



STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
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1.0 OBJECTIVE:

To lay down a procedure of training requirements for Good Manufacturing Practices (GMP) and related training program for employees ofto ensure that all employees receive appropriate training, which would enhance knowledge, skill, experience and behavior to execute their appropriate duties and responsibilities to achieve safety, identity, strength, quality and purity of the drug products.

2.0 SCOPE:

This standard operating procedure is applicable to all employees of those are engaged in Quality Management System (QMS), cGMP and allied activities – in the Manufacturing, Packaging, Warehouse, Quality Control, Quality Assurance, Engineering, Human Resources, Environment Health and Safety and all other associated departments at

3.0 RESPONSIBILITY:

3.1 Concerned Department Head/Designee shall be responsible for the training of the personnel.

3.2 Concerned Department Heads/Designee shall be responsible for the Training need identification, ensure compliance of this SOP and maintenance of training records.

3.3 HR-Personnel/Designee shall be responsible to train the contract employee or workmen.

4.0 ACCOUNTABILITY:

4.1 Head-Quality Assurance shall be accountable for ensuring compliance of Standard Operating Procedure.

5.0 DEFINITION:

Training is highly useful tool that can bring an employee into a position where they can do their job correctly, effectively, and conscientiously.

6.0 PROCEDURE:



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- 6.1 All the employees engage in Quality Management System (QMS), cGMP and allied activities manufacturing, Packing, warehouse, Quality Control, Quality Assurance, Engineering, Human Resources and all other associated departments, shall be adequately trained and such training must be assessed and documented.
- 6.2 Training shall be conducted in accordance with approved and written training programs/procedures by appropriately qualified expert resource/ trainer/ subject matter experts or respective department Head/Designee.
- 6.3 Only the trained personnel shall be allowed to carry out their respective activities independently.
- 6.4 Appropriate training shall also be provided for the personnel at all levels within the organization, the purpose of such training shall be to enlighten the awareness of quality management and the importance of compliance to cGMP and SOP's as applicable in the organization.

6.5 Types of Training:

The following types of training shall be imparted to the personnel to upgrade their skills and knowledge.

- 6.5.1 Induction Training (Refer: SOP for induction training)
- 6.5.2 cGMP Training (Initially and Refresher cGMP Trainings)
- 6.5.3 On-Job Training: Based on Job Description, Training Need Identification, Scheduled and ongoing trainings
- 6.5.4 External Training

6.6 Induction Training

Training which shall cover the overview of organization, units, company policies and departments is called induction training.

6.6.1 For New Entrant

- 6.6.1.1 The induction training shall be imparted to every new employee, who joins the organization. Induction training Program (refer SOP No. SOP/HR/002) shall be co-ordinated by HR & QA department.
- 6.6.1.2 Initial induction training is carried out by HR department, HR personnel shall give information regarding the company's profile, service rules, administrative rules, disciplinary rules, shift



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timing, leave policy and other employee benefit policies, Safety Procedures, Personal Hygiene procedures, Organizational Structure, Key personnel and organization structure of various departments, Product range.

6.6.1.3 As per the induction training schedule, the new entrants shall go to applicable departments for the interaction with concerned HOD and staff members.

6.6.1.4 HOD of various departments or his/her designee shall brief to the new entrants about their departmental structure, departmental functions.

6.6.1.5 All the new entrants shall be imparted induction training through induction schedule

6.6.1.6 Induction training program shall be signed by the trainer after completing the training.

6.6.1.7 After successful completion of induction program, personnel shall go to his/her concerned department for training program.

6.7 cGMP Training:

6.7.1 cGMP training covers various aspects of current Good Manufacturing Practices as per different regulatory guidelines.

6.7.2 cGMP training shall be given to all employees (existing and newly joined) those are directly or indirectly associated with the quality of the drug product, cGMP training also cover the safety aspects of the personnel engaged in manufacturing operation.

6.7.3 cGMP Training shall be imparted to all new entrants by QA immediately after completion induction program. cGMP training shall be part of Training Identification for the new joinee. Under this training, the employee is imparted training on Good Practices in Production and Quality Control, Personnel, Sanitation and Hygiene, Good Documentation Practice, QMS System and other aspects of cGMP (If Applicable).

