

Quality Assurance

Quality Assurance Department

SHIKHA (QA003) ▾

Masters:

 Products	 Materials	 Equipments	 Temperature
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Operations:

 IPQA	 Batch Release	 SOP Management	 Control Sample
 Deviation	 Change Control	 Incident Reporting	 Complaints
 CAPA	 Training	 Stability Management	 OOS

Software No : 1.0.1 | Sop No : SOP/01/00

Apr 14, 2021, 3:42:56 PM

 Document Management	 Audit / Self Inspection	 Rejection Management	 OOT
 Risk Management	 Product Recall	 APQR	 Equipment Qualifications
 Personal Qualifications	 Stereo Management	 Label Control	 Enviornment Management
 GMP Monitoring	 Vendor Management	 Technical Document	 Art Work Management

Other:

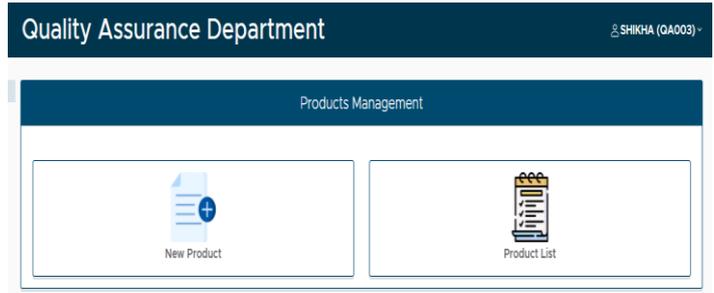
 Maintanance	 Stationary Management	 Job Responsibilities
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Quality Assurance

• Masters



1. Product Master



- 1.Solid
 - 2.Semisolid
 - 3.Liquid
-
- 1.Self
 - 2.LL
 - 3.Contract Manufacturing

New Product Entry Form

Product Code: Brand Name: Grade:

Item/Generic Name:

Type of Dose: Dosage Form: Packing Style:

Packing Mode: Shelf Life: Minimum Shelf Life:

Therapeutic Category: Approximate Testing Time: Retest After(Months):

Manufactured Under: Manufactured For Client: Category:

On the Basis of Retest Period PGMP will give you the reminder before 7days



After Entry of New Product to Product; Take approval from Manager login as shown in fig. aside



Quality Assurance

2. Material Master

The Equivalent to factor will be appear when you will add it in Material Master.

Quality Assurance Department

SHIKHA (QA003)

IUPAC Name:

Grade:

Special Grade:

Nature of Material:

Minimum Inventory Level:

Category:

Unit of Measurement:

HSN Code:

GST:

Storage Location:

Storage Condition:

Therapeutic:

Shelf Life: (Months)

Minimum Shelf Life: (Months)

Retest: (Months)

QC Lead Time (days):

Equivalent To	Factor	Add
<input type="text"/>	<input type="text"/>	<input type="button" value="ADD"/>

[Take approval of New Material in Manager's Login]

3. Equipment Master

Quality Assurance Department

SHIKHA (QA003)

Equipments Management

New Equipment

Equipment List

[Officer

Quality Assurance Department

SHIKHA (QA003)

New Equipment Form

Equipment Type:

Equipment Code:

Equipment Name:

Min. Capacity:

Capacity:

Make:

Type:

Department of Installation:

Section:

Model:

Calibration:

Purchase Date:

Installation Date:

Calibration Frequency: Daily Fourtingly Monthly Quarterly Half Yearly Yearly

[Manager Login]

Quality Assurance

Quality Assurance Department SHIKHA (QA003)

Pending Areas for Temperature Range

Department: Section:

Min Temperature: Maximum Temperture: Minimum Humidity: Maximum Humidity:

- The Department and section master is given in HR Department.

- After adding new Department and section through master from HR department it will come for area temp. and humidity record.

• IPQA

Quality Assurance Department SHIKHA (QA003)

IPQA CLOSE

Inprocess Sampling

Line Clearance

Inprocess Checks

Equipment Calibrations

Damage Inspection

1. **In process sampling** – The In process sampling entries will come from Production department.
2. **Line Clearance** – All kind of Line Clearance request from Stores, Production, Packing and QC department will come to QA.

Line Clearance CLOSE

Line Clearance Form

Line Clearance Log

New Area Checklists

Area Checklist Master Log

Quality Assurance Department SHIKHA (QA003)

01/00 Apr 16, 2021, 10:56:12 AM

Department: Quality Control Section: Sampling
Material / Product Name: Lincmoycin Hydrochloride GRN No: GRN032

Previous Product Details:

Product / Material Name: Cindamycin Phosphate	GRN No: GRN001
Area Cleaned By: QA003	Cleaning Date & Time: 2021-02-20 11:57:32
Activity Done By: QC006	Date: 2021-02-20 11:41:10

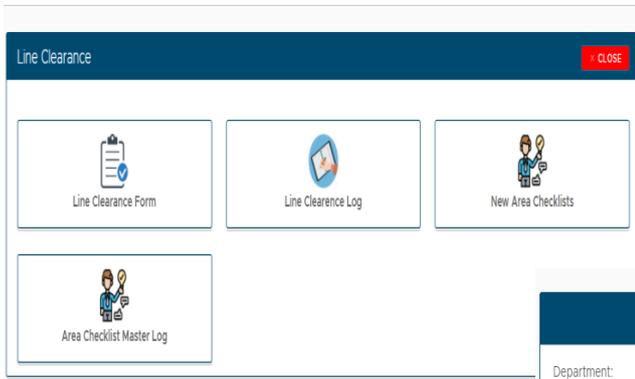
Equipment Name: Equipment Id: Area:

Traces of Previous Product: Is Sanitization Done: Temperature: °C

Humidity: % Status Label: Balance / Equipment Cleaned:

Remark:

Quality Assurance



- New Area Checklist- The Line clearance checklist can be prepared from this tab when you are adding the new department and section from HR depart.

You can add multiple checkpoints by just clicking on add button.

The screenshot shows the 'Line Clearance Checklist Master' form. It has a header bar with the title. Below the header are two dropdown menus for 'Department' and 'Section'. Underneath is a section for 'Checkpoints' which contains a table with three columns: 'Sr.', 'Checkpoint', and 'Action'. The 'Sr.' column has a value of '0'. There is an 'ADD' button to the right of the table. At the bottom of the form are 'SAVE' and 'CLOSE' buttons.

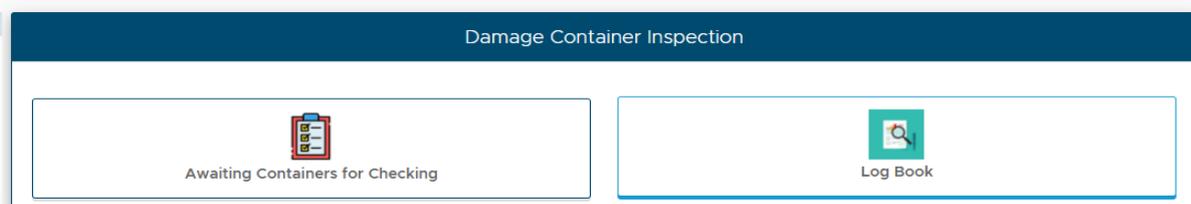
3. **In process Checks** – It will also come from production department.

4. **Daily Verification-**

- The Daily Verification of balance can be done from the given tab, Here the standard weights and tare weights you have to enter.
- If the calibration has not been done as per the frequency that equipment will not be accepted by software for performing operation.

