, Safety and Human Resources Requirements

The tier 1 training requirements are defined and managed by the Quality Assurance Department and Human Resources. These are requirements for all employees. Tier 1 requirements include but are not limited to the below items:

* **New Hire Orientation**

All newly hired employees or employees returning to LSI after at least a year from their last separation participate in an orientation program that prepares them for their position. Orientation includes, but is not limited to, quality system training (including the new hire’s importance and relevance of their activities and their impact on the organization), safety training (off-site staff may not be required to train on all safety topics), product demonstrations, IT policies, etc. New employees are then assigned document training requirements by the Quality Assurance Manager/Training Specialist or designee to be completed within the first 30 days of employment.

* + **Quality System Profile**

This profile includes training to required company polices, top tier quality procedures, and work instructions.

* + **Job Description**

All employees are required to read and understand their job description.

* + **cGMP Profile**

This profile includes training items that describe the purpose and content of the quality management system.

* + **Safety Profile**

This profile contains all company-wide required safety training items, including but not limited to lock-out/tag-out and emergency evacuation procedures.

* + **HIPAA and Off-Label Use Profile**

Per D005147,*HIPAA Work Instruction,*certain employees are required to train on HIPAA. Employees are required to understand LSI’s Off-Label Use policy.

### Tier 2: Domain Requirements

This category is comprised of procedures, DOPs, work instructions and safety training requirements pertinent to specific domains. These requirements are managed by the domain director or manager. Changes to these requirements are reviewed and implemented by the Training department and the domain director.

### Tier 3: Job Description - Based Requirements

This category is comprised of procedures, DOPs, work instructions, safety training requirements and general training items pertinent to the employee’s role in the organization as defined by their job description. These requirements are determined from the job description and maintained by the manager. Changes to these requirements are reviewed and implemented by the Training department and the manager. Creation of new job descriptions, or changes to current job descriptions, necessitate a review of this tier.

### Tier 4: Specific Task or Role Based Requirements

These training profiles are specific to either an employee’s task or role. They are comprised of work instructions, safety training requirements, and general training items pertinent to specific job responsibilities or functions, e.g. miniARM® project, Cleanroom- Staking, Supplier Quality. Tier 4 profiles could be cross-functional based on an employee’s role within the process or work environment. Examples of cross-functional profiles include, but are not limited to: Lean Methodology, Leadership and Management Training, or specific safety-related items.

The employee’s manager manages these requirements. Changes to these requirements are reviewed and implemented by the Training department and the employee’s manager.

### Tier 5: Specialized Skill Requirements

There are some high-risk tasks that require additional specialized training and may be cross-functional. These Tier 5 profiles include but are not limited to: Audits, Risk, Calibration, Validation, Regulatory, Supplier, Sterilization, Biocompatibility, Training, and CAPA tasks. In order to complete these profiles, competency must be demonstrated. Contents within these training profiles include but are not limited to procedures, DOPs, training to the practical application of related standards and industry certifications. Employees are required to demonstrate competency through applied practice and application of related tasks under the guidance of an SME.

### Non-QMS Awareness Training

Directors and Managers have the option to require their employees to be aware of certain controlled documents, however, might not require training to them. This is determined based on the scope of the employee’s job description and not included in the scope of the QMS. Directors and managers will ensure that awareness to these items is complete.

## External Training and Coursework

Upon completion of external training or coursework, employees are responsible for forwarding records of course completion, certificates, and/or grade reports to the Quality Assurance Manager/Training Specialist or designee for management within GAS. Upon hire, Human Resources will collect any relevant certifications obtained prior to employment at LSI. Human Resources will forward the evidence file to the Quality Assurance Manager/Training Specialist or designee to upload into the employee’s training record in GAS.

### Training Associated with Validations

Training for process and product development validations and to equipment is performed as defined in work instruction D007352, *Protocol Training Documentation Guidelines and Training to Equipment.*

## Assigning Training Requirements in Grand Avenue Software (GAS)

The Quality Assurance Manager/Training Specialist or designee is responsible for assigning an individual’s training requirements (in GAS) at initial hire, after changes to job titles or job functions, and at the request of the department manager or director. Training requirements are assigned using D000866, *Defining and Designating Training Profiles in GAS* as guidance. The training requirements are assigned, managed, and recorded in GAS’s Training Management module. This software module identifies the training requirements for all employees and manages the type of training to be performed, due dates, completion dates and training records.