6.7.4 cGMP training shall be conducted by certified trainer as class room training.

6.7.4.1 **Class room training:** This type of training is given to the employees in a hall or room which is facilitated with Power point presentations, slides, Projectors or videos for better understanding of cGMP.



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6.7.5 Evaluation of cGMP training shall be done through oral feedback or viva voice. If feedback is not found satisfactory another session shall be conducted and after satisfactory feedback training is completed.

6.7.6 All the employees attending cGMP training shall be recorded on Training Attendance Record.

6.7.7 cGMP Refresher Planner (Annexure-XIII) shall be prepared by QA department and training shall be given by certified trainer to all departments like QA, Production, QC, Warehouse, Engineering, HR with a repetitive frequency of every six month, mandatory for every employee.

6.8 On Job Training (OJT):

6.8.1 On the job training shall be imparted to all the new joinee by the concerned HOD or his / her designee related to the area of operation.

6.8.2 Training need identification for new joinee (Refer-Annexure-VIII) shall be prepared in by Concerned Department Head/designee/training coordinators in consultation with QA Head on the basis of individual's qualification, experience, and the job he/she is going to handle and his/her understanding of the topic.

6.8.3 Cross functional SOP's & SOP's related to QA shall be part of Training Need Identification (TNI) and certified trainer shall impart training on these SOP's.

6.8.4 Concerned Department Head shall mention the name of SOP's/documents, their reference number, planned date of training in printed format and forwarded it to QA department.

6.8.5 Head-QA/Designee shall approve the Training Need Identification and Officer/Executive QA shall put master stamp on it and issue controlled copy to concerned department for execution of training.

6.8.6 On job training program shall be approximately for the period of approximately 4 days or time period shall be decided by Department Head with the consultation of Head QA.

6.8.7 During on job training, the person shall be trained on actual area of working: this includes class room training as well as shop floor training, adherence to cGMP and Procedure related to Health safety and environmental standards of the working area, SOPs related to the equipments, instruments and working area, Unit operations, use and operation of equipment and instruments, change room practices.



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- 6.8.8 Topics of training for the training need identification/on job training shall be decided by the respective department heads.
- 6.8.9 During the period of on job training on the respective topics, the trainee should work under supervisor/guidance of the trainer/concerned department head/designee.
- 6.8.10 This type of training shall be imparted by the respective departmental certified trainer to all the respective departmental personnel on its own departmental SOPs and relevant cross-functional departmental SOPs.
- 6.8.11 The evaluation of the new entrant shall be done either by written examination or by reviewing a training report written on the topic of covered during training as given in Annexure-V and same shall be recorded and evaluated.
- 6.8.12 Trainees filled questionnaire shall be assessed for the satisfactory training, trainees who shall scores less than 80 % marks will be considered unsatisfactory and retraining shall be imparted Grade the individual based on percentage as follows:
1. Upto 100 % Excellent
 2. Less than 100% & upto 90%.....Very Good
 3. Less than 90% & upto 80%.....Satisfactory
 4. Less than 80 %Un Satisfactory (Require Retraining)
- 6.8.13 The participants scoring less than 80 % marks shall be retrained and reassessed on the same day or in second session.
- 6.8.14 In case trainee secures less than 100% but above 80% marks he/she shall be explained the relevant topic in detail for better understanding and good results during the routine activity.
- 6.8.15 Training evaluation shall be done by certified trainers of respective departments.
- 6.8.16 Based on the evaluation “job responsibilities” shall be assigned to the trainee and job responsibilities shall be signed by the concerned department head and photocopy of the job responsibilities shall be the part of trainee training file.
- 6.8.17 A certificate stating the declaration of the trainee to carry out the assigned activities/test and/ or handling of the selected equipment/instrument independently shall be issued based on technical training which is including on the basis of training need identification or as applicable.



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Certificate is to be signed by Head-QA as given in Annexure- XI. The date on which the certificate is signed by Head-QA is to be considered as effective date for that certification.

6.8.18 After certification person shall be assigned for his/her duties and responsibilities.

6.8.19 Employee transferred from one department to another or handling different/additional responsibilities within the department shall be trained before starting the job activity and his/her job responsibility shall be revised.