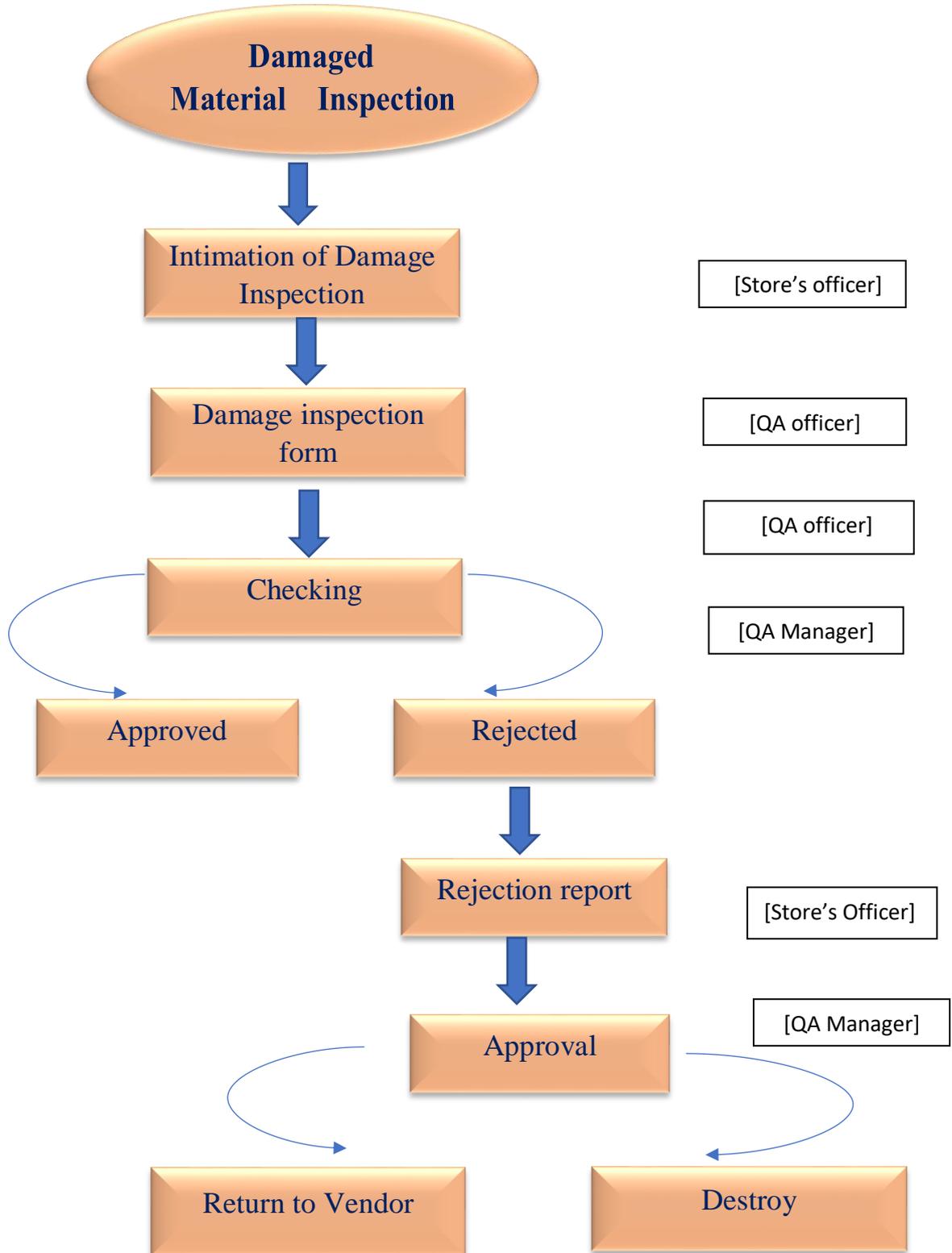
The screenshot shows the 'Quality Assurance Department' form. The header includes the department name and a user profile 'SHIKHA (QA003)'. The form contains several input fields: 'Balance Name' (Cubis II Premium Laboratory Balance), 'Make' (Internal, Automatic), 'Capacity' (70), 'Installation Area' (IPOA), and 'Tolerance Limit' ($\pm 0.1\%$). Below these is a section for 'Weights Verification' which contains a table with three columns: 'Sr.', 'Standard Weight', and 'Display Weight'. The table has five rows, each with a '0' in the 'Standard Weight' and 'Display Weight' columns. A 'SAVE' button is located at the bottom of the form.

5. **Damage Container Inspection:**



Quality Assurance

✚ Flow of Damage Container Inspection:



Quality Assurance

● BATCH RELEASE

Quality Assurance Department

SHIKHA (QA003)

21/00 | Apr 16, 2021, 11:46:54 AM

Batch Release [CLOSE]

Prepare Checklist Checklist Master

New Batch Release

1. Prepare Checklist

- for preparation of new batch release checklist: Prepare checklist » fill the form for Batch release checklist
- Add Checkpoints; Save

- The revision of Checklist only can be done after approval of manager.
- The executive or manager only can revise the checklist.

Batch Release Checklist [CLOSE]

Dosage Form: Product Name:

Checkpoints:

Sr.	Checkpoints	Add
0.	<input type="text"/>	<input type="button" value="ADD"/>

No Records Found!

2. New Batch Release

NEW BATCH RELEASE [CLOSE]

Dosage Form



Quality Assurance Department

SHIKHA (QA003)

21/00 | Apr 16, 2021, 2:00:15 PM

Product Details:

Product Code: 28
Product Name: DEMO PRODUCT
Grade: BP
Batch No.: 123
Mfg. Date: 2021-01-01
Exp. Date: 2021-05-31

Checkpoints:

Sr.	Checkpoints	Status	Remark
1.	test	<input type="text"/>	
2.	test 1	<input type="text"/>	

- The new batch release record can be maintained here.
- Select Dosage Form
- Add checkpoints, Remark, Save and approve it from QA manager.

Quality Assurance

• SOP MANAGEMENT

1. SOP initiation

Quality Assurance Department

SOP Management

SOP Initiation:

New SOP Request Prepare Draft Raise Change Control Initiated SOPs Log

Initiate New SOP

SOP Title:

SOP For:

SAVE

Prepare Draft for Initiated SOP

Department: Quality Assurance

SOP Title: Test computer

SOP For: GMS

Purpose

File Edit View Insert Format Tools Table Help

Paragraph B I Paragraph

Change Control:

Change Related to: SOPs

Change Title: SOP Change

Existing Procedure:

Proposed Change:

Reason For Changes:

- For SOP Initiation fill the form given in fig. by user department
- The initiated SOP's draft will be prepared by user department.
- Finally, it will come for checking and approval to QA Department

The Change control can be raising by just clicking on RAISE CHANGE CONTROL

2.

New SOP & Revision:

Direct SOP New SOP Upload Existing SOP Revision of SOP

- Through DIRECT SOP tab you can prepare the SOP directly.
- The drafted SOP will come for finalization in NEW SOP tab through which the New final SOP will get prepare.

Quality Assurance

- The Existing SOP can be upload through UPGRADE EXISTING SOP tab; there you can find the option for upload sop.

The screenshot shows a web interface for the Quality Assurance Department. At the top, there is a header with the department name and a user profile for SHIKHA (QA003). Below the header, there is a navigation bar with '01/00' and a timestamp 'Apr 19, 2021, 11:18:44 AM'. The main content area is titled 'Upload Existing SOP' and contains several input fields: 'SOP Title*', 'SOP For*', and 'Version No*'. There is also a file upload section labeled 'Upload SOP*' with a 'Choose File' button and the text 'No file chosen'. A 'SAVE' button is located at the bottom of the form.

