

<i>Insert Company Logo here</i>	SOP NAME	Personnel Training Procedure			
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Supersedes: Original	Prepared by G. Host			Date	XX/XX/XX
CONFIDENTIAL	Approved by G. Host			Date	XX/XX/XX

1. OBJECTIVE

To describe the procedure established for Training.

2. SCOPE (Optional)

2.1 The scope of this SOP applies to training requirements.

3. PERSONNEL RESPONSIBILITIES

3.1 It is the responsibility of the **Quality Manager** or a member chosen and trained by the Quality Department to ensure these procedures are being enforced and followed.

4. DEFINITIONS

4.1 N/A

5. REFERENCES

5.1 21 CFR **111.12**

5.2 **NSF Guidelines**

5.3 **GMP requirements are listed in NSF/ANSI 455-2 which is the only American National Standard in the dietary supplement industry developed in accordance with the FDA's 21 CFR part 111.**

6. SAFETY

Personnel working at **insert your company's name** shall follow necessary procedures to protect themselves and others from physical harm per the guidelines provided by the Company and/or OSHA.

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7. PROCEDURE

7.1 Job Descriptions

- 7.1.1 Job descriptions outline responsibilities pertaining to quality for all levels of employment at our facility. For example: each employee has the responsibility to prevent or stop nonconforming product from being produced. The use of job descriptions, organization chart, and our orientation program will enable us to attract and retain qualified employees. Job descriptions set expectations for new and existing employees by outlining their duties, responsibilities, and authority.
- 7.1.2 Job descriptions describe responsibility and skills required by the employee as well as the qualifications for the position and are maintained digitally by the Human Resources Department and are available for any employee to review upon request.

7.2 Organizational Charts:

- 7.2.1 The Organizational Chart provides ownership, accountability, and structure for employees. The orientation program developed by our Management Team will inform new employees of company policies, organizational structure, and safety and quality requirements.

7.3 Identification of Training Needs:

- 7.3.1 Employees are selected to perform specific job-related activities, based on their training, education and/or experience, as appropriate.
- 7.3.2 All newly hired employees are required to complete the appropriate training within their first 15 days of employment. This includes, full-time continuous, temporary and/or agency employees. The following are components of new hire training
- Basic cGMP rules.
 - Quality System Procedural Training by applicable Standard Operating Procedures.
- 7.3.3 Management identifies additional training requirements based on job duties and/or work areas. At least once every three years, employees and management discuss training requirements.
- 7.3.4 All employees are certified and re-certified in the processes that they support, as well as the framework (core processes) of the quality system.
- 7.3.5 When signing the acknowledgment of training, only the top most page of a stapled packet requires the signatures of the trainer and trainee
- 7.3.6 All processes have authorized trainers who are also “Certifiers”, whom are deemed the experts, owners and/or knowledge holders of the process/procedure. These are generally defined as Department Supervisors, Quality Assurance or Executive Staff members.

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7.4 Training Provisions:

- 7.4.1 Every employee that performs activities affecting product quality has a primary responsibility to ensure that his or her identified training requirements are met and valid.
- 7.4.2 This responsibility includes:
- Clarifying/Correcting training requirements and records.
 - Completing training requirements in a specified period of time.
 - Forwarding training records to the **Human Resources Manager** for entry into the Training Database (QAF-020)

7.5 Training Plans:

- 7.5.1 Training plans that address orientation and refresher training needs for all employees must be developed and reviewed at least once every three (3) years. Training plans may be developed by individual employee or by positions within the company. Training must be presented in the appropriate language(s) depending on employee needs.
- 7.5.2 In addition to training in the areas of company policies and procedures, safety, and job-specific topics, a comprehensive GMP training program must be developed that satisfies the requirements of the proposed GMP guidelines with emphasis on employee responsibilities to protect product safety. The following topics should be covered:
- Personnel
 - Plants and grounds
 - Sanitation of buildings and facilities
 - Equipment and utensils
 - Quality assurance/control and laboratory operations
 - Production and process controls
 - Warehousing, distribution and post-distribution processes
 - Files for substantiation of health claims and statements of nutritional support
 - Records retention
- All production forms (not matter for what activity) shall be completed in blue or black ink only.
 - Forms may not be corrected with “white-out” or erasure.
 - Simple corrections (i.e., date or time) shall be lined through once only and initialed and dated by the person correcting the data.
 - *Substantial** corrections must be approved and initialed and dated by the department Supervisor (or appropriate designate).
- * *substantial* corrections are those that pertain the formulas, BOMs, etc.