6.8.20 Contract/temporary worker should not be the part of training need identification/On Job Training, he /she shall be imparted training as per point number 6.6.2.

6.9 Scheduled and on-going training

6.9.1 In-house training shall be arranged for existing staff to upgrade their knowledge and skills to familiarize with the principle of new instruments, new equipment, process, methods and new dosages form etc.

6.9.2 Monthly training schedule shall be prepared from the Annual training calendar by each departments with the objective of targeted group (like cGMP Training Including all modules, Water System, HVAC system, Risk Assessment, Regulatory Requirements, Quality Manual, Pharmaceuticals Quality System, Annual Product Quality Reviews, Cross-Functional SOPs and etc.) and to be trained on such SOP as per monthly training schedule as given in Annexure- III, and duly approved by Head- QA

6.9.3 Training Calendar shall be controlled by QA and duly approved by Head-QA.

6.9.4 Executive/Officer/designee-QA shall stamp as “Master Copy” in Annual Training Calendar and Monthly Training calendar and same shall be distributed to concerned department as issued copy for the training execution and compliance.

6.9.5 In case of any urgent change in policy or regulatory requirements or any other change, training can be done and shall be recorded.

6.9.6 All employees shall undergo training in the topics whichever relevant to their area of operation. Each topic shall be covered on rotation basis or in different session of the scheduled month.

6.9.7 The Training planned in a particular month shall be completed in that particular month only irrespective of planned date.



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- 6.9.8 The topic covered under refresher/annual training would be critical areas of GMP/GLP/GDP.
- 6.9.9 In a situation, where personnel of any designation are the creator or approver or checker of a particular SOP of a concerned department, shall not be required to be trained on such SOP.
- 6.9.9.1 Training required, for qualifications and validation activities will be defined in individual protocol and recorded along with the qualification and validation expertise.
- 6.9.9.2 All SOPs shall be covered like department SOP's/Cross Functional SOP's (if applicable), operation, calibration, documentation, cleaning procedure of each equipment, process steps with precautions and safety aspects while handling chemicals and materials.
- 6.9.10 In case of Change in any operational procedure cleaning procedures, concerned employees shall be subjected to training as on job training before effective date of the SOP or before implementation of the change. The following changes may be considered but these are not limited :
- 6.9.10.1 Change in the nature of job and responsibilities.
- 6.9.10.2 Whenever a change shall be made in the SOP or whenever SOP shall be revised due to any revision of system.
- 6.9.10.3 Whenever the method of operation and analysis changes.
- 6.9.10.4 Whenever any changes are made in the operating parameters or conditions.
- 6.9.10.5 Changes required due to regulatory requirements.

6.10 External Training:

- 6.10.1 Any External training related to introduction of new System, new operational procedure for new equipment/Instrument /Apparatus from the manufacturer or vendor shall be imparted by outside faculty or Technical Person through workshops, seminars etc. shall be recorded in the "Training Card". However the proof of attendance shall be maintained by QA or by the respective department.
- 6.10.2 Such External training shall not be evaluated by any written examination. Only oral assessment is applicable.



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- 6.10.3 Add on training for this type of training, there shall be no plan and shall only be conducted on need base. Under this training the SOP and other scheduled trainings shall not be covered. The evaluation of this type of training may or may not be applicable.
- 6.10.4 The external trainer shall be identified by Head-HR/Designee in consultation with functional heads based on the expertise of the trainer on the topic.
- 6.10.4.1 Organization shall depute its employees for various seminars, lectures or demonstrations offered by the trainer which may be external agency, consultants, expert, products promoter etc. based on functional requirement and the training needs identified for the employee.
- 6.10.5 Such External training shall be attained by the certified trainers/subject matter experts to train further respective departments personnel, when required.
- 6.10.6 **For contract employee or workmen/New Workmen/Service provider**
- 6.10.6.1 Basic GMP training, safety training shall be imparted by the HR-Person in vernacular language from the printed GMP module on joining of new contract employee with respect to Good Practices in Manufacturing , Do's and don'ts, Sanitization ,Hygiene and entry, Exit Procedure from the change room.
- 6.10.6.2 Contract employee Basic GMP training is a formal training, this training shall not be recorded for training attendance.
- 6.10.6.3 Service provider shall be accompanied by company personnel. Service provider shall include those parties who are performing activities like calibration, maintenance, filter cleaning, HVAC validation, painting or civil works, pest control etc. this list is not a comprehensive list by itself. Before initiating any activity, service provider shall be instructed regarding basis norms of cGMP, hygiene, safety and entry and exit procedure etc.