3. SOP Index

The screenshot shows the 'SOP Index' interface. It features search filters for 'Departments', 'SOP For', and 'Status', each with a dropdown menu and a 'SEARCH' button. Below the filters is a table with the following data:

Sr.	Department	SOP No	SOP Title	SOP For	Status	Prepared By	Action
1.		SOP/001/00			pending	ST012	PROCEED
2.	store	SOP/001/00			reject	ST012	PROCEED

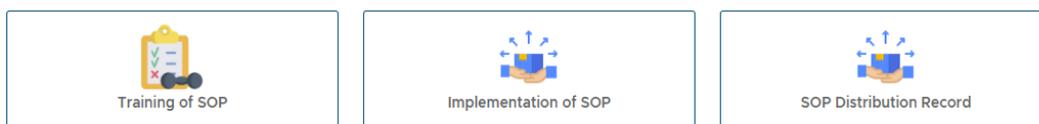
At the bottom right of the table, there is a 'DOWNLOAD' button.

- By clicking on the showing dropdowns for view of SOP index can be done from here.

- ✓ Receive Hard Copies
 - To get to know about the distribution of SOP in the form of Hard copies will be visible and to maintain the record of it in this tab we have given provision with the same.
- ✓ Obsolete SOP
 - The original SOP's which are get revised into new SOP's; it will be listed in obsolete SOP's.

4.

Training & Implementation:



- At the time of New SOP preparation, we have given the field about in which departments the given SOP training required, according to that the SOPs with pending training will come in the tab of PENDING SOP'S FOR TRAINING.

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Revision of SOPs



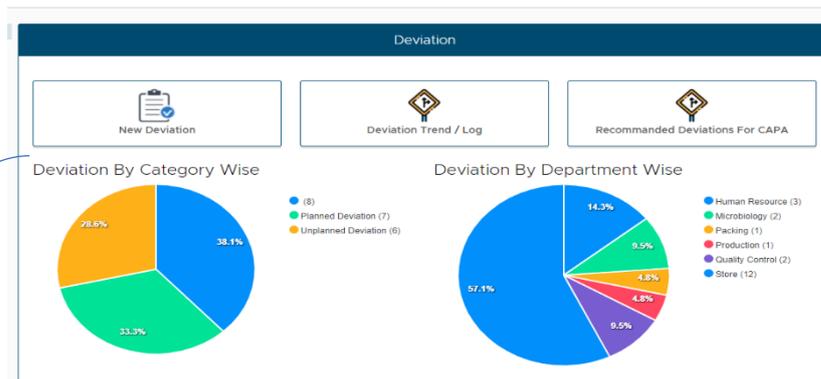
Pending SOPs for Training



SOP Training Log

- ✓ Pending SOPs for Implementation
- The SOPs for which the training has been done but the implementation is yet pending will come to this tab for the selection of Effective Date.
- ✓ SOP Distribution record will be maintained in SOP DISTRIBUTION RECORD tab.

• DEVIATION



Deviation Form

Deviation Related To: Deviation Category: Type Of Deviation:

Justification for type:

Cause of Deviation:

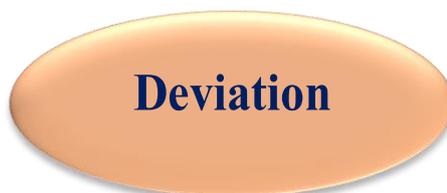
Description of Deviation:

Affecting Product / Material: Affecting Equipment:

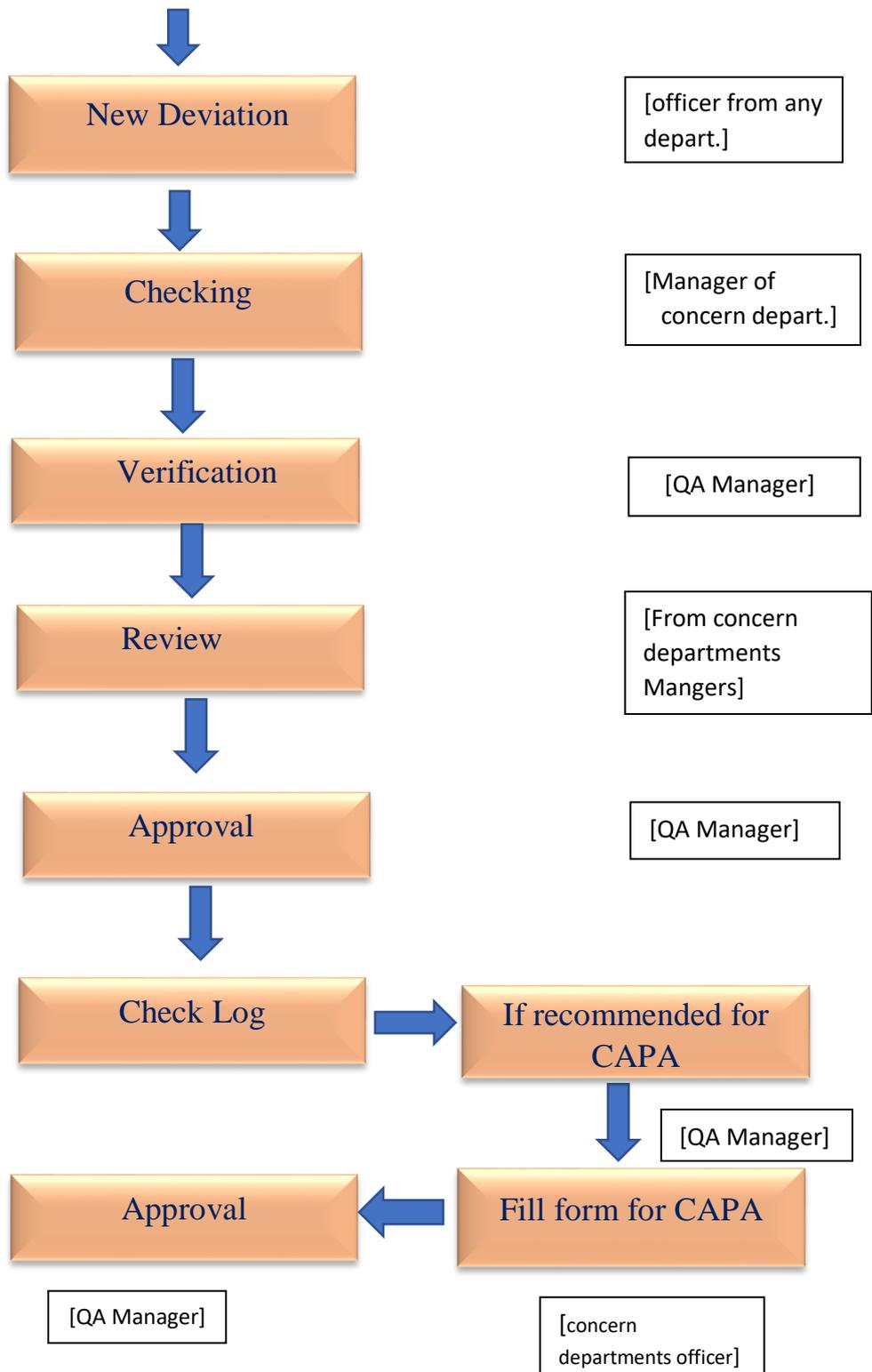
Name of Product: Batch No: Mfg. Date: Exp. Date:

Cross Functional Departments Remark: Store Production Quality Control Packing Marketing Client Regulatory Department Management HR Engineering

✚ Flow chart for deviation:



Quality Assurance

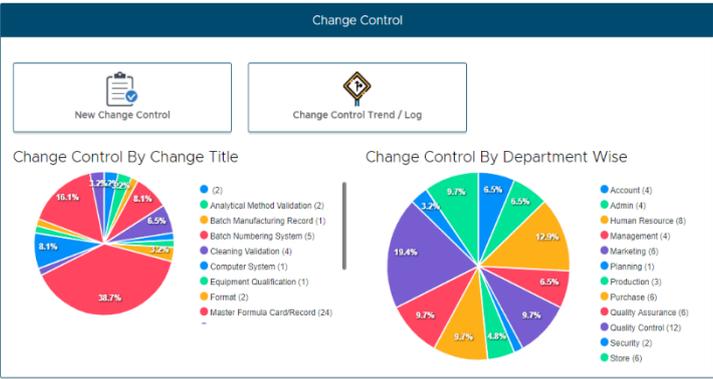


Quality Assurance

- CHANGE CONTROL**

- In Change Control you will find the New Change Control form we have and its trend or log.

