1.0 PURPOSE:

To lay down a procedure for training of the employees engaged in Manufacturing, Testing, Holding and Distribution of products.

2.0 SCOPE:

This procedure is applicable for all those employees, whose roles and responsibilities may impact the quality of the products manufactured at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1. Induction training: Concerned Department Head and HR.

3.2. Concerned Department Head is responsible for On-the-Job training, Refresher SOP training, Retraining (Remedial training).

3.3. Concerned Department Head is responsible to do Training needs identification.

3.4. Trainee shall be responsible for attending the training, report writing and keep up-to-date the Employee Training Card for self.

3.5. Concerned department in-charge is responsible to ensure that all employees to update the training cards.

3.6. QA department is responsible to conduct the cGMP training.

4.0 DEFINITIONS:

Induction Training: Includes an overview of organization, business unit and Parent department. All employees including management trainees shall undergo induction training

cGMP Training: Includes various chapters covered as per applicable market regulatory guidelines for cGMP, SOPs related training, On the Job, Technical and Functional related training. The training shall include both internal and external training imparted on cGMP and technical topics. The number of cGMP training hours calculated for individual shall exclude induction, behavioral and Safety related training.

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On the Job Training: Training through reading of documents followed by a practical training.

Un Schedules Training: Training given to employees due to introduction of new or changed /revised procedures, policies /protocols or guidelines followed in their areas of work and is not scheduled in the training curriculum of the employee.

5.0 PROCEDURE:

5.1 INDUCTION TRAINING:

5.1.1 A new employee joining the organization shall complete all joining formalities and HR shall induct them into an introductory training.

5.1.2 Induction training programme shall be organized for the new recruits (fresher / experienced) and for existing employee transferred to other departments.

5.1.3 The new employee to the plant shall be introduced to the respective HOD by HR department, who is responsible to help the employee through the induction period and beyond.

5.1.4 The general flow of induction training shall be overview of the organization / unit, structure, governing policies, rules and regulations, interacting departments, customer, parent department organogram, job responsibilities, interfacing activities besides understanding of functional procedures and activities.

5.2 NEW RECRUITS (FRESHER):

5.2.1 Training shall be imparted for a period of 30 days for new recruits (fresher) as per 'Induction and assessment Record' (QA022-FM030, Current version).

5.2.2 HR department shall introduce the new recruit to all Heads of departments (HODs) and then fix up a schedule for further interaction. During this period new recruit shall be introduced to various departments and their activities.

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5.2.3 Once induction is completed to all function, HR personnel shall handover the employee to concerned department. The concerned HOD shall assign the new recruit under supervision of senior person.

5.2.4 Recruit shall observe and learn work in the department under the guidance of the senior person. New recruit shall record the learning in the "Induction and assessment record (As per current version of QA022-FM030).

5.2.5 All new recruits (fresher) shall undergo job training in their respective functions under the supervision of the senior person and record the same in Induction and assessment record.

5.2.6 After satisfactory completion of training, the HOD/In-charge of the department shall interview / conduct an oral /written test and shall evaluate the employee.

5.2.7 The trainee shall be allotted regular duties upon satisfactory assessment of the head if required, shall extend the training period by appropriate period.

5.2.8 Once the assessment is completed, job responsibilities shall be prepared and shall sign off.

5.2.9 After satisfactory completion of training the trainee shall hand over the training record to QA.

5.2.10 Quality Assurance shall ensure that new recruit signs the specimen signature log that shall be the evidence of the activities performed in the due course.

5.3 **NEW RECRUITS (EXPERIENCED):**

5.3.1 The HR department shall introduce the new recruit to all Heads of Departments (HODs) and then fix up a schedule for further interaction. During this period new recruit shall be introduced to various functions and their activities.

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5.3.2 Once the introduction is completed, HR department shall send new recruit to the concerned department. He / She shall undergo training for 15 days. The trainee shall undergone training as per HOD instructions and can read the SOPs and shall record the details in Induction and assessment Record' (QA022-FM030, Current version)

5.3.3 Induction and assessment Record shall be handed over to QA after completion of the training. Quality Assurance shall ensure that new recruit signs the specimen signature log that shall be the evidence of the activities performed in the due course.

5.3.4 The new recruit shall fill the self assessment & Declaration form.

5.3.5 Once the training is completed the respective employee shall be assigned work and the job responsibilities shall be prepared by the employee and same shall be approved by respective HOD.

5.4 **TRAINING FOR THE EXISTING EMPLOYEE:**

5.4.1 All the personnel shall be trained in their field of activities either in-house or External as per the requirements decided by the department head.

5.4.2 Training shall be conducted as a class room training with or without required study material and respective trainers shall ensure the relevance and adequacy of the topic.

5.4.3 All the personnel shall be trained on all the SOPs (new and revised) pertaining to their duties by the concerned HOD

5.4.4 Personnel shall be trained on all documents before its effective date or when the employee starts referring the document (as identified in Change control document).

5.4.5 Refreshment trainings shall be conducted to the employees to upgrade the skills, based on changes in applicable cGMP and regulatory guidelines, technology changes.

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5.4.6 Employee working in Production, Quality Control, Quality Assurance, Warehouse and Engineering (whose role may impact the quality of the products) shall undergo training for a minimum of 15 hours in a calendar year.

5.4.7 The training shall include training on various topics covered as per applicable Regulatory/Guidelines awareness training, SOPs related training, On the Job and Refresher training, Technical and Functional related training.

5.4.8 **On Job Training:**

5.4.8.1 Training calendar shall be prepared for every year based on identified training needs. i.e. as part of regular / refreshment training, the concerned HOD shall identify the training needs and shall prepare schedule for the year.