6.11 Methods of Training:

- 6.11.1 Off the job or class room training – In-house and out house, both.

6.12 Training Aids Tools:

Training may be given by using the following training Aids / Tools:

- 6.12.1 Approved Training Module, Audio visual media, Power Point Slides.



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6.12.2 Other appropriate methods of display like, white board, papers and posters, Over Head Projector, LCD or any other electronic device, to train the group

6.13 Identification of Certified Trainers:

6.13.1 Trainers shall be identified on the basis of their qualification; SME's and experience in related trade and regulatory inspections experiences.

6.13.2 Identified trainer shall be assessed through the trainer checklist as per Annexure-VII by concerned department-Head and Head QA.

6.13.3 If the trainer meets the acceptance criteria as per the requirement defined in the trainer checklist the trainer shall be certified as certified trainer as per Annexure-IX by Head-QA.

6.13.4 After certification, the trainer shall be included in the list of certified trainer (Refer Annexure-I).

6.14 Execution of Training:

6.14.1 Concerned Department-Head/Designee or Training Co-coordinator shall inform individual trainee as per planner either by written or verbal communication with details of time, place, certified trainer/faculty and subject of internal/external training program.

6.14.2 In case of on job training, the personnel responsible for the implementation of the change shall inform to all concerned persons and cross functional departments regarding the topic of training, date, venue, personnel to be trained and certified trainer.

6.14.3 HR-Department shall organize all relevant accessories for any external/internal training like projector, training/Conference Hall, Marker and drinking water and etc.

6.14.4 Training shall be given through reference SOP's of Master SOP or approved training module by the trainer in advance. .

6.14.5 All training activities shall be properly documented through training attendance record. (refer Annexure-IV)

6.14.6 Training Attendance Record shall be distributed to all departments to maintain the records and assures that qualified and appropriately trained individuals are carrying out all the activities at the site, resulting in the manufacturing of quality product.



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6.14.7 All the trainees assessed for their understanding through a questionnaire (Refer Annexure-V) on the subject of training. In case a trainee fails to understand, he shall be retrained and reassessed on the same day or 2nd session.

6.14.8 Individual Training Cards (Refer Annexure-VI) shall be recorded for traceability and acknowledgment of the trainees.

6.15 Assessment of Training:

6.15.1 All types of training, imparted to the employee shall be evaluated by trainer to ensure that the employee has understood the training contents.

6.15.2 The 'Awareness' or the knowledge shall be assessed by the percentage of marks obtained.

6.15.3 Trainees filled questionnaire shall be assessed for the satisfactory training, trainees who shall scores less than 80 % marks will be considered unsatisfactory and retraining shall be imparted
Grade the individual based on percentage as follows:

1. Upto 100 % Excellent
2. Less than 100% & upto 90%.....Very Good
3. Less than 90% & upto 80%.....Satisfactory
4. Less than 80 %Un Satisfactory (Require Retraining)

6.15.4 The participants scoring less than 80 % marks shall be retrained and reassessed on the same day or in second session.

6.15.5 Evaluation of re-training shall be done and same shall be recorded in training attendance record.

6.15.6 A person shall be allowed to work in the respective area after successful re-evaluation

6.15.7 The criteria for re-evaluation shall be not more than two re-evaluation chances for respective personnel. And, if one is not able to comply the re-evaluation criteria, then, that personnel shall be assigned a job of nontechnical nature or a job less technical than his/her present job and his/her job responsibility shall be revised.

6.15.8 In case trainee secures less than 100% but above 80% marks he/she shall be explained the relevant topic in detail for better understanding and good results during the routine activity. This case shall be recorded in Annexure-V (Training Attendance Sheet).