- additionally, the graphical representation has been given which gives us up to date.



Change Control Form

Change Related to:

Change Title:

Existing Procedure:

Proposed Change:

Reason For Changes:

Market Details:
 Export Domestic

Probable Impact on Quality of Product:

Departments for Review:
 Human Resource Quality Control Account Security Purchase Production Microbiology Engineering Store Packing
 RND Marketing Vendor Management Planning Admin IPOGA

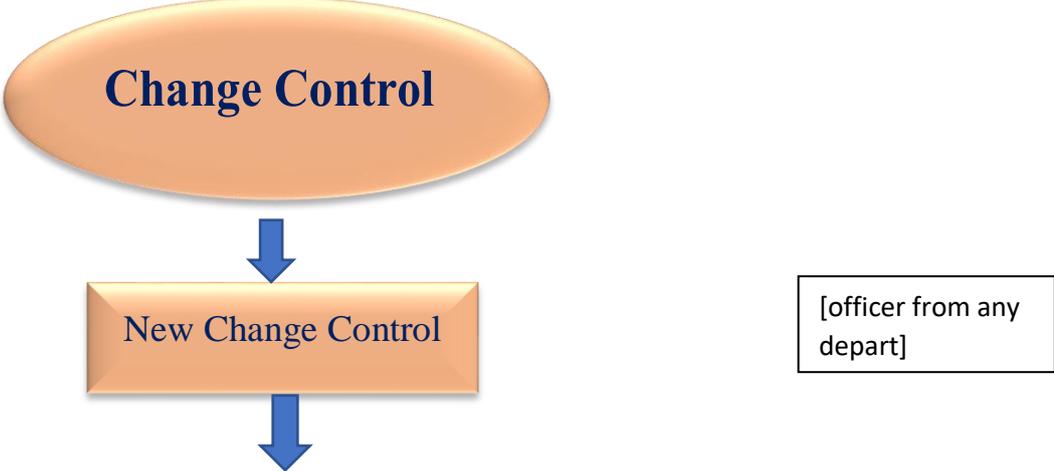
In Change Control form we have given the cross functional departments for review, tick on the department which is concern for that particular change control.

-Manual sign pdf and electronic sign pdf can be download for each form in software.

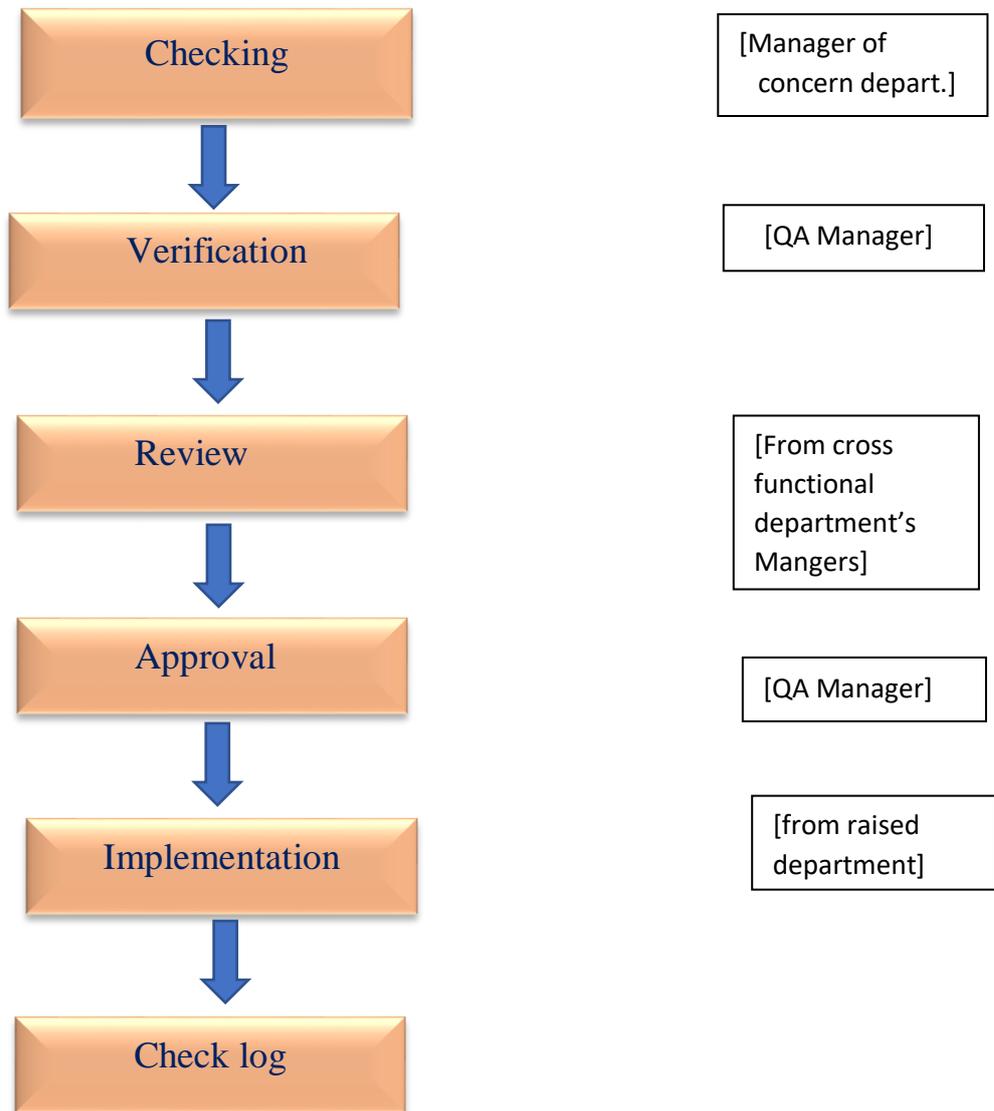
Closing & Implementation:
 Remark:

QA Department user ID: Date:

