	STANDARD OPERATING PROCEDURE			
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TITLE: PERSONNEL TRAINING				

1.0 PURPOSE:

To lay down a procedure for training conduct to personal working in the cGMP environment.

2.0 SCOPE:

This procedure is applicable to train the personnel 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:

4.1 **Induction Training**:

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

4.2 **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.

4.3 **On the Job Training:**

	Prepared by	**Reviewed by**	**Approved by**
Sign & Date			
Name	A. Ravi	Ch. Mahendar Reddy	N. Sreedhar
Department	Quality Assurance	Quality Assurance	Quality Assurance

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Training through reading of documents followed by a practical training.

4.4   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 in to 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.

5.2   The general flow of induction training shall be:

5.2.1   Overview of the organization / unit, structure, governing policies, rules and regulations.

5.2.2   Overview of the other interacting departments, customer and supplier departments, basic processes, interfacing activities in relation to his/her job.

5.2.3   Overview of the parent department, organogram, job responsibilities, interfacing activities besides understanding of functional procedures and activities.

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

For cGMP trainings   : Yellow colored card

For On the Job trainings / Schedule trainings : Green colored card

	Prepared by	**Reviewed by**	**Approved by**
Sign & Date			
Name	A. Ravi	Ch. Mahendar Reddy	N. Sreedhar
Department	Quality Assurance	Quality Assurance	Quality Assurance

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For Un schedule trainings   : White colored card

5.3 NEW RECRUITS (FRESHER):

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

5.3.2 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.

5.3.3 HR department shall send new recruit to the concerned department. The concerned HOD shall assign the new recruit under supervision of senior person.

5.3.4 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).

5.3.5 All new recruits (fresher) shall under go on the job training in their respective functions under the supervision of the senior person and record the same in training record.

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

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

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

5.3.9 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.

	Prepared by	**Reviewed by**	**Approved by**
Sign & Date			
Name	A. Ravi	Ch. Mahendar Reddy	N. Sreedhar
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5.4 **NEW RECRUITS (EXPERIENCED):**

5.4.1 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 departments and their activities.

5.4.2 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 individual training record.

5.4.3 The training 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.

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

5.5 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.

5.6 **ON THE JOB TRAINING:**

5.6.1 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 for major changes).

5.6.2 **Training Need Identification:**

5.6.3 As part of regular / refreshment training, the concerned HOD shall identify the training needs and shall prepare schedule for the year.

5.6.4 Following are the training indicators to prepare the schedule, but not limited to:

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

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Sign & Date			
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5.6.4.2 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.

5.6.4.3 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.

5.6.5 cGMP Training:

5.6.5.1 All personnel associated with cGMP activities shall undergo cGMP training for a minimum of 15 hours in a calendar year.

5.6.5.2 The cGMP training shall include training on various chapters covered as per applicable market regulatory guidelines for cGMP, SOPs related training, On the Job and Refresher training, Technical and Functional related training.

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

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

5.6.5.5 Details of participants shall be recorded in participant details record.

5.6.5.6 The Trainer shall carry out evaluation of cGMP training to ensure that it fulfills the intended requirements.

5.6.5.7 The Training schedule shall be prepared by the QA department in advance.

5.6.5.8 The training imparted to the employee shall be evaluated to ensure that the employee has understood the contents.

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Sign & Date			
Name	A. Ravi	Ch. Mahendar Reddy	N. Sreedhar
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5.6.5.9 On completion of training program the Trainee shall be evaluated through a 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.

5.6.5.10 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.

5.6.5.11 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.

5.6.5.12 If trainee fails to obtain the minimum qualification marks, retraining (remedial) shall be conducted and the same shall be recorded in Participants details.

5.7 **UN SCHEDULES TRAINING:**

5.7.1 Specific training requirement based on outcome of the compliance monitoring and any non-compliance raised by the internal and external audits, Non-conformance / OOS / Deviation, Change controls Market complaints, Product recalls.

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

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

5.7.4 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.

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Sign & Date			
Name	A. Ravi	Ch. Mahendar Reddy	N. Sreedhar
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5.7.5 All the personnel shall be trained on all the SOPs (new and revised) pertaining to their duties by the concerned HOD

5.7.6 The training details shall be documented in the training record and participants details form.

5.8 **TRACKING OF TRAINING:**

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

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

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

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

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

5.9 **SELECTION OF TRAINER:**

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

5.9.2 Trainer shall be selected on the basis of the following

Basic Education

Work Experience

Expertise in the area

5.9.3 QA shall document the trainer's profile.

	Prepared by	**Reviewed by**	**Approved by**
Sign & Date			
Name	A. Ravi	Ch. Mahendar Reddy	N. Sreedhar
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5.9.4 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 Questionnaire : QA022-FM027

6.5 Induction and assessment Record : QA022-FM030

6.6 Employee Training Card : QA022-FM055

6.7 Self-Assessment & Declaration Form : QA022-FM116

6.8 List of the Trainers : QA022-FM131

6.9 Certification of the Qualified Trainer : QA022-FM132

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

6.11 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	-
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

	Prepared by	Reviewed by	Approved by
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Revision No.	Effective Date	Details of Revision	Reference CCF No.
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

	Prepared by	Reviewed by	Approved by
Sign & Date			
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Department	Quality Assurance	Quality Assurance	Quality Assurance