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6.15.9 Department Heads shall self read & understood the SOPs.

6.15.10 In training assessment sheet not less than 5 questions to be incorporated.

6.15.11 The format of training assessment sheet is presented in Annexure-V.

6.16 Retraining:

6.16.1 Retraining plan shall be considered under the following circumstances:

- If any deficiencies are noticed in working, during self-inspections, audits, unexpected event (deviations, OOS/OOT and analyst error)
- If any participant, failed to meet the acceptance criteria for evaluation of training.

6.16.2 The training (if triggered) shall be imparted to the personnel associated with the event (especially, the area in charge, operator, IPQA personnel and the training records shall be compiled with the specific unexpected event report as a supportive document.

6.16.3 Person who join the organization as Manager and above shall self-read & understood the SOPs related to their Job Responsibilities.

7.0 ABBREVIATIONS:

cGMP	Current Good Manufacturing Practices
OJT	On Job Training
EHS	Environment, Health & Safety
ETP	Effluent Treatment Plan
GDP	Good Documentation Practice
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
NA	Not Applicable
OHP	Overhead Projector
QA	Quality Assurance
QC	Quality Control
F&D	Formulation and Development
HR	Human Resource



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SOP	Standard Operating Procedure
SME	Subject Matter Expert
GEP	Good Engineering Practice
QMS Tool	Quality Management System Tool like Change Control, Deviations, CAPA, Non-conformance report ,yield non-conformance report, OOT, OOS, Market Complaint, Product Recall
CFR	Code of Federal Regulations

8.0 ANNEXURE:

ANNEXURE No.	ANNEXURE TITLE	FORMAT No.
Annexure-I	List of Certified Trainers	
Annexure –II	Annual Training Calendar	
Annexure-III	Monthly Training Schedule	
Annexure-IV	Training attendance Record	
Annexure-V	Training Assessment Sheet	
Annexure-VI	Training Card	
Annexure-VII	Checklist for the assessment of Trainer	
Annexure-VIII	Training Need Identification for new joinee	
Annexure-IX	Certified Trainer	
Annexure-X	Flow Chart of Training Process	
Annexure-XI	Trainee Certificate	
Annexure-XII	Training Protocol of employee resuming duty after long leave/absence	
Annexure-XIII	cGMP Refresher Planner	



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Annexure-I

LIST OF CERTIFIED TRAINERS

Effective date:

Revision No.:

S.No.	Name of Trainer	Department	Qualification	Experience

Approved By

(Sign/Date)



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Annexure-II

ANNUAL TRAINING CALENDAR

For Year:

Department:

Effective Date:

Revision No.:

S.No.	Training Subject	Targeted Group	Training Program																							
			Jan		Feb		Mar		Apr		May		Jun		Jul		Aug		Sep		Oct		Nov		Dec	
			S	E	S	E	S	E	S	E	S	E	S	E	S	E	S	E	S	E	S	E	S	E	S	E

S=Schedule : *E = Executed

Prepared By
Officer/Executive
(Sign/Date)

Checked By
Department Head
(Sign/Date)

Approved By
Head QA
(Sign/Date)



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Annexure-III
MONTHLY TRAINING SCHEDULE

Department:

Month:

S.No.	Training Subject/SOP No.	Planned Date	Executed Date	Targeted Group	Remarks

Approved By:
Head QA
(Sign & Date).....



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Annexure-IV

TRAINING ATTENDANCE RECORD

Training Details

Type of Training: OJT/cGMP/SOP revision/other

Date of Training:

Topic /Subject of Training:

Ref. SOP/Doc. No.:

Time: From _____ to _____

Attendance

S.No.	Name	Employee Code	Dept.	Design.	Signature	Remarks (If Any)

Trainer:

Name:

Department:

Designation:

Sign & Date:

Remarks of Trainer:



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Annexure-V

TRAINING ASSESSMENT SHEET

Name: _____ **Date:** _____

Designation: _____ **Department:** _____

Training Subject:

Ref. SOP/Doc. No.:

Total Marks:

Marks obtained:

Trainee Signature:

S.No.	Question and Answer	Marks
1.	Question: Ans:	
2.	Question: Ans:	
3.	Question: Ans:	
4.	Question: Ans:	
5.	Question: Ans:	

*Excellent = Upto 100%

**Satisfactory = Less than 90% & Upto 80%

**Very Good = Less than 100% & Upto 90%

*Unsatisfactory = Less than 80%

*Put ✓ or X as applicable

* In case trainee secures less than 100% but above 80% marks:

Trainee did not understand the procedure for.....