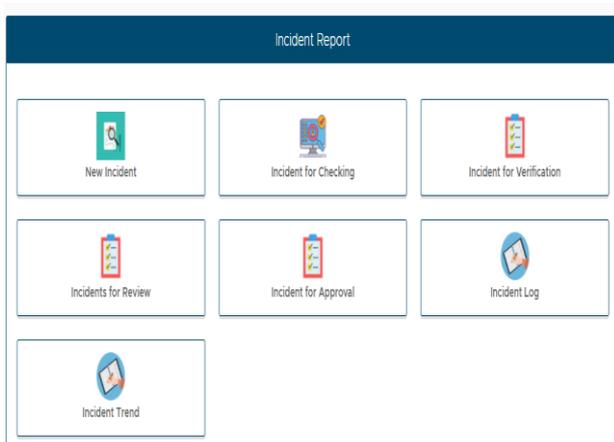
- Flow Chart for Change Control:**



Quality Assurance



- **Incident Report**



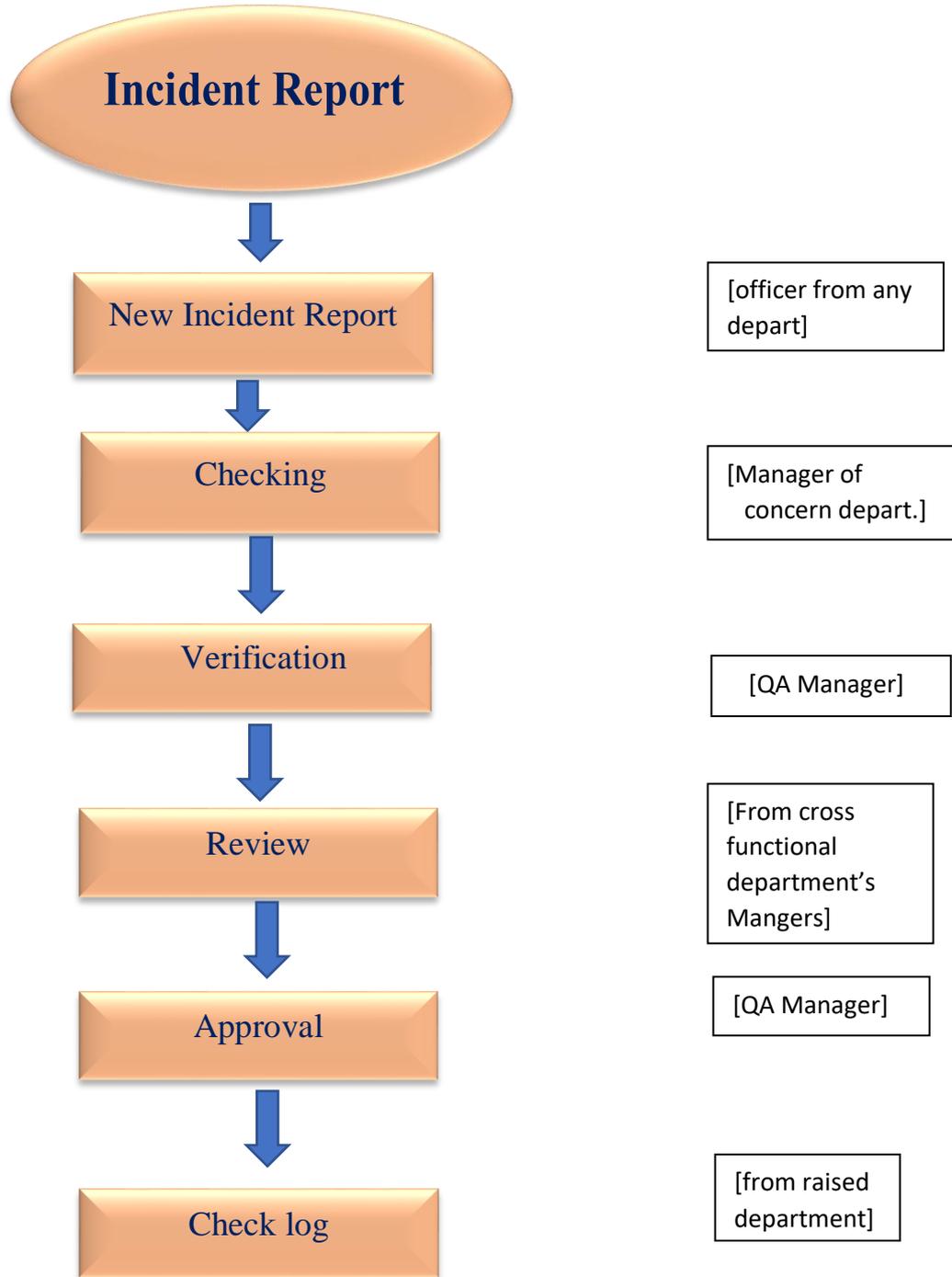
The 'New Incident' form includes the following fields:

- Incident Related To: [Dropdown]
- Incident Category: [Dropdown]
- Type Of Incident: [Dropdown]
- Justification for type: [Text area]
- Cause of incident: [Text area]
- Description of incident: [Text area]
- Affecting Product / Material: [Dropdown]
- Affecting Equipment: [Yes/No]

- In New incident reporting form if there is any product or equipment is getting affected then according to that the fields get appear for mentioning the details

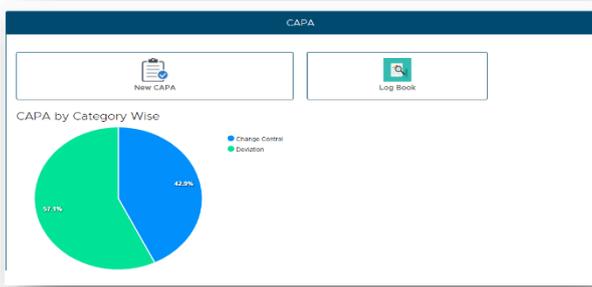
Quality Assurance

- Flow Chart for Incident Report:



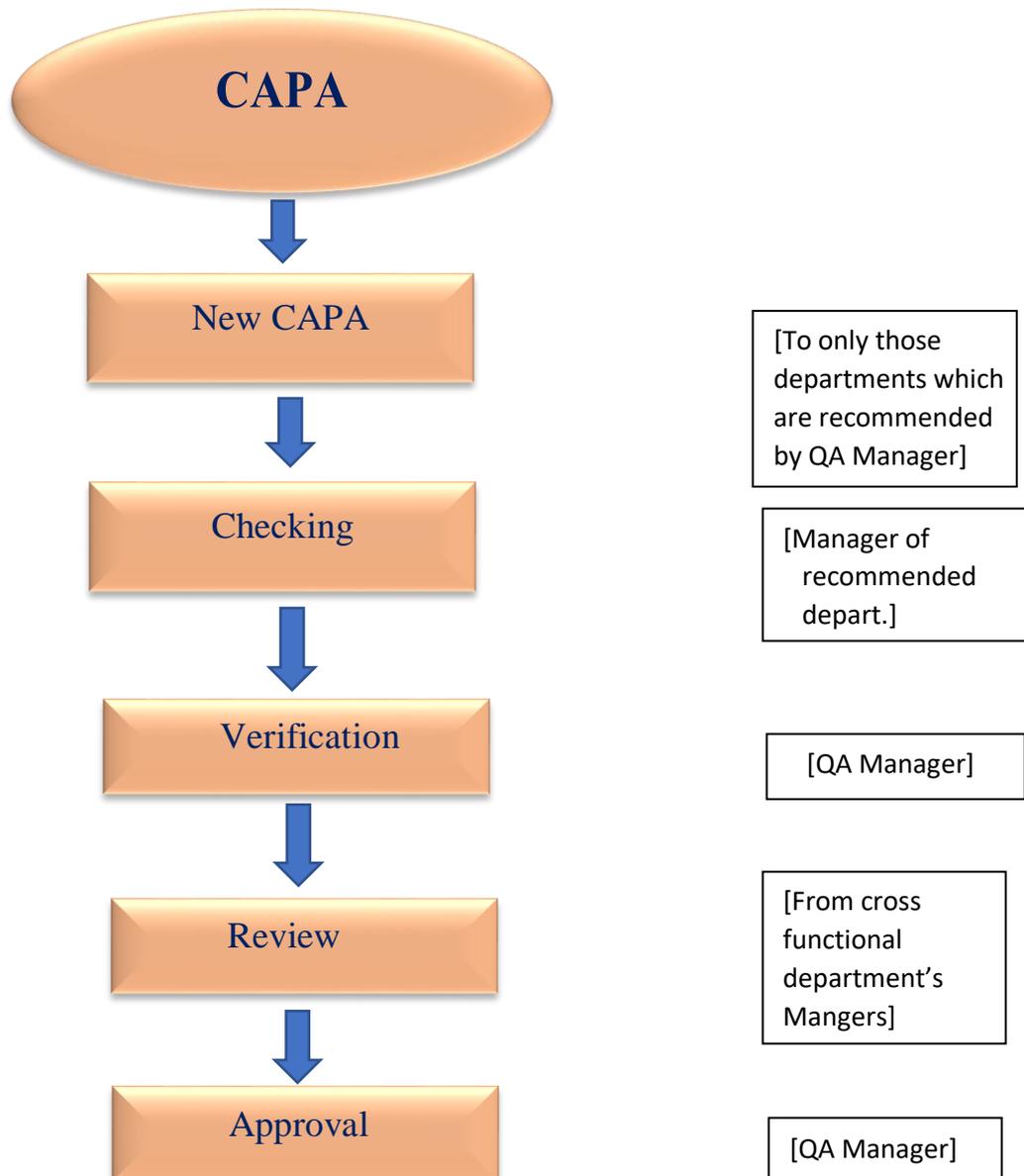
Quality Assurance

- CAPA

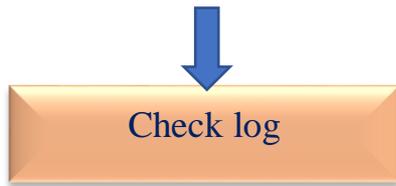


The screenshot shows a "Corrective Action / Preventive Action Form". It includes fields for "CAPA No." (CAPA-7), "Department" (Quality Assurance), "CAPA For" (Deviation), and "Document No.". There are dropdown menus for "CAPA required in-System", "Category", and "Need to implement corrective action". Below these are text input fields for "Planned correction" and "Corrective Action". At the bottom are "SUBMIT" and "CLOSE" buttons.