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7.6 Orientation Training:

- 7.6.1 No employee or contractor is permitted to enter into production areas prior to receiving training on GMP basic principles. This will consist of documented acknowledgment of the 10 basic cGMP Rules as outlined in OPLP-G004.
- 7.6.2 OPLP-G004 is posted at every entrance into the production or warehouse areas. Contractors requiring access to the plant floor must be escorted by a staff member at all times and may not be left alone.
- 7.6.3 Contractors that work in the plant frequently may proceed without the escort if wearing a security pass issued at the reception desk. This pass must be displayed prominently below waist level.
- 7.6.4 Temporary employees are given this training by their agency before being dispatched to this facility.
- 7.6.5 Orientation training addresses all elements of the “Personnel” section of the rule, with special emphasis placed on personal hygiene and disease control as well as Safety Requirements and Human Resource Issues.
- 7.6.6 This training includes a discussion of the regulations and the role of SOPs in maintaining quality in the dietary supplement manufacturing environment. New hires attend an orientation that includes:
 - Safety requirements
 - Quality requirements
 - Human resource issues

7.7 New Hire Training:

- 7.7.1 New hires must be trained in the basic cGMP rules before reporting to the first duty station
- 7.7.2 A new hire becomes certified after passing all required tests which includes completion of the applicable *General Employee Training Guide*.

7.8 Job Transfer Training:

- 7.8.1 Transfer employee needs to be certified according to the new Job Description, Work Instruction and Quality Plan using the same deadlines as for new employees.
- 7.8.2 Supervisors (old and new) decide on transfer date.
- 7.8.3 New Supervisor reviews new MTRs and deadlines with employee\ partner.

7.9 Cross Training:

- 7.9.1 Supervisor will request cross-training of any new MTR's for the new position to the Quality Assurance dept.

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7.10 Refresher Training:

7.10.1 Current employees receive GMP training every 12 months (as outlined in the training plan below):

- a) Every employee is Certified in the following processes/procedures to ensure proper maintenance of the core processes within the quality system and to ensure adequate cross-functional support:

XXXXXXXXXXXXXXXXXXXXXXX list below XXXXXXXXXXXXXXXXX

7.11 Effectiveness of Training:

7.11.1 Supervisors must follow up to ensure that training and procedures are being followed by employees on the work floor. Supervisors should monitor employee performance and provide regular feedback to the employee on his or her observations.

7.11.2 Requiring Certification to be maintained

- a) Employee-partner must complete and pass any required annual training/must retake tests as required.
- b) Employee-partners will have a grace period of 1 month from any due date for any retesting necessary.

7.11.3 GMP comprehension testing shall be conducted to encompass the four (4) primary memory recall styles:

- a) **Recollection** (Benjamin, Hopkins, & Nation, 1994. p.268-269)(Hasher & Griffin, 1978). This is the type of remembering used in reconstructive memory. Pieces of memories are fit together and an event or a fact is recreated based on the logical organization of partial memories and clues.

An essay test may well test one's ability to recollect the material.

Nancy presumes that she was eating lunch at school with her friends Suzy and Shannon on Tuesday, October 5th, 18 years ago, when she was in fifth grade. However, she doesn't remember it exactly, it could be that this was not the case on that particular day.

- b) **Recall** (Loftus, 1900.p.393)

Recall is being able to regenerate the memory without being provided any part of the memory.

A fill in the blank question on a test reflects one's ability to recall the material.

Nancy remembers one specific day that she had to eat alone at school because she had had a fight with Shannon that day, Suzy was sick, and she was too shy to sit with anyone else.

- c) **Recognition** (Loftus, 1900.p.393)

Recognition is being able to identify something as a memory once the stimuli from the memory is experienced once again.

Multiple choice or matching questions on a test reflect one's ability to recognize the information learned.

Nancy cannot recall Shannon or Suzy's face. She cannot generate the image in her head. But when she looks back at the fifth grade class photo, she can pick them out immediately.

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d) **Relearning** (Loftus, 1900.p.393)

Relearning is evident when one has an easier time remembering something when he or she learns it for the second time. This is even if the material was forgotten in the meantime.

Even though Nancy doesn't remember any of the other children in the fifth grade picture, she reads through the names on the bottom and with very little practice, she can soon identify everyone without referring back to the list. Her husband, who never knew Nancy's fifth grade class, took a much longer time memorizing everyone's name in the picture.

7.11.4 The cGMP certification examination is divided into four sections. Each section covers basically the same theories but presents it consistent with one of the memory recall styles described above.

7.11.5 Employees are required to attain a score of at least 75% on at least one of the 4 sections of the cGMP test in order to become certified/recertified or, to maintain current certification.

7.12 Annual Evaluation of Supervisors/Managers:

7.12.1 Supervisors are responsible for maintaining their qualification and suitability as supervisors in a cGMP environment.

7.12.2 Supervisor candidates as well as active supervisory personnel will be evaluated initially and reevaluated at least annually on the following criteria:

- Language skills – Supervisory personnel must maintain fluency in English
- *Fluency* requires a score of at least 73% on the Language Arts examination.
- Education - Supervisory personnel must possess at least an Associate's degree (A. A.) or equivalent; or 2 years related experience and/or training; or equivalent combination of education and experience.
- Continue to be qualified for their position based on the criteria listed in the Job Description.

7.13 Consequences for Loosing Certification:

7.13.1 Training certification can be lost by

- Failing to attend training within the time limit.
- Loss of a required permit (Fork Truck, etc.,).
- Employee leaving company (termination or resignation).
- Disciplinary actions: Safety, Quality or Production – Two written occurrences of the same offense within 12 months.

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7.14 Removal From Supervisory Duties:

- 7.14.1 In any case in which **enter your company's name** management concludes that a supervisor's conduct May justify discharge, the supervisor shall be suspended without pay initially for not more than three (3) working days.
- 7.14.2 The associates Department Manager shall be notified as soon as possible.
- 7.14.3 During this five (5) working day suspension period, at least 3 members of the **enter your company's name** management Team will meet to consider the facts.
- 7.14.4 By the end of this suspension period, final determination will be made and the affected supervisor will be notified.
 - A simple majority vote will rule.

7.15 Documentation:

- 7.15.1 A Meeting Attendance Form (QF-019) with the participant's name, signature, course name and number, date of the session, and the instructor's name and signature is kept on file for each class held. The participant's signature attests to his or her attending the complete session; the trainer's signature attests that the program was given and that the people listed did attend.

7.16 Trainers

- 7.16.1 Training for each position is performed by an Authorized Trainer* and is based on the SOP for the task being trained on.

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8. FORMS

- 8.1 QF-019 Meeting Attendance Form
- 8.2 OPLP-G004 Ten Basic cGMP Rules
- 8.3 QF-020 Training Database
- 8.4 Job Descriptions
- 8.5 Organization Chart

9. RECORD RETENTION

- 9.1 Any record and/or document pertaining to this procedure shall be kept and maintained by the **Quality Department**.
- 9.2 In general, any documentation in regards to this procedure, shall be kept, at minimum, per 21 CFR Part **111.605**:
 - 9.2.1 “(a) You must keep written records required by this part for 1 year past the shelf-life date, if shelf-life dating is used, or 2 years beyond the date of distribution of the **last batch of dietary supplements** associated with those records.
 - 9.2.2 (b) Records must be kept as original records, as true copies (such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records), or as electronic records.

10. NOTES

10.1 xxx

11. FLOW CHART

N/A

12. APPENDIX

N/A

REVISION	CHANGE CONTENT	No.	EFFECTIVE
G004.00	New procedure	CO xxx-xxx	XX/XX/XXXX
G004.01			