In the event that a document that requires training has been revised, the Quality Assurance Manager/Training Specialist or designee is responsible for assessing the need for retraining (per Training Risk Table) and updating training materials. If training is required, all appropriate employees will be sent a training task in GAS, which will specify the type of training to be performed and the due date. Training to procedures and work instructions is required to be completed prior to the effective date of the document.

If classroom training is required and an employee in unable to attend, it is the manager/supervisor’s responsibility to ensure the employee is trained by the specified due date.

Documents that require training are as follows: Procedures, DOPs, Work Instructions, and Job Descriptions. Alldocument identifers with a “D” prefix should be assessed for their impact to training. Not all “D” documents require training (e.g. certain forms, templates, IIPs).

## Periodic Review of Training Profiles

Periodic reviews of training profiles are required as follows:

* + Directors are required to complete a periodic review of the tier 2 profiles for their respective domains to ensure the content is correct.
  + Managers are required to complete periodic review of tier 3 profiles for all their employees’ job descriptions to ensure the content is correct.
  + Directors, Managers, or individual contributors are required to complete periodic review of tier 4 profiles to ensure they are assigned to the correct employees.
    - The content of tier 4 profiles in production are reviewed continually, so no periodic review is required.
  + Managers along with the appropriate SME are required to conduct a periodic review of tier 5 profiles to ensure they are assigned to the correct employees.
  + SMEs are required to complete a periodic review of the content of tier 5 profiles.

The periodic reviews listed above are required annually. This review is conducted to ensure that the contents of the profiles are accurate with respect to job responsibilities and that these profiles are assigned to the correct individuals. The periodic review is initiated by a periodic review task assignment in GAS. The Quality Assurance Manager/Training Specialist or designee will ensure that the reviews are completed. Any changes to training profile requirements required as a result of a Periodic Review will be completed by the Quality Assurance Manager/Training Specialist or designee within GAS. Directors, Managers, Supervisors, or SMEs will not make any changes directly to the content of the training profiles. Profiles are reviewed using D004472, *Periodic Review of Training Profiles Template,* and require appropriate management sign off. The completed forms will be stored in the periodic review task for each profile. If a tier is to be updated with additional training, it will be added to the annual review. When required training is removed from a tier, DCR approval is required.

## Training Risk and Training Effectiveness

Training requirements are determined based on risk related to the document or item. Table 1 defines the minimum training requirements and required measures of training effectiveness for high, moderate, and low risk items.

### Risk Levels

For the purpose of training, the risk levels are defined as follows:

**Low**: No impact to product and production or QMS processes. Sub-level work instructions governed by parent documents that are trained on. Examples: Work Instructions – PM, Work Instructions – IPI, Work Instructions – IIP, Work Instructions – Test, Process Flow Diagrams, Periodic Review of Training Profiles, Reference Document, Process Control Plans.

**Moderate**: Indirect impact to product and production or QMS processes. Procedures, DOP, Work Instructions – General (not on BoM), Templates.

**High**: Direct impact to product and QMS processes. Examples include Work Instructions – Assembly, Manufacturing Inspection Plan, Work Instructions – General (on BoM). Forms – Production.

### Types of Training

The types of training are defined as follows:

**Classroom**: Instructor-led training by LSI personnel and employs the use of D000227, *Employee Training Record* to document training completion.

**External**: Training provided by non-LSI personnel, such as external coursework, webinars, on-line seminars, conference related trainings, etc. In some cases (e.g. webinars) employ the use of D000227, *Employee Training Record* to document training completion or certificates.

**On the Job**: Training where demonstration of competency can be provided through various means, such as hands-on skill / task completion, quiz, completion of checklist of items, or verbal explanation. In Production environments, Training Within Industry (TWI) is the methodology used for on the job training. On the Job training is used for the following: new high-risk documents or processes, revision to high risk documents where process is changed.

**Read and Understand**: Self-directed learning. Reading a document for awareness purposes. Uses: Revisions that do not impact the product to high risk documents and moderate risk documents.

### Types of Document Revision Changes

Document revision changes are evaluated based on the type of impact that the changes create. Changes are considered non-impactful or impactful. If document updates create both types of change, the higher risk impact is applied.

**Non-impactful change:**

* Administrative Change
* No process change
* Change to Title, Scope, Purpose, References
* Change for clarity (e.g. improved version of an image, re-wording that does not change the intent)

**Impactful change:**

* Initial training on document
* Change to the process
* Changes for clarity (e.g. instructions re-written)
* Changes to Records retention
* Changes to Responsibilities
* Linkages to other QMS processes

### Risk Table

Evaluation of training effectiveness is documented based on the risk. Higher risk trainings are those that are directly linked to product quality and therefore require more robust effectiveness measures.