✚ Flow Chart for CAPA:



Quality Assurance



[from raised department]

• Training

Training

- Trainers
- Training Need Identification
- Training Schedule
- Training Attendance
- Training Evaluation
- Individual Training Record
- Training Log / Record
- Training Feedback
- Induction Training
- Self Certification
- Retraining Training
- Daily Training
- Trainers Certification

- On the left we have shown the dashboard of Training Module.

Trainers Master

- Inhouse Trainers
- External Trainers

- In Trainers tab; Inhouse Trainers Name will come from where you have filled the form for Employee and assigned him the job as trainer.
- External trainers can be added by filling the form for new trainer and get the Approval.

External Trainers

- New
- Approval
- External Trainers List

✓ Training Need Identification

Identification of Training Needs

NEW TRAINING NEEDS DOWNLOAD ALL

Sr.	Department	Proposed Date	Subject	Proposed Trainer	Prepared By	Approved By	View
1.	Quality Assurance	2020-12-08	GMP Training	VAIBHAV	SBOA003	SBOA003	VIEW PDF
2.	Qua						
3.	Qua						

Training Evaluation

Name of Department: Quality Assurance
Date of training: 2020-12-08
Trainers Name: VAIBHAV
Venue of Training: test
Training Subject: GMP Training
Reference Document No./System: test
Training Tools Used: test
Training Start Time: 16:27:00
Training End Time: 16:29:00

Sr.	Name of the Trainee	Department	Designation	Attendance	Marks
1.				present	1.00
2.				absent	0.00

-The Training Need Identification form can be view or can be download as pdf also.

- Choose training sub. From dropdown.
- Multiple Employee can be select by just click on ADD button

Quality Assurance

Pending Training to Schedule

Department: Quality Control
 Training Subject: GMP Training
 Reference Document: RESUME
 Trainer:
 Justification for Training Needs: UYFJGHBSGJHAF
 Proposed Training Date: 2020-12-29

Add Attendy:

Name of Employee	Employee Code	Department	Designation	Add
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="ADD"/>

Training Date: 29/12/2020
 Training Time:

Venue:

Training Attendance Record

Name of Department: Quality Assurance
 Date of training: 2020-12-22
 Trainers Name: VA@HAV
 Venue of Training: Corporate
 Training Subject: GMP Training
 Reference Document No./System: DFGHe
 Training Tools Used:
 Training Start Time:
 Training End Time:

Sr.	Name of the Trainee	Department	Designation	Attendance
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="PRESENT"/> <input type="button" value="ABSENT"/>
2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="PRESENT"/> <input type="button" value="ABSENT"/>
3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="PRESENT"/> <input type="button" value="ABSENT"/>

- The additional employees can be added at the time of scheduling of Training.
- The attendance record of Employees can be maintained here by click on present or absent.

✓ Training Evaluation

Training Questionnaire & Evaluation Sheet Format



Training Questionnaires



Training Evaluation

Training Questionnaires

Department: Quality Assurance
 Trainers Name: VA@HAV
 Subject: GMP Training

Training Date: 2020-12-17
 Venue: Corporate
 Reference Document: andiauth

Producers Name:
 Duration:
 Total Marks:

Sr.	Questions	Option 1	Option 2	Option 3	Option 4	Answer	ADD
#	<input type="text"/>	<input type="button" value="ADD"/>					

No Records Found!

Venue of Training: test
 Training Subject: GMP Training
 Reference of Document No./System: test
 Training Tools Used: test
 Training Start Time: 10:37:00
 Training End Time: 16:20:00

Sr.	Name of the Trainee	Department	Designation	Attendance	Marks
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	present	1.000
2	<input type="text"/>	<input type="text"/>	<input type="text"/>	absent	0.000
3	<input type="text"/>	<input type="text"/>	<input type="text"/>	present	0.000
4	<input type="text"/>	<input type="text"/>	<input type="text"/>	present	0.000
5	<input type="text"/>	<input type="text"/>	<input type="text"/>	present	0.000

- Training Questionnaire can be prepared which will go to Attendees for the evaluation and Evaluation of training will be done on the basis of marks they obtained in the questionnaire.

✓ Individual Training Record

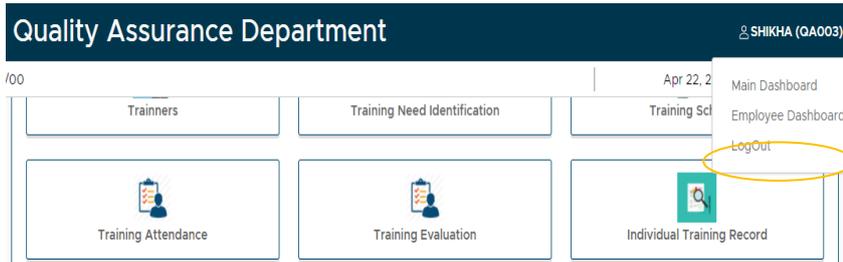
Individual Training Record

Department: Employee Name: Designation: No. of Trainings Attendds:

Sr.	Date	Subject	Venue	Duration	Trainers Name	Attendance	Marks	Feedback
<input type="text"/>								

Quality Assurance

✓ Self-Certification



- for self-certification go to employee dashboard first

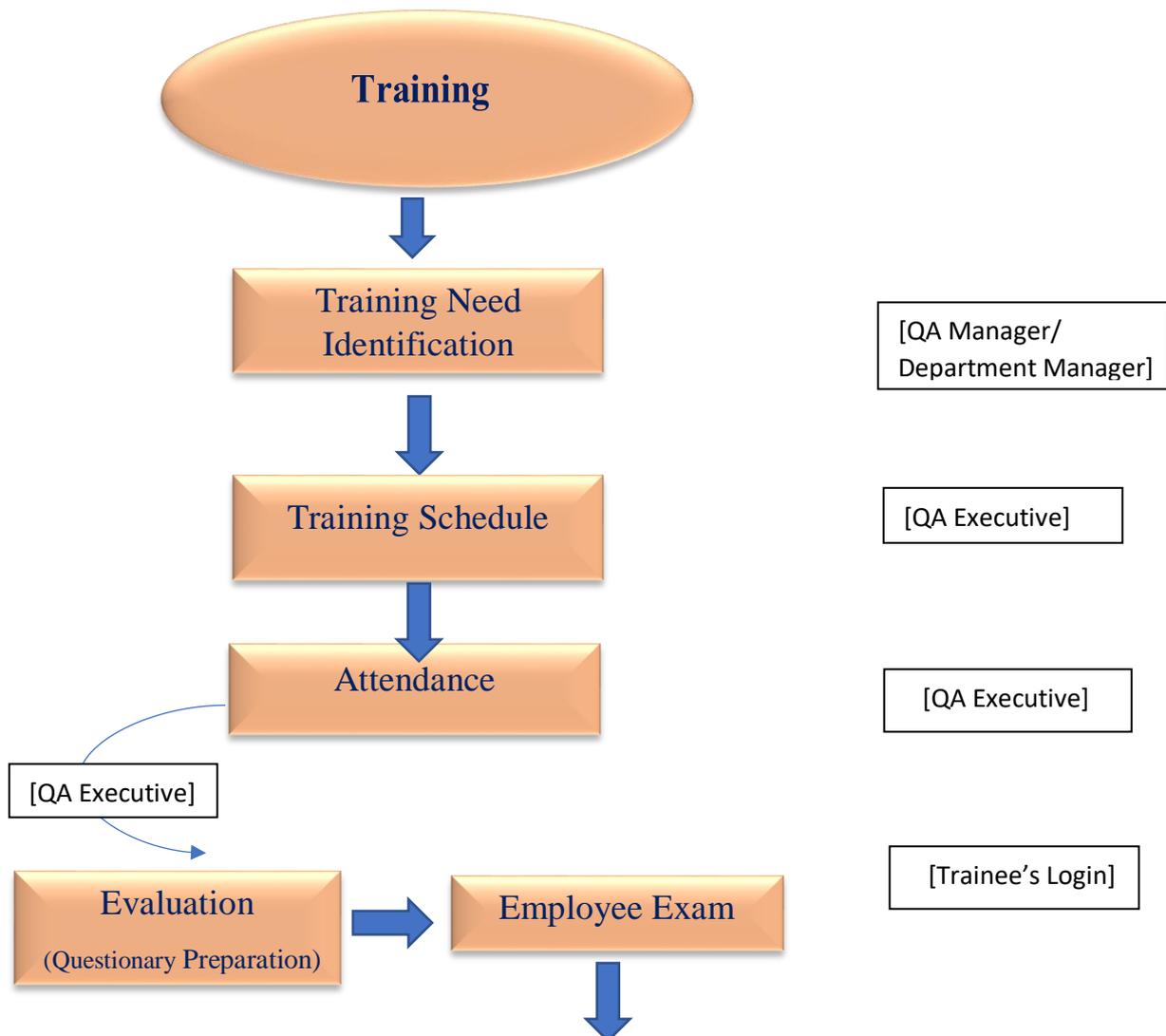
- Open SELF CERTIFICATE fill the form.

- Submit

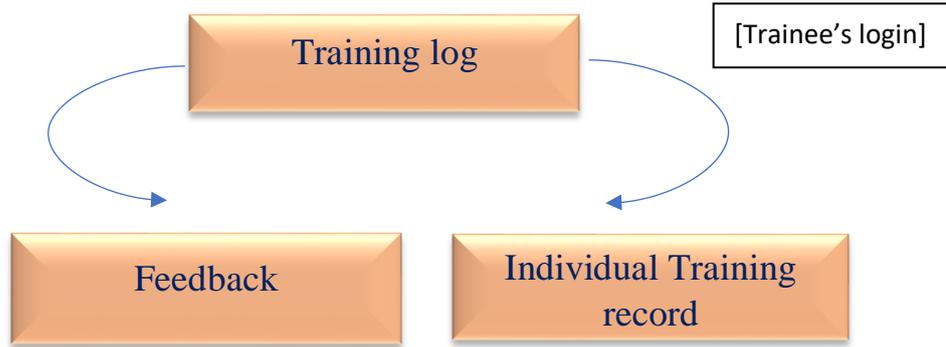
- Get Approval from QA Manager.

- Record will be maintained at Self Certificate log.

Flow Chart of Training:



Quality Assurance

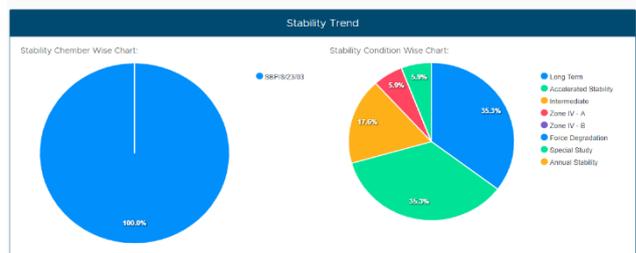


- Stability Management**

Packing: Market: No. of Batches to be charged: Batch Type:

Action	Condition	Intervals	Total Intervals	Sample Qty	Single Analysis	Total Sample Qty
<input type="checkbox"/>	Long Term	0, 3, 6, 9, 12, 24, 36, 48	8			Specification Not Available
<input type="checkbox"/>	Accelerated Stability	0, 3, 6	3			Specification Not Available
<input type="checkbox"/>	Intermediate	0, 3, 6, 9, 12	5			Specification Not Available
<input type="checkbox"/>	Zone IV - A	0, 3, 6, 9, 12, 24, 36	7			Specification Not Available
<input type="checkbox"/>	Zone IV - B	0, 3, 6, 9, 12, 24, 36, 48	8			Specification Not Available
<input type="checkbox"/>	Force Degradation	0	1			Specification Not Available
<input type="checkbox"/>	Special Study	0	1			Specification Not Available
<input type="checkbox"/>	Annual Stability	0, 12, 24, 36	4			Specification Not Available

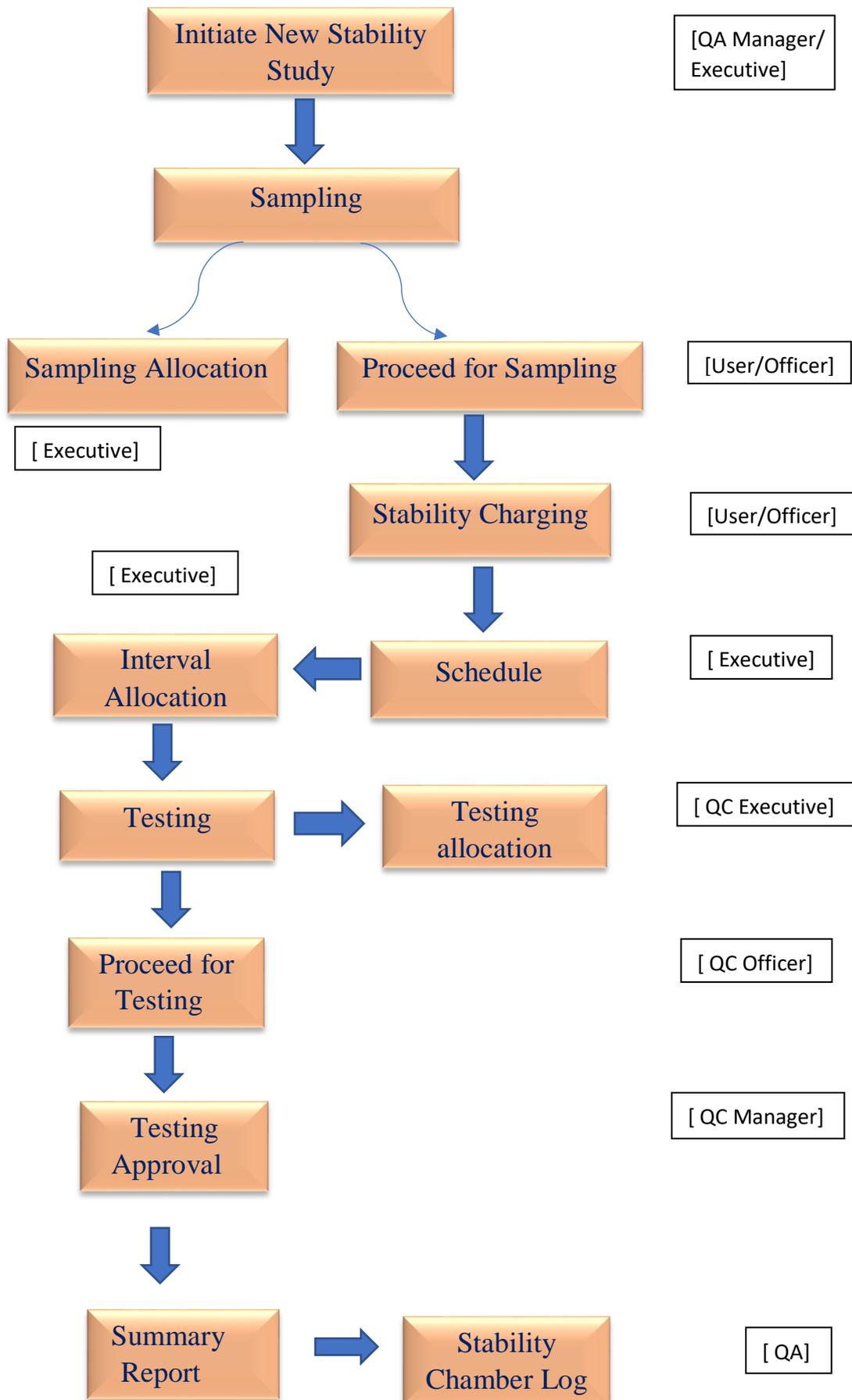
- Initiate new stability form is having provision that just have to click on which stability study you want to initiate and automatically interval calculation will be done for the



Flow Chart of Stability Study:

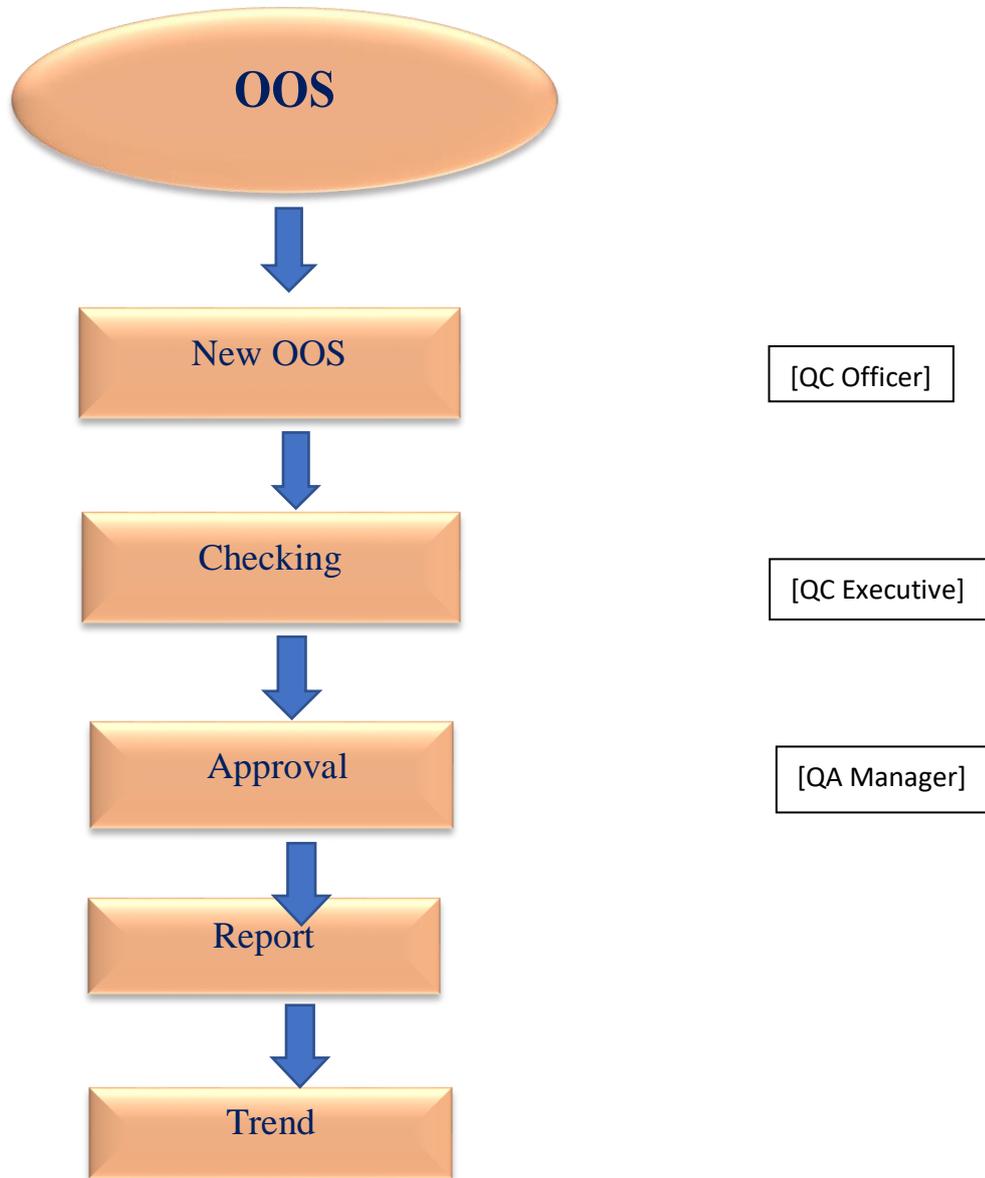


Quality Assurance



Quality Assurance

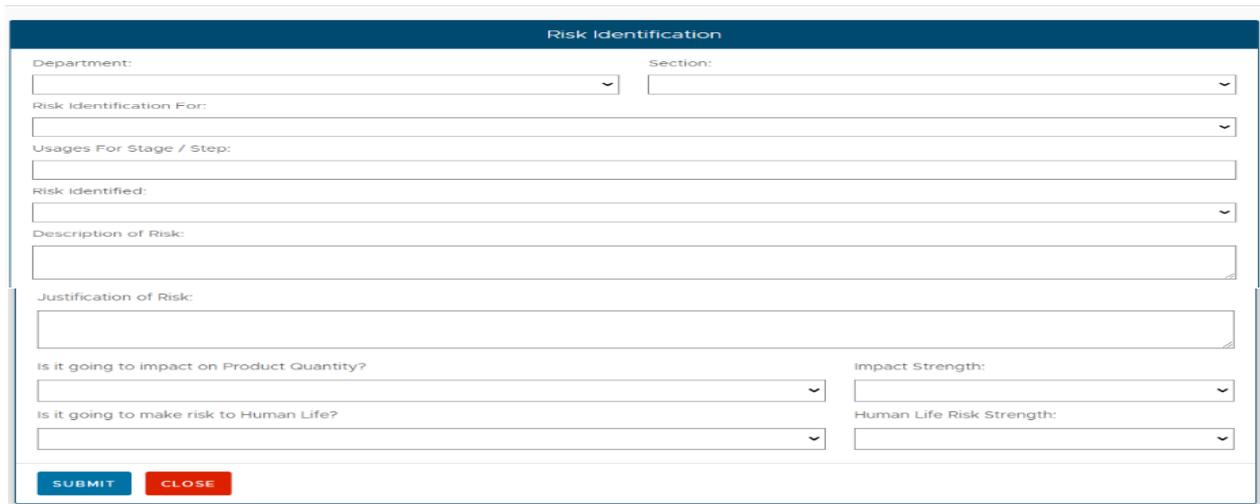
- **OOS:**



- **Risk Management:**



Quality Assurance



- The Risk Identification, Assessment, Analysis, Evaluation, Control, Review, Risk CAPA, Risk Log. Can be done with the Risk Management tab.
- Risk probability and severity will be determined.

- After Each stage of Risk Management, it will come to Manager for approval

Flow Chart of Risk Management:



Quality Assurance