Above topic has been explained again to the trainee and on the basis of feedback received it is found that he/she has well understood the topic. Hence trainee shall continue the routine activity.

Re-training Required/Not Required

Evaluated By Certified Trainer

Name :

Sign & Date :

Dept. :

Designation :



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Annexure-VII

CHECKLIST FOR THE ASSESSMENT OF TRAINER

Name of Trainer : _____ **Department** : _____

Training Topics : _____ **Observer Name** : _____

S.No.	Assessment Parameters	Marks	Obtained Marks
1.	Trainer shall be Educated, Qualified and Experienced in cGMP Awareness and Pharmaceuticals Quality System.	10	
2.	Trainer shall be skilled and well behavioral to trainees.	10	
3.	Subject matter experts/Fluency of Languages.	10	
4.	Well Experienced/Technical Competences/Level of Confidence.	10	
5.	Trainer has to be capable to deliver the content or good Speaker and ability to answer the questions.	10	
6.	Regulatory Audit faced.	10	
7.	Teach to the learning objectives/ appropriate use of training techniques (Introduction /conclusion /Use of Ice Breakers/Examples/Questions and Answers).	20	
8.	Over all technical competency.	20	
Total		100 Marks	

Overall rating:

Above 80: Excellent	Between 70-80 : Good	Below 70 : Poor
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Note: Person is deemed to be certified as trainer if he/she scores 70% and above in overall rating.

Certified Trainer Comments/Concerned Department Head Comments



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Annexure-VIII

TRAINING NEED IDENTIFICATION FOR NEW JOINEE

Employee Name:
Date of Joining:

Designation:
Employee Code:

Department:
Experience:

Training Need and Plan				Execution and Report		Retraining, If Applicable	
S.No.	Training Subject	Reference SOP No./Doc. No.	Date of training planned	Employee Sign/Date	Trainer Sign/Date	Employee Sign/Date	Trainer Sign/Date

Prepared By
Head- Concerned Department
Assurance/Designee
Sign/Date

Approved By
Head-Quality
Sign/Date



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Annexure-IX CERTIFIED TRAINER

This is to certify that Mr./Ms. _____ of _____ Department /Section is assigned as "In house Trainer " based on his/her qualification , experience and skill. He/she is authorized to conduct in-house training in the followings functions/Operation/Activity and Standard Operating Procedure and cGMP Trainings.