5.4.8.2 Respective department shall prepare the training to the respective department personnel and QA shall approve the same.

5.4.8.3 Based on training need identification, HOD shall define the target audience in the schedule. To cover all the target employees multiple session shall be carried out.

5.4.9 **cGMP Training:**

5.4.9.1 In case of Regulatory/Guidelines awareness training, QA shall prepare the training calendar in coordination with the concerned HOD and QA Head or designee shall review and approve the training calendar.

5.4.9.2 QA shall prepare a schedule based on the training needs identification, in the year beginning for cGMP training and shall conduct the training programs.

5.4.9.3 QA personnel shall be responsible for organizing the cGMP training program.

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5.4.9.4 Details of participants shall be recorded in participant details record and the employee shall be evaluated to ensure that the employee has understood the contents.

5.4.9.5 On completion of every training program, the Trainee shall be evaluated through an oral test, written test or a discussion or using workout sessions. Where necessary like in new SOP training, to evaluate the understanding, a questionnaire shall be used.

5.4.9.6 Training shall be assessed for competency wherever the subject is related to execution of job function. Such training shall be assessed through questionnaire or practical demonstration, as deemed suitable.

5.4.9.7 Where evaluation is done through questionnaires, the Trainee shall be qualified, if he has scored minimum qualification mark, which shall be 80% and above of the total marks allotted to the questionnaires.

5.4.9.8 If trainee fails during assessment, retraining (remedial) shall be conducted and the same shall be recorded in Participants details.

5.4.9.9 HOD/ Designee shall track the participants and shall make the list of absentees and shall repeat the same topic during next month schedule / shall conduct separate session.

5.4.9.10 If any trainee is not available to conduct the trainings against targeted participants the same shall be discussed in the absentees list.

5.4.10 **Un schedules Training:**

5.4.10.1 Specific training requirement based on outcome of the compliance monitoring and any non-compliance raised by the internal and external

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![Discovery Labs logo] Discovery Labs	STANDARD OPERATING PROCEDURE			
	SOP No.:	SOP-QA-022-10	Effective Date:	20.06.2019
	Supersedes :	SOP-QA-022-09	Next Review Date:	19.06.2022
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audits, Non-conformance / OOS / Deviation, Change controls Market complaints, Product recalls.

5.4.10.2 In case of market complaints, incidents, deviations or OOS, the concerned Department Head shall prepare a specifically designed training programme.

5.4.11 The training details recorded as per Employee Training Card (QA022-FM055) as follows:

- For cGMP (Regulatory/Guidelines awareness) trainings : Yellow colored card
- For On the Job trainings / Schedule trainings   : Green colored card
- For Un schedule trainings   : White colored card

5.5   TRACKING OF TRAINING:

5.5.1   The training program of the each employee in the departments shall be reviewed by concerned department training coordinator for every month.

5.5.2   The un-attended employees training details shall be recorded in the "List of Training Absentees and Reschedule details" format (Current version of QA022-FM173).

5.5.3   The head/ Designee of the concerned department shall review list of training absentees and Reschedule details.

5.5.4   The Head-QA/Designee shall approve the "List of Training Absentees list and Reschedule" details and assign the reschedule date.

5.5.5   "Absentees list and Reschedule" details shall be informed to the concerned employee by concerned department training coordinator.

5.6   SELECTION OF TRAINER:

5.6.1   Trainers shall be chosen from internal functions / experts external to organization.

5.6.2   Training shall be conducted by appropriately qualified expert staff, in addition to the respective departmental Head.

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5.6.3   Trainer shall be selected on the basis of the following

- Basic Education

- Work Experience

- Expertise in the area

5.6.4   QA shall document the trainer's profile.

5.6.5   The trainer shall be selected by the Head, concerned department based on the qualification and work experience in the respective area.

6.0   FORMATS/ANNEXURES:

6.1   Participant details   :QA022-FM005

6.2   Job Description   :QA022-FM014

6.3   Training Schedule   :QA022-FM025

6.4   Induction and assessment Record   :QA022-FM030

6.5   Employee Training Card   :QA022-FM055

6.6   Self-Assessment & Declaration Form   :QA022-FM116

6.7   List of the Trainers   :QA022-FM131

6.8   Certification of the Qualified Trainer   :QA022-FM132

6.9   List of Training Absentees and Reschedule details   : QA022-FM173

6.10 Training Needs Identification Chart   : Annexure – 1

7.0   CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Reference CCF No.
00	01.07.2009	New SOP is introduced	-
01	24.08.2010	SOP Procedure is updated and formats also included.	-
02	24.11.2011	Formats included for Individual training Record	-

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Revision No.	Effective Date	Details of Revision	Reference CCF No.
03	15.06.2012	One Format included for Absence employees Record	-
04	01.01.2013	Training record for all employee included	-
05	15.06.2014	Formats are the part of SOP. So prepared Separately and more clarity	-
06	01.08.2016	SOP revised by rephrased procedure with better clarity.	-
07	01.04.2017	SOP revised inline with "SOP-QA-001-04".	QA-CRF-014/16
08	01.01.2018	SOP format changed make to inline with SOP-QA-01-05.	CCF/GEN/17037
09	12.04.2018	1. Tracking of training procedure introduced. 2. List of Training Absentees and Reschedule details format introduced. 3. Training card colour code practices was defined. 4. Altogether procedure has been rephrased for better clarity.	CCF/GEN/18006
10	20.06.2019	1. The absentees tracking against the targeted participants and its training completion procedure elaborated. 2. Remarks column included in "List of Training Absentees and Reschedule details" format. 3. "Questionnaire" (QA022-FM027) Format was removed.	CCF/GEN/19011

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