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| **TITLE:** |  | | |
| **sop #:** |  | **revision #:** |  |
| **EFFECTIVE DATE:** |  | | |
| **OWNER:** |  | | |

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# 1.0 purpose

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To outline the procedures for training staff on Standard Operating Procedures (SOP’s), Quality Forms, requirements for GMP compliance and other non-GMP training. This SOP also outlines the requirements for training files.

# 2.0 SCOPE

This document pertains to all Radiant permanent and temporary employees, as well as consultant requiring specific training in accordance with GMP regulations.

# 3.0 equipment

N/A

# 4.0 definitions

| **Definition** | **Explanation** |
| --- | --- |
| **CTO** | Human Cells, Tissues and Organs |
| **Device** | Means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in:  a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,  b) restoring, correcting or modifying a body function or the body structure of human beings or animals,  c) the diagnosis of pregnancy in human beings or animals, or  d) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring, and includes a contraceptive device but does not include a drug. |
| **Drug** | Includes any substance or mixture of substances manufactured, sold or represented for use in:   1. the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals, 2. restoring, correcting or modifying organic functions in human beings or animals, or   disinfection in premises in which food is manufactured, prepared or kept |
| **GxP** | Series of laws, regulations and guidance governing the research, development, testing, manufacturing and distribution of pharmaceutical & biopharmaceutical products that constitutes "Good X Practice" (i.e. Good Clinical Practice, Good Laboratory Practice, Good Distribution Practice, Good Manufacturing Practice, Good Documentation Practice and Good Pharmacovigilance Practice) of the business. |
| **Job Description** | Summary of the job position, key responsibilities and duties, and key requirements. |
| **Medical Device** | A device within the meaning of the Act but does not include any device that is intended for use in relation to animals. |
| **Natural Health Product (NHP)** | A substance set out in Schedule 1 of the Regulations or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine that is manufactured, sold or represented for use in   1. the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; 2. restoring or correcting organic functions in humans; or   modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health. |
| **QA** | Quality assurance, providing confidence that quality requirements will be fulfilled. |

# 5.0 Responsibility

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| **Responsibility** | **Activity** |
| **All Employees** | * Responsible for reviewing, accepting and signing their job description * Responsible for ensuring that they receive adequate training |
| **Functional Manager** | * Responsible for on-going assessment of the effectiveness of training of their direct reports * Responsible for writing a Job Description * Responsible for training their employees on job specific requirements and documentation of such training |
| **Warehouse Manager** | * Responsible for on-going assessment of the effectiveness of training of their direct reports * Responsible for training their employees on job specific requirements and documentation of such training |
| **Quality** | * Responsible for GMP related training of employees or designating other individuals to conduct this training * Responsible for the initial assessment of the effectiveness of training * Responsible for maintaining Job Descriptions * Responsible for preparing and updating training matrices * Responsible for training on GMP SOPs and Quality Forms |

# 6.0 policy

## JOB DESCRIPTION

**Functional Manager shall:**

* + 1. Write a Job Description for each job function that is a direct report to him/her.
    2. Provide the Job Description to each employee to whom the description applies. The employee must read the job description and sign it as evidence that they have accepted these duties.
    3. Sign each job description.
    4. Retain the original (signed) Job Description, with a copy provided to the employee for their records.
    5. Update a job description when there have been major changes to job responsibilities, such as those changes which result in new GxP responsibilities for an employee.

## Training MatRices

**Quality shall:**

* + 1. Determine the training requirements for his/her employees, based on job function and tasks to be performed.
    2. Identify and maintain GMP training needs as per **OPS07-QF42 Training Matrix**.

## IN-HOUSE SOP TRAINING

**Quality shall:**

* + 1. Conduct training by group presentations (training sessions), assign a self-reading of SOPs, or hands-on training. In all cases, training should be documented using **OPS07‑QF51 Training Verification Form and/or OPS07-QF52 Group Training Verification Form**.
    2. Ensure that employees responsible for training must have the background, experience and technical knowledge in the subject matter and in training practices and techniques, appropriate to the training objective.
    3. Provide employees that have access to emails if training consists of reading an SOP, an email including:
       1. List of training documents to review (SOPs, forms, etc.)
       2. Instructions (if applicable)
       3. Due date for completing training
    4. Arrange and conduct training for employees that do not have access to email.
    5. If employees are training by self-reading, a maximum of ten SOPs can only be trained on in a day. If training is provided as a formal presentation and key points are summarized, depending on the complexity of the SOP, up to twenty SOPs can be trained on.
    6. Assess the effectiveness of training. The primary means for assessing the effectiveness of training will be a written test. Job shadowing may also be employed as a means of assessing whether or not the employee is able to carry out the requirements of the SOP. Verbal assessment or other methods may also be used, as required.
    7. Train all staff prior to the effective date of an SOP. If training takes place after the effective date for an existing employee, an explanation must be provided (e.g. sick leave, vacation, etc.).
    8. If an employee is off from work for extended periods of time such as sick leave, maternity, etc., re-training on SOPs and GMP training must be provided.
    9. Retrain staff on SOPs every two years and must be documented. A two-week window from the pre-established due date for re-training will be allowed in order to accommodate employees’ schedules and unforeseen situations.

## Annual GMP Training

* + 1. Retraining on GMPs will take place annually.
    2. GMP training sessions will be scheduled throughout the year, and all staff will be expected to attend one of the sessions. Each employee will be assigned to a training session every year; however, it is expected that due to scheduling restrictions, some employees might need to attend one of the alternate sessions. This will be acceptable as long as training is completed once a year.
    3. New employees will be expected to attend the first session to take place before the start of their employment.

## Training on Client procedures

**Quality shall:**

* + 1. Train applicable employees on client procedures before the procedure is implemented, before the employee is expected to conduct the activities covered by the procedure.
    2. Re-train employee as required.
    3. Document training on **OPS07-QF51 Training Verification Form and/or OPS07-QF52 Group Training Verification Form**, unless the client requires their own form to be used.

## training Files

**Quality shall:**

* + 1. Maintain training files for each employee. For the quality department, the following will be included:
       1. Current CV
       2. Signed Job Description
       3. Copies of Relevant Degrees, Diplomas or Licenses
       4. Training Certificates
       5. Internal training records (i.e. OPS07-QF51 and OPS07-QF52)

For all other employees, only sections 6.6.1.2 and 6.6.1.5 will be maintained in their training files.

* + 1. File all current training documents in binders and retain in the central QA area. All superseded documents will be archived.
    2. Maintain the training files as per **OPS07-24 Electronic File Back-up & Record Retention**.

# 7.0 records

7.1 The signed hard copy of this procedure is the official copy and must be maintained in the SOP binder.

7.2 Records must be maintained in accordance with **OPS07-33 Management of Standard Operating Procedures**.

# 8.0 Revision history

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| **Revision #** | **Revision Date** | **Description** |
| Revision 001 | Oct 1, 2017 | Initial rewrite of procedure |
| Revision 002 | Apr 27, 2018 | * Quality Assurance and Regulatory Affairs Coordinator was added to the training matrix. * SOP was revised to remove Quality Forms as appendices. * SOP revised to be in-line with the GMPs * Updated as per CCN-2018-009 |
| Revision 003 | March 01, 2019 | * Updated as per CCN-2019-002 |
| Revision 004 | May 30, 2019 | * Updated as per CCN-2019-011 |
| Revision 005 | Sept 03, 2019 | * Updated as per CCN-2019-025 * Revised SOP template |

# 8.0 revision history

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