DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Training of Personnel in factory	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for organizing and conducting training programs in the factory for plant personnel.

2.0 SCOPE:

This SOP is applicable for all personnel at all levels at …….

3.0 RESPONSIBILITY:

All department heads and training coordinator for organizing, conducting and assessing the trainees.

HRD Personnel for conducting induction training to all new recruits. Head – Quality Assurance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Preparation procedure:

5.1.1 Training shall be given to all personnel in the production, Quality Assurances, Quality Control, Engineering, Stores and Personnel departments.

5.1.2 The training needs of each employee shall be identified based on their job responsibility and consequently the training schedule cum card as per Annexure –I shall be prepared. The Training schedule cum cards shall be prepared for individuals or groups whose job responsibilities are similar.

5.1.3 Training schedule cum card shall be prepared by the training coordinator and shall be checked by the department head and approved by Head Quality Assurance.

5.1.4 Training program shall consist of following five categories:

- Induction program
- cGMP/cGLP training
- Job related training (Standard Operating Procedures)

- Safety training

NCR (Non conformance report) related training

5.1.5 Human resources Department shall be responsible for the induction program for the new recruits, which shall include the overview of the organization and its general policies.

5.1.6 The quality Assurance department shall be responsible for organizing and conducting cGMP/cGLP training/awareness program through internal and external trainers.

5.1.7 The job related training shall be given the concerned department heads his designee or external trainers having sufficient knowledge on the subject.

5.1.8 Safety training shall be conducted by Engineering head, his designee or external trainers having sufficient knowledge on the subject.

5.1.9 For NCR related training, appropriate training sessions shall be carried out and the same shall be recorded in unscheduled training card as per Annexure-II. Any external training or SOP revision training shall also be recorded in the similar way.

5.1.10 The mode of training shall be either oral or through visual presentations prepared as modules.

5.1.11 The trainees shall be evaluated through written questionnaire or orally. If the evaluation score is less than 80%, the trainee shall be required to undergo retraining.

5.1.12 Department Head shall ensure that new recruits are suitably trained for their work before assigning them with independent activities. Each new recruit shall be given the New Recruit Induction/Training certificate (Annexure - III) after the successful completion of the training program.

5.1.13 A Training Manual shall also be prepared by the training coordinator which shall include the following but not limited to:

- Policy of training
- Identification of trainers
- Training Modules
- Methods of Training and Evaluation
- Methods of Recording

The relevant annexures will be update as per requirement.

5.1.14 At the end of the year, each employee shall be evaluated through the long-term evaluation format (Annexure –V) and retraining requirements shall be identified for the individual during such evaluation by the department head.

5.1.15 The frequency of the training program is as follows:

- One cycle per year shall be completed in a maximum of 12 months for SOPs and cGMP/cGLP training.

NOTE: Schedule of the training programs may be changed to suit work exigencies.

5.1.16 External trainings shall be coordinated by Quality Assurances Department along with HRD and concerned department. The training details shall be recorded in the training format (Annexure –IV). The trainees shall handover the training materials to the training coordinator for reference.

5.1.17 Advanced technical training topics shall be identified by the respective department heads from recent publication, external training and Pharmacopoeial revisions. Such trainings may be conducted through classroom training or issuing materials for reading.

5.1.18 The training records of all existing employees shall be retained by Quality Assurance department. For resigned employees, only the training schedule cum card shall be retained for a period of maximum three years.

5.1.19 Feedback forms shall be obtained through “Feedback about Training program and Trainer/ Facility” (Annexure –VI) only for the training programs conducted by external faculties.

5.1.20 To assess the technical and presentation skills of the internal faculty, feedback form shall be obtained from the participants for the first program of the faculty. Evaluation shall be done by QA Manager.

5.1.21 The training records shall be preserved with the Quality Assurance Department.

6.0 ABBREVIATION(S):

Dept. : Department

QA : Quality Assurance

QC : Quality Control

SOP : Standard Operating Procedure

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

ANNEXURE I: Training Schedule cum card

ANNEXURE II: Unscheduled Training Card

ANNEXURE III: New recruit Induction/Training Certificate Training Format

ANNEXURE IV: Training Format

ANNEXURE V: Long term Evaluation

ANNEXURE VI: Feedback about Training Program and Trainer/Faculty

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION