DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
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1 Purpose: The purpose of this SOP is to define the procedure for handling of Planned modification system.

2 Scope: This procedure is applicable at ……..for the modification and or breakdown related to following:

2.1 Area (Facility/Building),
2.2 Utility (Water system, Steam, Air vacuum, Nitrogen gas, AHU/HVAC) and pipelines,
2.3 Equipment,
2.4 Machine,
2.5 Instrument (Physical relocation of existing or introduction of new instrument which require installation except software updation of QC instruments which is covered under scope of change control procedure).

3 References, Attachments and Annexures:

3.1 **References:**

3.1.1 ……

3.2 **Attachments:**

3.2.1 Attachment-1: Planned Modification Form
3.2.2 Attachment-2: Planned Modification Issuance Register
3.2.3 Attachment-3: Checklist for Impact Analysis
3.2.4 Attachment-4: Flow Chart for Handling of the Planned Modification
3.2.5 Attachment-5: Format for Extension of Tentative Schedule Time for PMF
3.2.6 Attachment -6: Check list for EHS impact evaluation

3.3 **Annexures :** NA

4 Responsibilities:

4.1 **Concerned Department:**

4.1.1 To initiate planned modification form.
4.1.2 To fill the form in consultation with relevant departments.
4.1.3 To provide support for required modification and ensure the completion of recommendation given in planned modification form.
4.1.4 To apply for the target date extension (If required).

4.2 **Concerned Department Head or Designee:**

4.2.1 To approve or reject the planned modification.
4.2.2 To assign tentative schedule time for planned modification.
4.2.3 To ensure clearance prior to start of Planned modification.
4.2.4 To verify the planned modification activity and completion as per the procedure.

4.3 **Engineering Department:**

4.3.1 To prepare the design as per the modification suggested and execute the approved modifications.
4.3.2 To provide support for required modification and completion of recommendation.

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4.4 **Environment, Health & Safety (EHS):**

4.4.1 To provide support for required modification and completion of recommendation. to review, evaluate & sign the Planned modification form.

4.4.2 To recommend the impact analysis on Planned modification system.

4.4.3 To review, evaluate & sign the Planned modification form.

4.5 **Quality Assurance:**

4.5.1 To issue planned modification form to concerned person.

4.5.2 To ensure the modification is carried out as per the approved planned modification.

4.5.3 To provide support for required modification.

4.5.4 To monitor implementation of the recommendations.

4.5.5 To ensure the recommendations are completed as per approved plan modification form.

4.5.6 To evaluate the data after completion of recommendation and to maintain records.

4.6 **Engineering Head:**

4.6.1 To review planned modification form.

4.6.2 To give recommendation if any in to planned modification form.

4.6.3 To approve planned modification.

4.7 **Quality Assurance Head**:

4.7.1 To evaluate and approve the planned modification.

4.7.2 To ensure the PMF activity is being followed as per the procedure.

4.7.3 To approve the tentative date extension.

4.8 **Quality Head:**

4.8.1 To review and approve the planned modification.

4.8.2 Intimate to Regulatory Authority for Information or approval as per guideline.

4.8.3 To inform/approval from Customer, as applicable.

4.9 **Factory Head:**

4.9.1 To review and approve the planned modification.

5 Distribution:

5.1 . Quality Assurance
5.2 . Maintenance
5.3 . Production
5.4 . Quality Control
5.5 . Personnel and Administration
5.6 EHS

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6 . **Abbreviations & Definition of terms:**

6.1 **Abbreviations:**

6.1.1 QA: Quality Assurance

6.1.2 QC: Quality Control

6.1.3 PMF: Planned Modification Form

6.2 **Definition of terms:**

6.2.1. **Planned modification:** A modification which is planned for the introduction, alteration, deletion, upgradation, repair, replacement of equipment, facility, area, machine, utility, pipelines which may be due to breakdown maintenance or identified during preventive maintenance. A modification planned for physical relocation of existing or introduction of new instrument which requires installation.

7. **Procedure:**

7.1 **Issuance, Approval and Execution of Planned Modification Form:**

7.1.1 Need for planned modification arises,

7.1.1.1 While introduction or deletion of new equipment/machine/utility/pipelines/area /instrument.

7.1.1.2 Based on recommendation given in breakdown maintenance record or preventive maintenance record.

7.1.1.3 Based on product or project or safety requirement.

7.1.2 Engineering department and/or concerned department shall decide for requirement of modification, replacement, alteration, deletion, repair, or upgradation of new equipment/machine/utility/pipelines/area/introduction or relocation of instrument.

7.1.3 Concerned department shall intimate to QA for issuance of planned modification form.

7.1.4 QA shall issue planned modification form and fill necessary entries in to planned modification form (Attachment –1).

7.1.5 QA shall fill necessary entries in to planned modification issuance register (Attachment –2)

7.1.6 QA shall issue the planned modification form to initiator department .

7.1.7 Concerned department shall initiate the modification to be carried out in their respective department.

7.1.8 Initiator shall fill the planned modification form as per procedure for filling Planned Modification Form along with the complete details/specifications and get it approved from department head.

7.1.9 Concerned department head shall review and give recommendation if any in to planned modification form and approve it.

7.1.10 Initiator shall submit planned modification form to engineering department for review and approval.

7.1.11 Engineering Department Head shall give recommendation, if any in planned modification and approve it.

7.1.12 After approval from Engineering Head, QA Head/Designee shall review recommendations made by Concerned Department Head.
7.1.13 After review from QA Head/Designee, Initiator shall circulate planned modification form to Quality head and Factory head for approval.
7.1.14 Quality head and Factory head shall review the planned modification form and give recommendation if any in planned modification and then approve it.
7.1.15 In case, if the planned modification form is not approved at any stage the same shall be returned back to QA with reason for cancellation.QA shall put the cancellation remarks in final evaluation section and put sign and date.
7.1.16 QA Department shall maintain the cancelled planned modification form along with supporting documents in respective file and make necessary entries in the issuance register (Refer attachment-2).

7.2 **. Planned modification form numbering system:**

7.2.1 QA shall assign planned modification form number as per following procedure.

7.2.1.1 Planned modification form number shall contain total 10 characters.
7.2.1.2 First three alphabets stand for Planned Modification Form as “PMF”.
7.2.1.3 Next one character stands as “ - ”.
7.2.1.4 Next two numeric stands for current year to be mentioned as:
'12' for year 2012; '13' for year 2013; '14' for year 2014; and so on.
7.2.1.5 Next character stands as “/ ”.
7.2.1.6 Last three numeric shall be serial number starting from 001.

For example, first planned modification number of year 2014 shall be numbered as PMF-14/001.

Note: This numbering system is for guidance purpose only and planned modification numbering can be changed by location if required.

7.2.2 **Procedure for Filling Planned Modification Form and Issuance Register :**

7.2.2.1 QA shall fill the following details in Planned Modification Form:
7.2.2.2 **Planned Modification No.:** Mention planned modification number.
7.2.2.3 **Allotted to:** Mention name of the person to whom the form is issued.
7.2.2.4 **Date of Issuance:** Mention date in this column on which planned modification form is issued.
7.2.2.5 **Issued By:** QA person who issues the planned modification form shall put signature and name.
7.2.2.6 **Department:** Mention department name to which the planned modification form is to be issued.
7.2.2.7 **Area (Facility/building) /Utility /Pipeline/Equipment/Machine /Instrument Name:** Mention the name of area (facility/building)/Utility/Pipeline Equipment /Machine /Instrument for which modification is planned.

7.2.2.8 **ID/Code No. (if applicable):** If PMF is raised for existing area (facility /building) /Utility /Pipeline Equipment /Machine/Instrument then respective ID/Code No. shall be mentioned (if applicable).

7.2.2.9 Concerned Department shall fill following information in the planned modification form.

7.2.2.10 **Existing System:** Mention existing system in detail with reference of supporting document such as drawings/layouts, specifications etc if required.

7.2.2.11 **Brief Details of Modification:** Mention brief details of modification with reference of supporting document such as drawings/layouts, specifications etc.

7.2.2.12 **Reason for Change with Justification:** Mention the purpose of modification along with justification of modification.

7.2.2.13 **Initiated By /Date:** After filling the details in the form, the initiator shall put signature and date.

7.2.2.14 **Tentative Schedule Time:** Engineering/Concern Department shall mention the tentative schedule time.-Mention schedule time in DD/MM/YY format.

7.2.2.15 **Impact Evaluation:** Depending on modification, mention the possible impact as per checklist given in Attachment – 3.

Note:

During Impact Evaluation based on nature of modification, detailed execution plan with preliminary drawings, flow charts etc shall be prepared and attached with PMF.

Recommendation can be given by all the concerns (Initiator, Reviewer, and Approval authorities).

Mention no impact in case where there is no impact. Do not keep any impact section blank.

7.2.2.16 **Sign. of Impacted Department Head:** The initiator shall take the impacted Department Head sign in this column. The impacted department Head shall ensure the impact and shall give recommendation /suggestion if any in to the planned modification.

7.2.2.17 **CAPA No.**: QA shall issue CAPA no. against each recommendation (if required) to monitor the same as per CAPA system.

7.2.2.18 **Approval:** The initiator shall get approval of the planned modification from Department Head, Engineering Head, Quality Head and Factory Head.

7.2.2.19 **Clearance Prior to Start of Modification :**

Clearance to start execution of the modification shall be given by concerned department and the same shall be checked by concerned department Head. Details of clearance shall be mentioned in the provided columns.

7.2.2.20 **Modification Verification:**

7.2.2.20.1 **Modification Started on:** Engineering Department /Concerned Department shall mention date on which modification is started.

7.2.2.20.2 **Modification Completed on:** Engineering Department /Concerned Department shall mention date on which modification is completed successfully.

7.2.2.20.3 Brief details of modification work done shall be mentioned by Engineering Department/Concerned Department.

7.2.2.20.4 **Modification Verified By:** Concerned Department and Engineering Department shall verify for planned modification is completed. If Engineering Department is not involved, mention NA in the respective column.

7.2.2.20.5 **Remarks:** Based upon completion of modification, concerned department and Engineering Department shall document remarks if any.

7.2.2.20.6 **Implementation status of recommendation :**

Concerned Department supervisor shall review the completion of CAPA and shall mention date of completion and status of the CAPA (open/close/cancelled) in impact section.

7.2.2.21. **Hand over after Modification:**

7.2.2.21.1 After completion of the all modification activity, the respective Area/Utility/Pipeline/Equipment/Machine/Instrument and all impacted surrounding area shall be cleaned.

7.2.2.21.2 For equipment cleaning, respective equipment cleaning procedure (complete cleaning) available for at location shall be followed.

7.2.2.21.3 For Area Cleaning, respective area cleaning and clearance procedure available at location shall be followed.

7.2.2.21.4 After cleaning and completion of all CAPA respective Area /Utility/Pipeline/Equipment/Machine/Instrument shall be handed over to the user Department for further qualification /validation /use (as applicable).

7.2.2.21.5 After completion of all activities, QA Head /Designee shall evaluate the modification and based on that Quality Head shall give approval to go ahead with the production activity /operation.

7.2.2.22 **Final Evaluation:**

7.2.2.22.1 **QA Evaluation:** QA shall evaluate all the documents required for completion and closing the planned modification and shall put evaluation comments.

7.2.2.22.2 **Closing of PMF:** Quality Assurance shall close the PMF with remarks (if any) and put sign and date. Accordingly the closing entry shall be updated in the Planned modification form issuance register.

7.2.2.23 QA shall make following entries in planned modification form issuance register before issuance of planned modification form.

7.2.2.23.1 **Sr. No.:** Mention assigned serial number.

7.2.2.23.2 **Planned Modification Form No.:** Mention planned modification number allotted to the initiator.

7.2.2.23.3 **Date of Issuance:** Mention date on which the planned modification form is issued to the initiator.

7.2.2.23.4**Department Name and Initiated By:** QA shall mention the department name and name of the person who has initiated the Planned Modification.

7.2.2.23.5**Area (Building /Facility) /Utility /Equipment (Machine) /Pipelines Name:** Mention Area (Building /Facility) /Utility /Equipment (machine) name of which modification /installation /relocation is planned.

7.2.2.23.6**ID /Code No. (If applicable):** Mention Id /Code no. of Area (Building /Facility) /Utility /Equipment /Machine) if applicable.

7.2.2.23.7**Brief Modification Details:** Mention brief modification details.

7.2.2.23.8 **Modification Work Completed on:** Mention modification completion date after getting planned modification form from Concerned Department.

7.2.2.23.8.1. **CAPA no.** : Include all CAPA numbers alloted for the PMF recommendations.

7.2.2.23.9 QA shall make following entries in planned modification form issuance register after receipt and evaluation of executed and complete PMF form received from concerned department.

7.2.2.23.10 **PMF Status /Remarks :**

7.2.2.23.10.1 If all the given recommendations are not satisfactory and /or incomplete shall remain open.

7.2.2.23.10.2 Concerned persons shall be informed for pending actions if any and the same shall be monitored through CAPA system.

7.2.2.23.10.3 If all the given recommendations are satisfactory and complete, mention “close”.

7.2.2.23.10.4 If the modification is cancelled, mention “Cancelled” with reason in remarks column.

7.3 **Procedure for filling EHS Impact Evaluation form:**

7.3.1. Initiator of the PMF shall submit the PMF to site EHS department for review, evaluation, signing and for recommending impact analysis. (Attachment -6)

7.3.2. Depending on the modification , EHS department shall use the checklist for doing Impact Evaluation. If there is no impact is evaluated accordingly it shall be mentioned in the PMF form.

7.3.3. Checklist shall be attached with the PMF document.

7.3.4. EHS head shall review the completion of all recommendations.

7.4 Execution of Planned Modification:

7.4.1 On receipt of the approved planned modification, Engineering Department shall make the detailed specifications along with required drawings such as schematic drawing, area layout, isometric drawing.

7.4.2 New drawing shall be highlighted and marked as Rev-01, Rev-02 and so on.

7.4.3 Approval shall be taken on the detailed specifications and drawing from the Quality Head and Factory Head before proceeding with the modification.

7.4.4 The final proposal shall be intimated to the Concerned Department Head.

7.4.5 In case, if any authority is not in agreement with the recommendations, a group meeting shall be organized by Engineering and mutually agreed decision shall be finalized.

7.4.6 On receipt of the approval on the specifications and drawing, Engineering Department shall make the cost estimate with tentative completion schedule in co-ordination with in house /outside agency.

7.4.7 In case of any major modifications, which requires approval from any external regulatory bodies, the same shall be taken before commencing the activity.

7.4.8 Production activity /operation of utility or machine shall be stopped before starting execution of the planned modification. Proper storage of product and segregation of area (by means of partition or other suitable technique) shall be ensured to avoid contamination. The same shall be documented in section “Clearance prior to start of modification”.

7.4.9 On completion of all the above formalities, contracts shall be granted to commence the work. The work shall be carried out under the strict compliance of approved proposal and schedule.

7.4.10 On completion of the modification, Concerned Department and Engineering Department shall ensure that the modification is completed as per proposed approved specification.

7.4.11 Brief details of modification work done: After completion of the planned modification activity, brief details of the modification work done shall be mentioned.

7.4.12 In case if Planned Modification exceeds the tentative schedule time, Concern Department shall request for the Tentative date extension of PMF as per attachment-5. QA Head shall assign new date for completion of PMF based on the justification for extension.

7.4.13 If there is any change or deviation noticed while physical evaluation of modification against approved proposal, the same shall be mentioned in remark section and shall brought into notice of the Quality Head.

7.4.14 Concerned Department shall ensure that all recommendation are completed after modification.

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7.5 Validation/Qualification of the modification:

7.5.1 After completion of the modification if it is recommended, the equipment /utility/facility/area shall be validated/qualified to confirm that the same is performing as per its intended use.

7.5.2 Validation/qualification shall be carried out by Concerned Department in consultation with QA Department and Engineering Department.

7.5.3 All the supportive documents, reports, specifications, details of the modifications carried out during or after the modification work shall be attached along with the planned modification form.

7.5.4 The full set of the qualification /validation document shall be submitted to QA department.

7.5.5 If the modified facility does not meet the required specifications, re-modification/rework shall be initiated by Engineering with new planned modification form.

7.5.6 Production activity /operation shall not start unless and until all the recommendations completed.

7.5.7 After completion of all activities, QA Head /Designee shall evaluate the modification and based on that Quality Head shall give approval to go ahead with the production activity/operation.

7.5.8 QA shall review and evaluate all the documents. QA shall ensure that all the recommendations are completed.

7.5.9 QA shall close PMF based on final evaluation.

7.5.10 QA shall maintain final completed records.

7.5.11 If modification is not completed as per approval, Concerned Department, Engineering Department shall decide the further action to be taken in consultation with Quality Head and Factory Head.

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Attachment -1
Planned Modification Form

Planned Modification No.:	**Allotted to:**
Date of issuance:	**Issued By:**
Department:	
Area (Facility/Building)/Utility/Pipelines/Equipment/ Machine /Instrument Name:	
Code No. /Id No. (If applicable):	

Existing System:
Brief details of Modification:
Reason for change with Justification: _____ Initiated By/Date
Tentative Schedule Time: _____ Sign and Date (Concerned dept. / Engineering Dept.)

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Impact Evaluation

(To be filled by Concern Department)		Sign. of Impacted Dept. Head	(To be filled by QA)	(To be filled by Concern Department)	
Impact on	**Recommendation**		**CAPA No.**	**Date of CAPA completion**	**CAPA status (Open/Close/cancelled)**
Process					
Product					
Validation					
Qualification					
Calibration					
Training					
Environment/Health/Safety (As per Attachment 6)					
Cleaning/Passivation /Sanitation					
Preventive maintenance schedule					
Regulatory Approval (Govt. Body)					

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Attachment-1

Planned Modification Form

(To be filled by Concerned Department)		Sign. of Impacted Dept. Head	(To be filled by QA)	(To be filled by Concerned Department)	
Impact on	**Recommendation**		**CAPA No.**	**Date of CAPA completion**	**CAPA status (Open/Close/ Cancelled)**
Documents (SOP, Layout, drawing, Diagram etc.)					
Segregation of the Area /Caution display					
Utility Impact					
Any other					

Note: During Impact Evaluation based on nature of modification, detailed execution plan with preliminary drawings, flowcharts etc shall be prepared and attached with PMF.

APPROVAL:

APPROVED BY	**Sign and Date**
Department Head:	
Engineering Head:	
Quality Head:	
Factory Head:	

Clearance prior to start of modification

S.No.	Details of clearance	Clearance done by

Given by (Concerned Department):	Checked by (Department Head):
Date :	**Date :**

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MODIFICATION VERIFICATION

Modification Started on:

Modification Completed on:

Brief details of Modification work done:

Modification verified By	
Concerned Department Date:	
Remarks :	
Engineering Department /Date	
Remarks :	
QA Head /Designee/Date	
Remarks :	

FINAL EVALUATION

Approval From Quality Head: **Remarks:**
QA Evaluation: _____ **Evaluated by (QA) /Date**
Closing of PMF: **Remarks:** _____ **Quality Assurance/Date**

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Attachment-2
Planned Modification Issuance Register

S.No.	Planned modification No.	Date of Issue	Department Name	Building /Facility /Area /Utility /Equipment /Machine/Instrument Name	Code /ID No (If Applicable)	Brief Modification details	Modification work completed on	CAPA No.	Status of PMF (Close /Canceled) and Date	Remarks

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Attachment-3
Checklist for Impact Analysis

Modification/Introduction	Possible impact on (but not limited to)
Utility and pipelines	• EQMP/Qualification schedule /utility qualification protocol. • Area qualification, Utility validation /Qualification (e.g. water system validation) • IQ OQ, PQ of system (in case new utility) • Impact on sampling schedule (in case water system, steam, compressed air etc.) • Passivation and Sanitization of line/equipment. • Existing utility. • BMR. • If utility is supplied to any equipment then impact on equipment performance. • Preventive maintenance checklist. • Calibration /Calibration schedule. • SOP preparation/updation. • Training. • QC specification preparation/updation (e.g. Nitrogen gas). • Site master file. • Process validation. • Regulatory approval. • Media fill. • Lay out/P&ID /drawings
Equipment	• Equipment list. • Site master file. • Availability of utilities required to run the equipment. • EQMP. • Equipment qualification /re qualification schedule. • Equipment qualification. • Calibration /Calibration schedule • Passivation of equipment. • SIP qualification of equipment. • Cleaning validation /verification. • Area qualification. • SOP related to new /modified equipment operation, cleaning,

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Modification/Introduction	Possible impact on (but not limited to)
	calibration, qualification. • Training to Concern for the operation, cleaning, calibration, qualification of equipment. • Preventive maintenance schedule. • Preventive maintenance check list. • Revision of Batch manufacturing /packing record. • Process validation. • Media fill. • Regulatory approval. • Impact on ERP master list. • Safety certification before use and updating of periodic safety • Lay out/P&ID /drawings • Equipment operating programs (PLC/Software)
Facility (Area) , Utility , Equipment (machine)	• Batch Manufacturing Record /Batch Packing Record (Packing Order) /Standard Operating Procedure change. • Batch Manufacturing Record /Batch Packing Record (Packing Order) /Standard Operating Procedure change. • EQMP/CVMP. • Cleaning /process validation protocol. • Area /Room /Equipment /Utility Qualification report • Calibration certificate • Training record • Safety challenge report • Cleaning /Passivation /Sanitation record • Changed Preventive Maintenance Schedule record • Dossier submitted to Regulatory authority. Regulatory Approval. • Qualification schedule /protocol . • Changed drawings, Specification, Standard Operating Procedure. • Equipment History Card. • Equipment list • Lay out/P&ID /drawings

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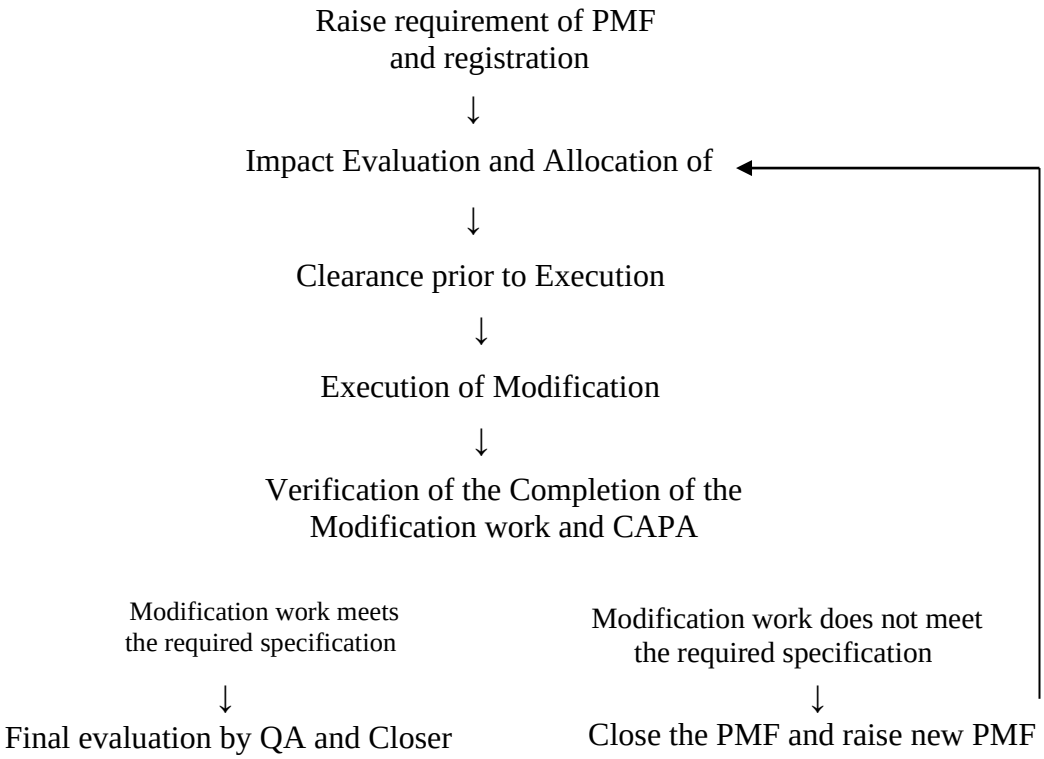
Attachment – 4
Flow Chart for Handling of the Planned Modification



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Attachment -5
Format for Extension of Tentative Schedule Time for PMF

PMF No. : _____

Initial Tentative schedule time (Date) : _____

Current status of Modification:

Pending activities :

Justification for delay:

Requested by:
Concerned Department

Reviewed by:
Department Head

New date for completion of PMF:

Approved by QA Head:

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Attachment -6

Check list for EHS impact evaluation

Put √ where ever it is required.

1	ENVIRONMENT	YES	No	N/A	Recommendation/ Remark
A	Will there be any new or increased wastes, against the quantity of effluents mentioned in PMF in consent to air, water, solid waste?				
B	What will be the treatment mode of the waste generated.				
2	**SAFETY**				
A	Is there a safety impact ? If yes , Risk Assessment needs to be done.				
3	**OCCUPATIONAL HEALTH**				
A	Will the PMF affect the noise level in the area.				
B	Is the existing illumination Level adequate				
4	**EMERGENCY RESPONSE**				
A	Is existing fire protection system adequate to cope with fire hazard from this PMF				
B	Is there any modification or relocation to existing fire protection equipment or facility?(Eg. Fire hoses, fire extinguisher, fire doors etc.)				
C	Does the PMF block fire protection equipment, and emergency exits?				
D	Does the PMF involve storage of flammable or combustible materials?				
E	IS there any potential of static charge accumulation? Grounding / Bonding or other means of static dissipater required?				
F	Is there any requirement for new emergency response equipment e.g Safety showers, eye wash stations, manual call point, smoke detector?				
G	Onsite emergency plan need to be revised/ updated?				
H	Fire fighting system drawing need to be updated.				
5	**STATUTORY COMPLIANCE**				

A	Any new approval or amendment in existing approval. NOC needed from government authorities / agencies e.g Factory inspector , Pollution Control Board (PCB), Local Fire office / chief Controller of explosive etc.				
B	Is stability certificate required from competent person for this PMF?				
C	Any drawing / documents to be submitted to government offices.				

Authorized By EHS Head:

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8. **History**

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