This table is used to establish the Risk Level, Type of Training Required and Type of Training Effectiveness required for any document requiring training. In some cases, Training Effectiveness may not be required for the SME or Trainer. This is based on their knowledge, skills, ability and/or certifications to conduct training as the SME or Trainer.

**Table 1**

|  |  |  |  |
| --- | --- | --- | --- |
| **Risk Level** | **Revision Level Change** | **Minimal Type of Training Required** | **Minimal Training Effectiveness Measure** |
| Low | Non-Impactful Change | No Training Required | No Training Effectiveness measures required |
| Moderate | Non-Impactful Change | Read and Understand | No Training Effectiveness measures required |
| Moderate (Procedures) | Impactful Change | Read and Understand | Quiz |
| Moderate (DOP, WI-General (not on BoM, Templates)) | Impactful Change | Read and Understand | No Training Effectiveness measures required |
| High | Non-Impactful Change | Read and Understand | No Training Effectiveness measures required |
| High | Impactful change | On the Job | Training Effectiveness Measures are Required. (e.g. D001091, *Employee Training Effectiveness Record*, safety evaluation forms, evidence of competence for specialized profiles) |

### Training Effectiveness Measures in Production Environments

Each month a sample of 5\* cleanroom employees and training tasks/product lines will be re-evaluated for training effectiveness by the production training group. The training tasks and product lines will be selected randomly. The employees will be selected randomly but without replacement, which means that employees and product lines will not be repeated (depending on the production schedule) within a given interval. Selected employees will not be repeated within any given three-month period. All completed D001091, *Employee Training Effectiveness Record*, forms will be filed with the Quality Assurance Manager/Training Specialist. The information of the results will be reviewed by the Quality Assurance Manager/Training Specialist or designee to provide a measure of overall system training effectiveness in production. \**Sample size of 5 evaluations per month over the course of 12 months will provide a sufficient sample size in excess of 95% confidence level in a 5% confidence interval (95% reliability).*

### Training Effectiveness Quizzes

If a quiz is associated with an assigned training, quiz completion is mandatory prior to sign off. A score of 70% or higher is required to pass the quiz. Quiz results are tracked and maintained within content authoring software.

## Training Completion and Records

All employees are responsible for completing their required training by the due date specified in GAS. Instructions for completing training requirements in GAS can be found in D000824, *Completing and Reviewing Training in GAS*. Classroom, On the Job Training, Specialized Skill (Tier 5), and External Training items require the use of D000227, *Employee Training Record*, to document completed training. Completed D000227, *Employee Training Record* forms should follow the requirements of D000507, *Good Documentation Practices.* Upon training completion, the Employee Training Records are given to the Quality Assurance Manager/Training Specialist or designee to document training within GAS. In Production areas, Production Trainer or Team Leads have the ability to scan in completed training records for their teams.

The records of training completion are maintained in accordance with the requirements of D000344, *Control of Records*.

## Sales and Marketing Training Records

Sales and Marketing training records and storage are documented in D000374, *Sales and Marketing Training Procedures*. Upon completion of training, the records will be forwarded to the Quality Assurance Manager/Training Specialist or designee for management within GAS. Training of hospital staff and distributors by LSI sales team is documented on D000333, *In-Service Training Checklist* used for Sales’ training of hospitals / distributors.

# Records

See D000344, *Control of Records* for the retention and disposition of these records.

|  |  |  |
| --- | --- | --- |
| **Name** | **Owner** | **Location** |
| D000227, *Employee Training Record* | Quality Assurance | Grand Avenue Software |
| D001091, *Employee Training Effectiveness Record* | Quality Assurance | Grand Avenue Software |
| D004472, *Periodic Review of Training Profiles* Template | Quality Assurance | Grand Avenue Software |
| D003717, *Recruiting, Transfers & Promotions Work Instruction* | Human Resources | Grand Avenue Software |
| Job Descriptions | Human Resources | Grand Avenue Software |
| Training Certificates | Quality Assurance | Grand Avenue Software |
| D000333, *In-Service Training Checklist* | Clinical Education Manager/Quality Assurance Manager/Training Specialist | Grand Avenue Software |
| Safety Training | EHS Manager | Grand Avenue Software/ ProProfs Training Online |
| Training Effectiveness | Quality Assurance | ProProfs Training Online |