*Approved By
(Sign/Date)*



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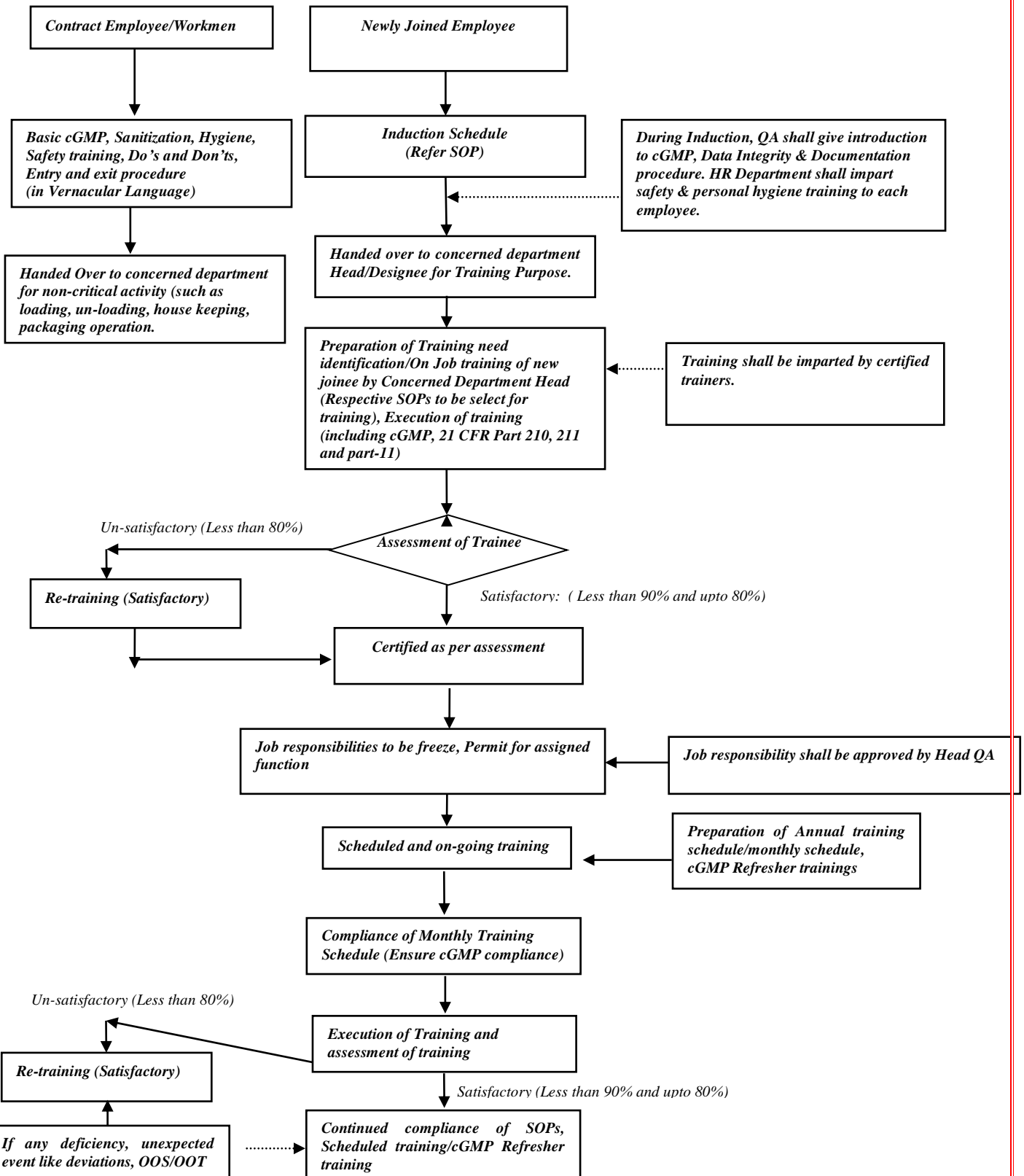
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Annexure-X FLOW CHART OF TRAINING PROCESS





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Annexure-XI

TRAINING CERTIFICATE

This is to certify that Mr./Ms.....Employee No.has been trained in the cGMP / operations of equipments/instruments/system or perform activity as per the respective standard operating procedure in the area/section mentioned below.

His/Her post training evaluation assessment is found satisfactory.

He/She is qualified to carry out unit operations/activity and can operate the below stated equipment/instrument /system or perform activity along with documentation

*Approved By
(Sign/Date)*



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Training of Personnel	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Annexure-XII

TRAINING PROTOCOL OF EMPLOYEE RESUMING DUTY AFTER LONG LEAVE/ABSENCE

Name :

Employee No.....

Leave/Absence Period From:

to.....

Note: Training needs should be identified based on the changes in system/procedure. During his/her leave/absence period, affecting his/her work area.

Date	Topics	Reference Document/SOP No.	Version No.	Dept. Head/ Concerned Officer Name	Trainer's Signature and date

This is to certify that, Mr./Ms....., has successfully completed training program arranged prior to performing job assigned to him/her,

His/her post training evaluation is found satisfactory.

He/She can continue independent work in Section ofDepartment.



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: Training of Personnel

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Annexure-XIII

cGMP REFRESHER PLANNER

YEAR:

Training Subject	Scheduled Month of Training	Training Executed on	Targeted Groups
cGMP			

Prepared By:
Officer/Executive-QA
Sign & Date:

Approved By:
Head QA
Sign & Date: