





Quality Assurance













Quality Assurance Department

SHIKHA (QA003) v

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

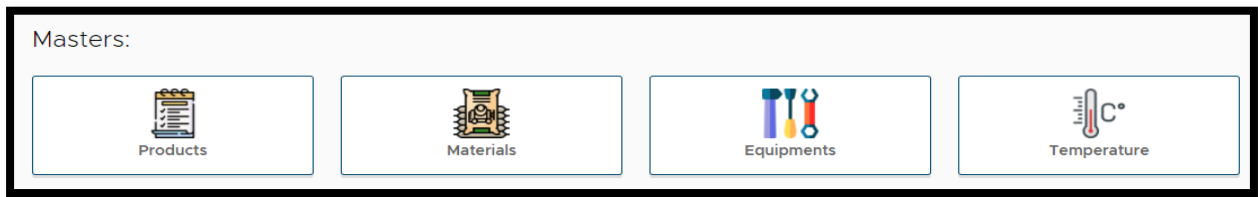
 Document Management	 Audit / Self Inspection	 Rejection Management	 OOT
 Risk Management	 Product Recall	 APQR	 Equipment Qualifications
 Personal Qualifications	 Stereo Management	 Label Control	 Enviornment Management
 GMP Monitoring	 Vendor Management	 Technical Document	 Art Work Management

Other:

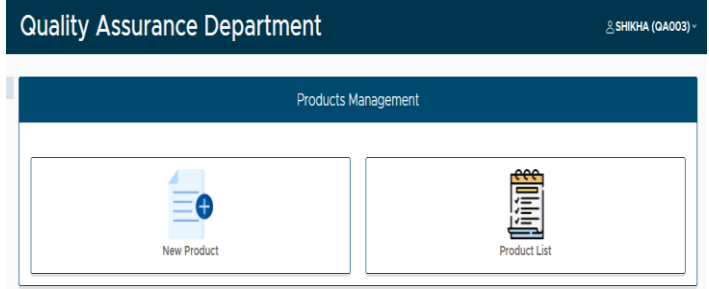
 Maintanance	 Stationary Management	 Job Responsibilities
--	--	---

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:

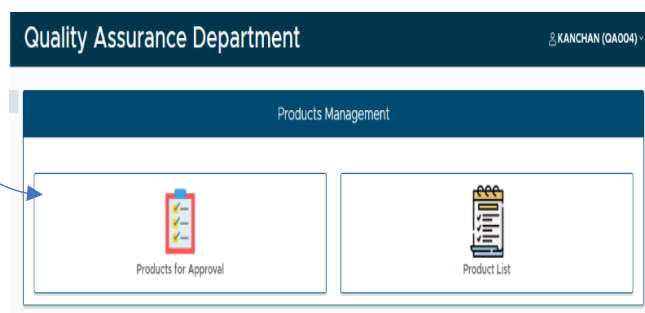
Type of Dose: Dosage Form: Packing Style:

Packing Mode: Shelf Life: Minimum Shelf Life:

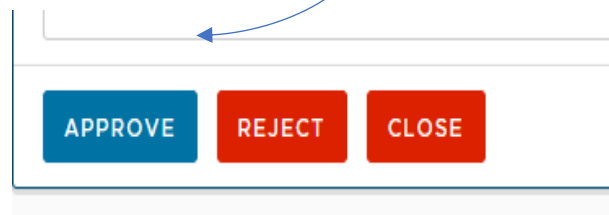
Therapeutic Category: Approximate Testing Time: Retest After(Months):

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

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

3. Equipment Master

Quality Assurance Department SHIKHA (QA003)

Equipments Management

[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 ☐ Fourtinghtly ☐ Monthly ☐ Quarterly ☐ Half Yearly ☐ Yearly

[Manager Login]

Quality Assurance

Quality Assurance Department

SHIKHA (QA003)

Pending Areas for Temperature Range

Department

Human Resource

Section

Min Temperature

Maximum Temperture

Minimum Humidity

Maximum Humidity

SAVE

- 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: Lincomycin Hydrochloride

GRN No: GRN032

Previous Product Details:

Product / Material Name: Clindamycin 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: Cleaned

Traces of Previous Product: No

Is Sanitization Done: No

Temperature: °C

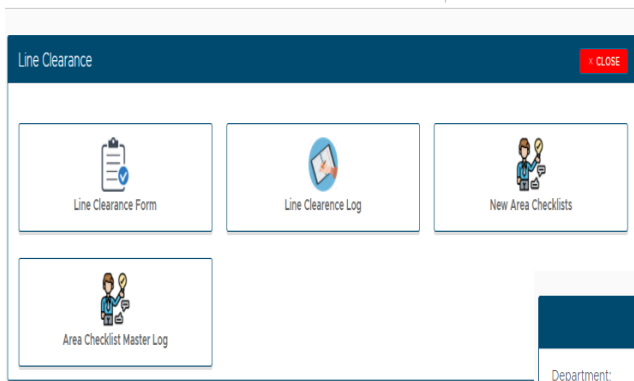
Humidity: %

Status Label: Available

Balance / Equipment Cleaned: Cleaned

Remark:

Quality Assurance



Line Clearance

Line Clearance Form

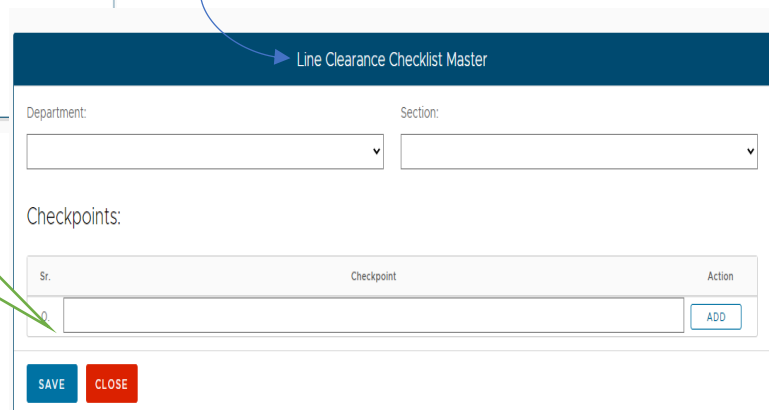
Line Clearance Log

New Area Checklists

Area Checklist Master Log

- 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.



Line Clearance Checklist Master

Department:

Section:

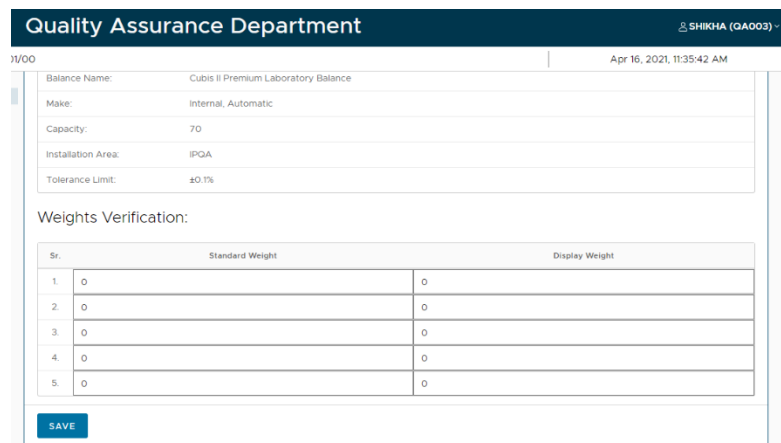
Checkpoints:

Sr.	Checkpoint	Action
0	<input type="text"/>	<input type="button" value="ADD"/>

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.



Quality Assurance Department

SHIKHA (QA003)

11/00 | Apr 16, 2021, 11:35:42 AM

Balance Name: Cubis II Premium Laboratory Balance

Make: Internal, Automatic

Capacity: 70

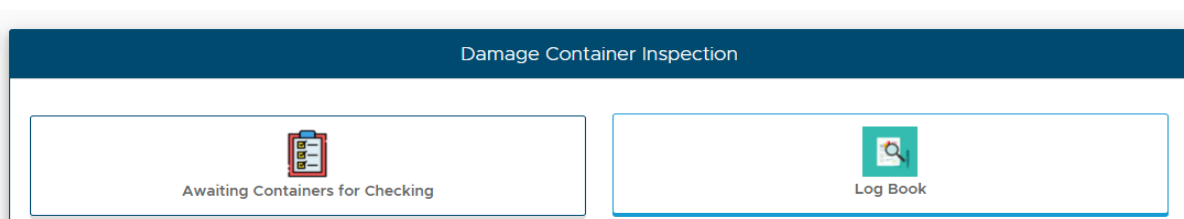
Installation Area: IPOQA

Tolerance Limit: $\pm 0.1\%$

Weights Verification:

Sr.	Standard Weight	Display Weight
1.	<input type="text"/>	<input type="text"/>
2.	<input type="text"/>	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>
5.	<input type="text"/>	<input type="text"/>

5. Damage Container Inspection:



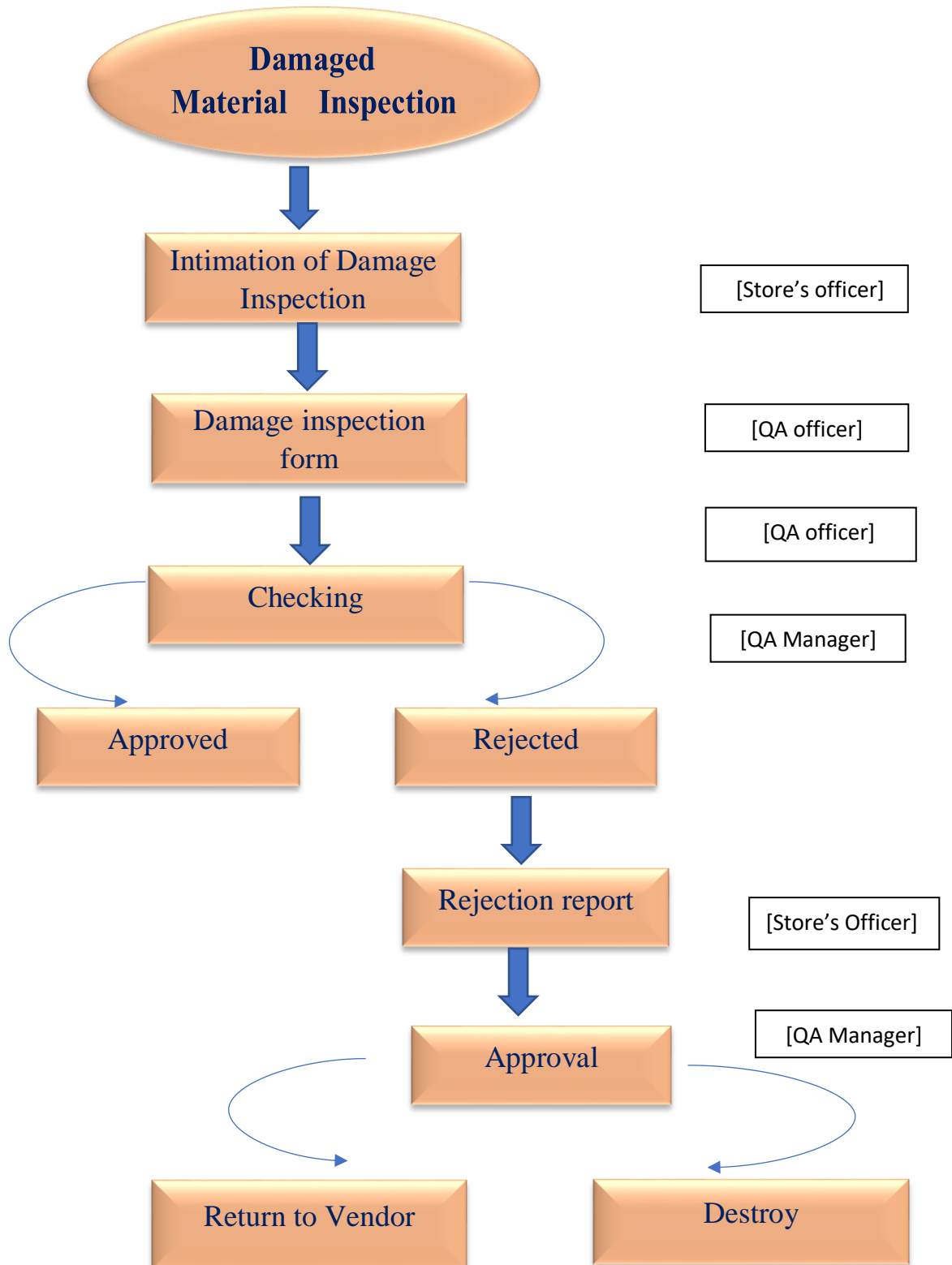
Damage Container Inspection

Awaiting Containers for Checking

Log Book

Quality Assurance

✚ Flow of Damage Container Inspection:



Quality Assurance

● BATCH RELEASE

Quality Assurance Department SHIKHA (QA003)

01/00 | Apr 16, 2021, 11:46:54 AM

Batch Release CLOSE

Prepare Checklist

Checklist Master

New Batch Release

Batch Release Checklist CLOSE

Dosage Form: Product Name:

Checkpoints:

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

No Records Found!

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

1. Prepare Checklist

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

2. New Batch Release

NEW BATCH RELEASE CLOSE

Dosage Form

↓

Quality Assurance Department SHIKHA (QA003)

01/00 | 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

SHIKHA (QA003)

11/00

Apr 16, 2021, 2:10:08 PM

SOP Management

SOP Initiation:

New SOP Request Prepare Draft Raise Change Control Initiated SOP's Log

Initiate New SOP

SOP Title:

SOP For:

SAVE

Prepare Draft for Initiated SOP

Department: Quality Assurance

SOP Title: Test computer

SOP For: QMS

Purpose

File Edit View Insert Format Tools Table Help

Paragraph B I [Rich Text Editor Icons]

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.

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

Quality Assurance Department

SHIKHA (QA003)

01/00

Apr 19, 2021, 11:18:44 AM

Upload Existing SOP

SOP Title*

SOP For*

Version No*

Upload SOP*

Choose File No file chosen

SAVE

3. SOP Index

SOP Index

Departments:

SOP For:

Status:

SEARCH

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

DOWNLOAD

- 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:

Training of SOP


Implementation of SOP


SOP Distribution Record

- 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.

Quality Assurance

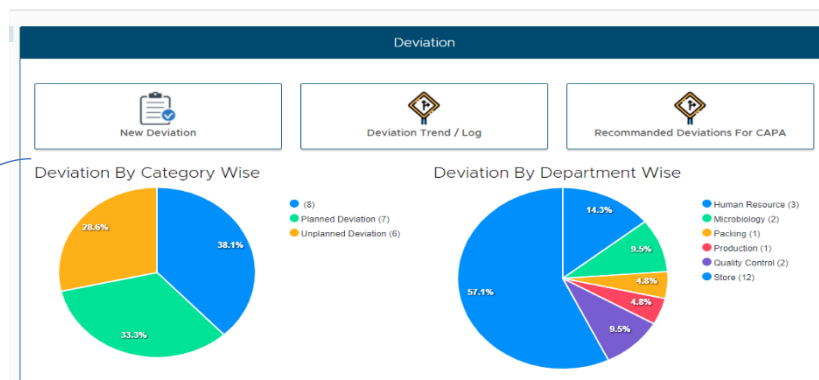
Revision of SOPs


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

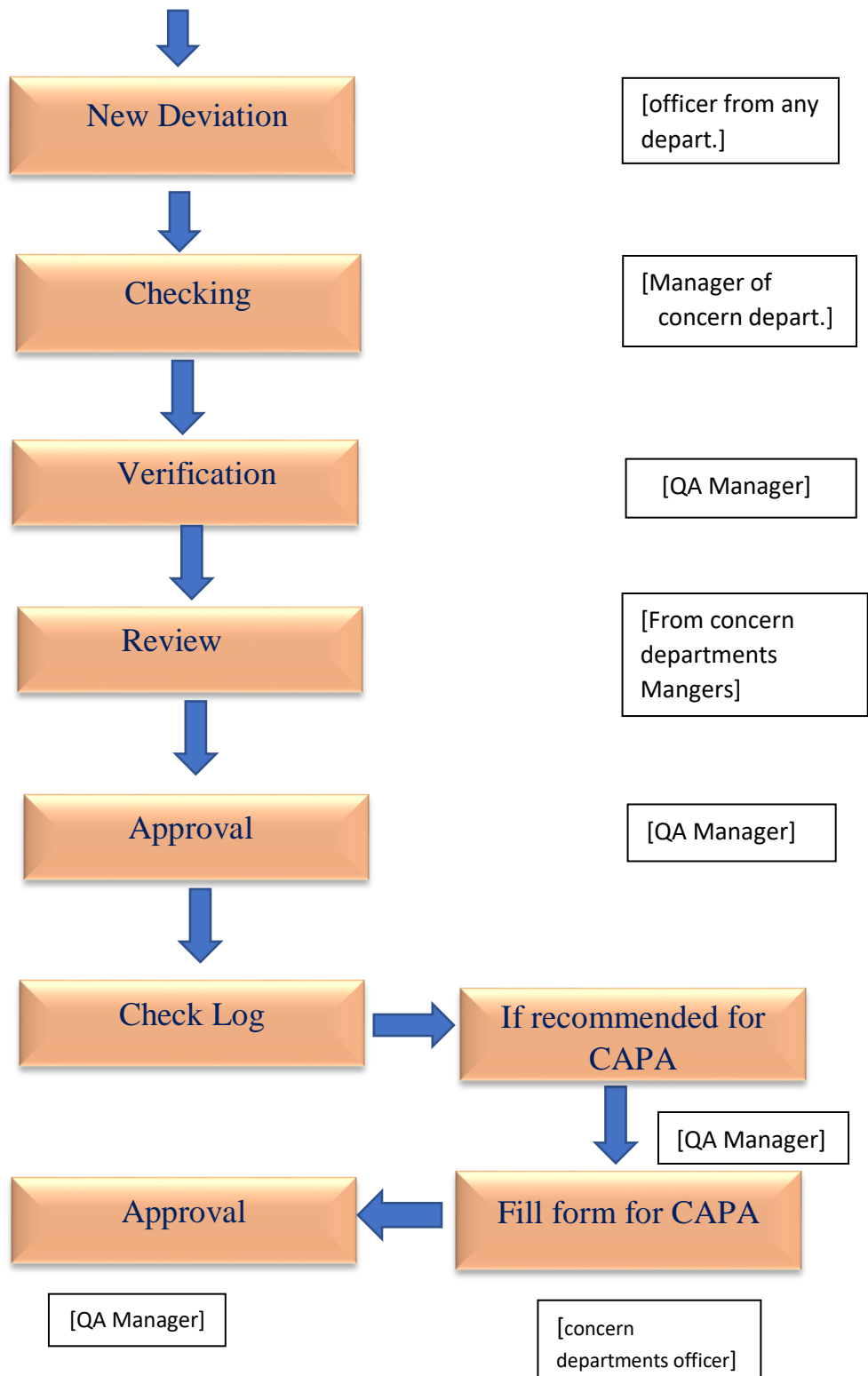
SUBMIT

CLOSE

✚ Flow chart for deviation:

Deviation

Quality Assurance

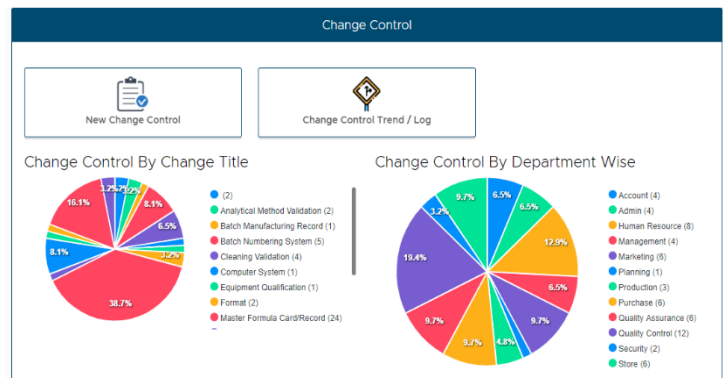


Quality Assurance

- 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 ☐ IPOA

SUBMIT **CLOSE**

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:

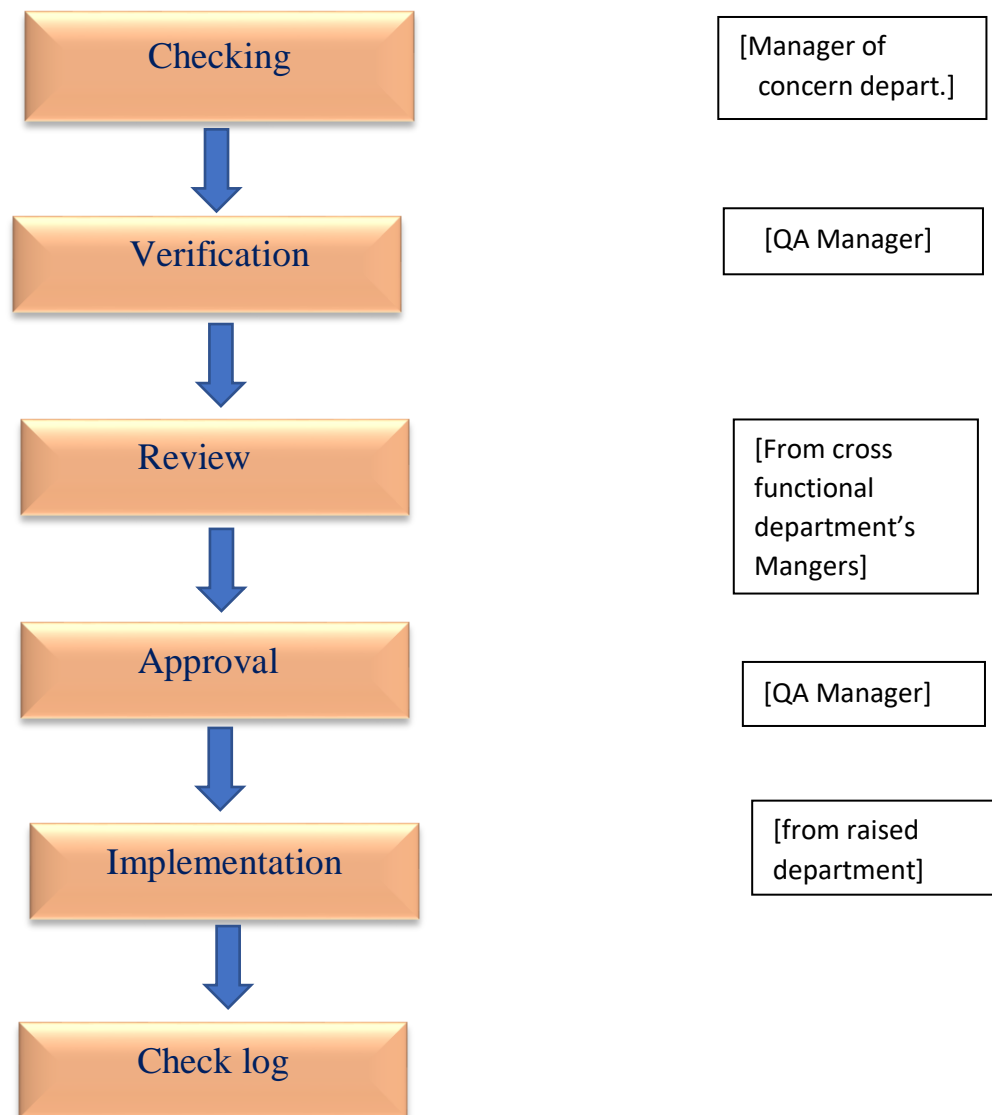
MANUAL SIGN **ELECTRONIC SIGN** **CLOSE**

- Flow Chart for Change Control:**



[officer from any depart]

Quality Assurance



- Incident Report**

The Incident Report dashboard features a grid of icons for various report types:

- New Incident
- Incident for Checking
- Incident for Verification
- Incidents for Review
- Incident for Approval
- Incident Log
- Incident Trend

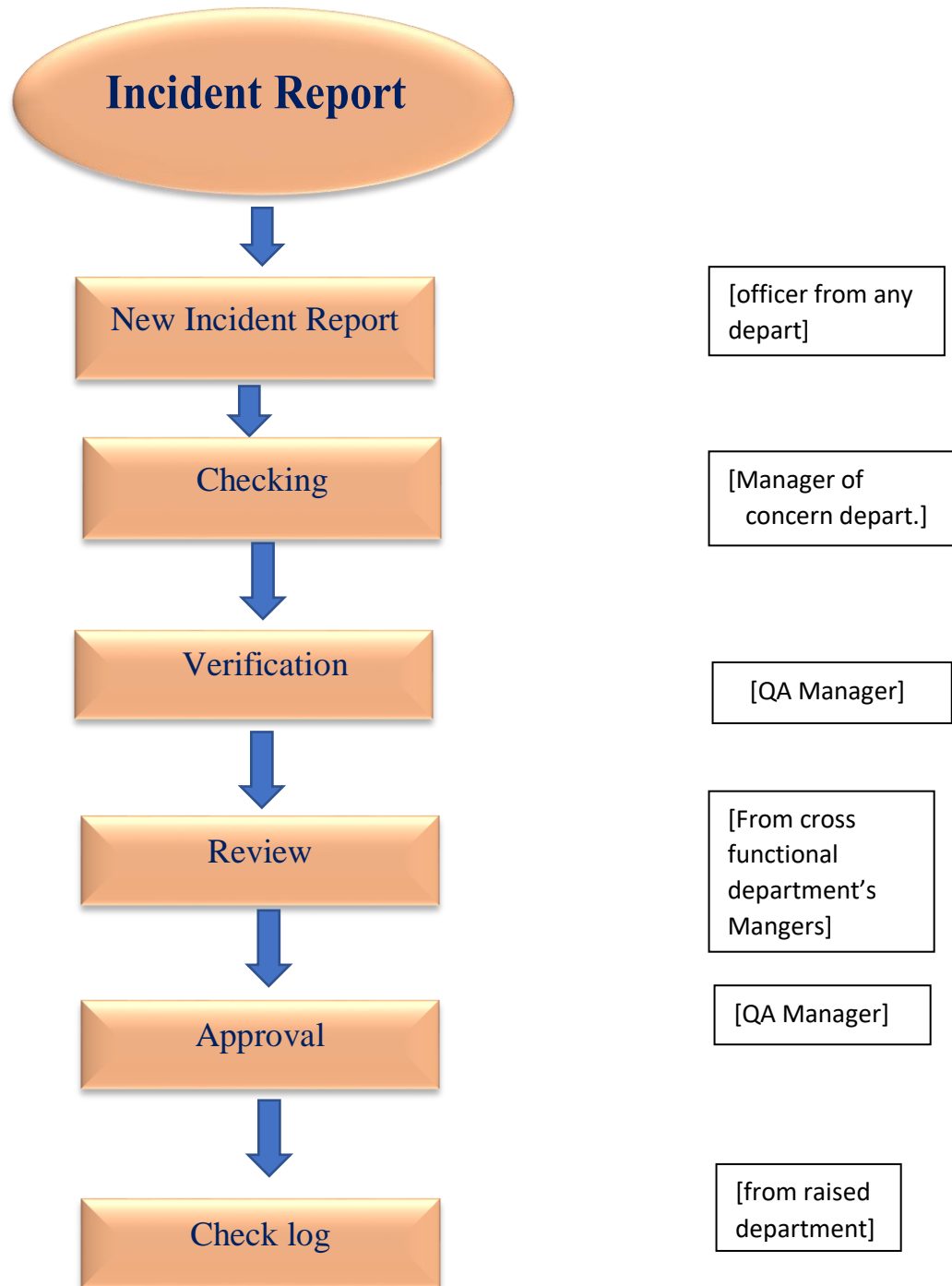
The New Incident form includes the following fields:

- Incident Related To:
- Incident Category:
- Type Of Incident:
- Justification for type:
- Cause of Incident:
- Description of Incident:
- Affecting Product / Material:
- Affecting Equipment:

- 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

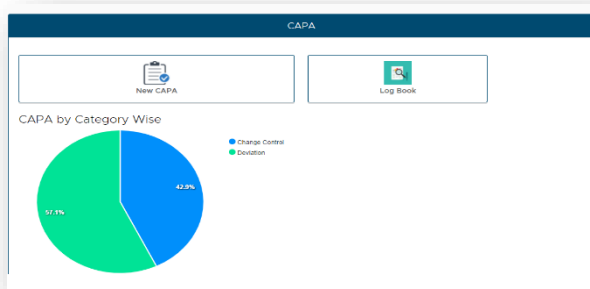
Quality Assurance

- Flow Chart for Incident Report:



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- CAPA



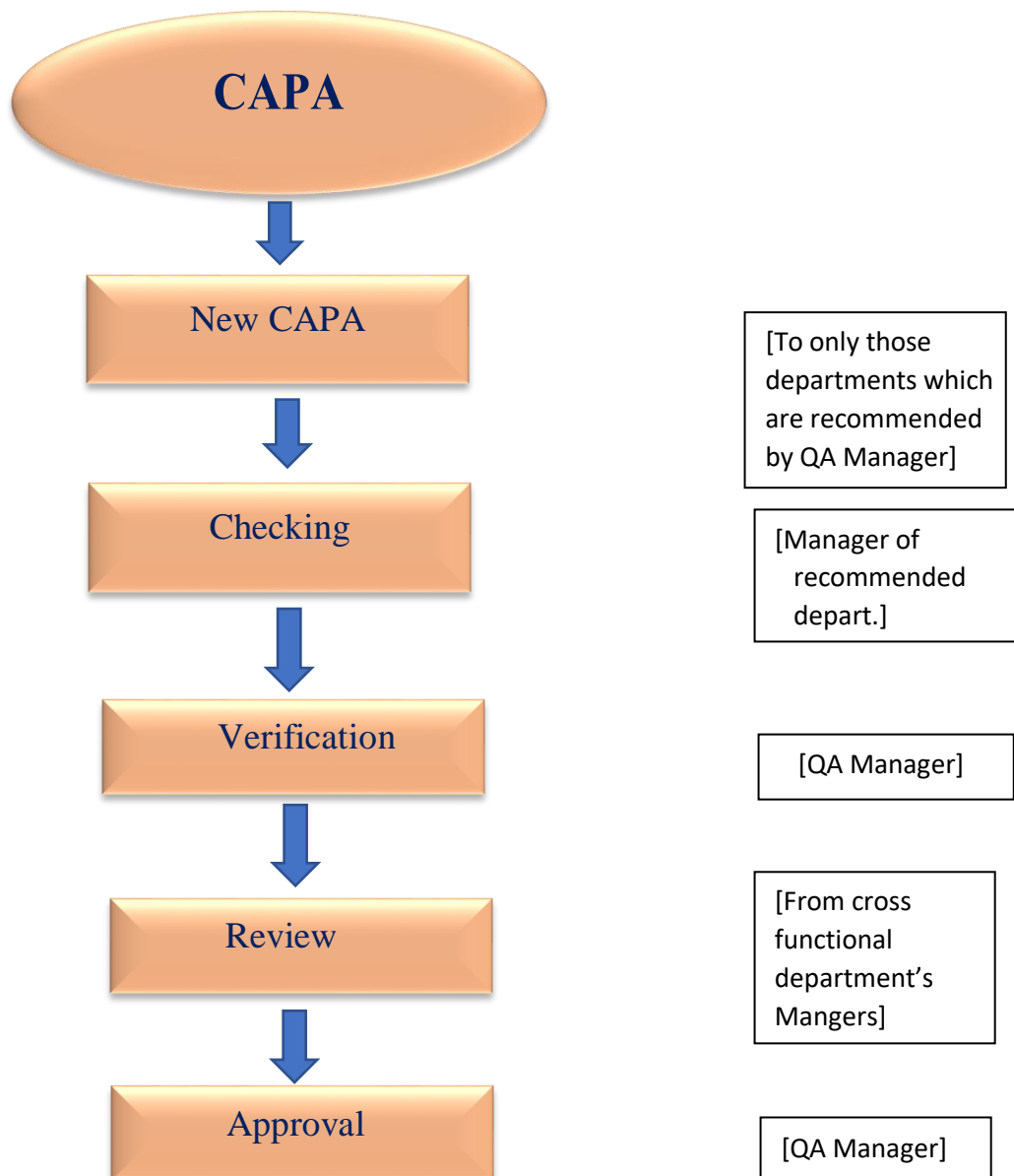
SCREENSHOT OF CAPA FORM

The form is titled "Corrective Action / Preventive Action Form". It contains the following fields:

- CAPA No.: CAPA-7
- Department: Quality Assurance
- CAPA For: Deviation
- Document No.:
- CAPA required in System: (dropdown menu)
- Category: (dropdown menu)
- Need to implement corrective action: (dropdown menu)
- Planned correction: (text area)
- Corrective Action: (text area)

Buttons: SUBMIT, CLOSE

✚ Flow Chart for CAPA:

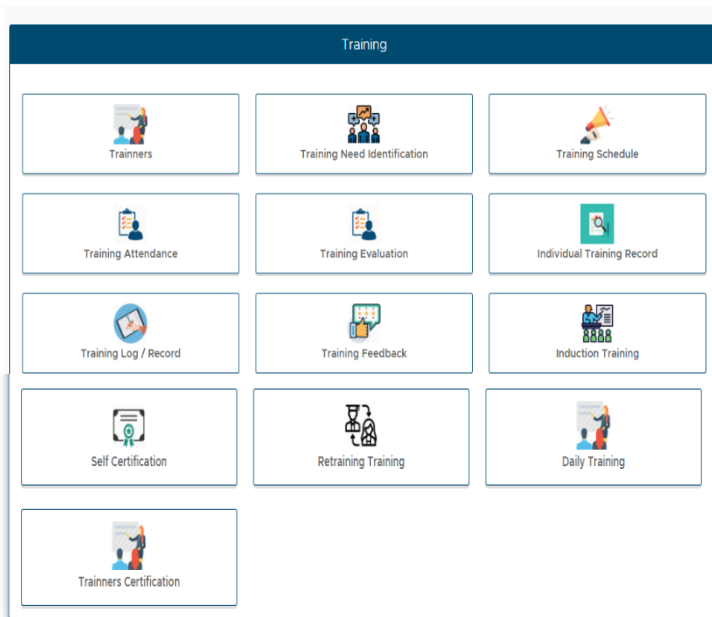


Quality Assurance

Check log

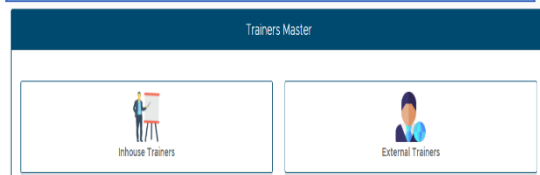
[from raised department]

• Training



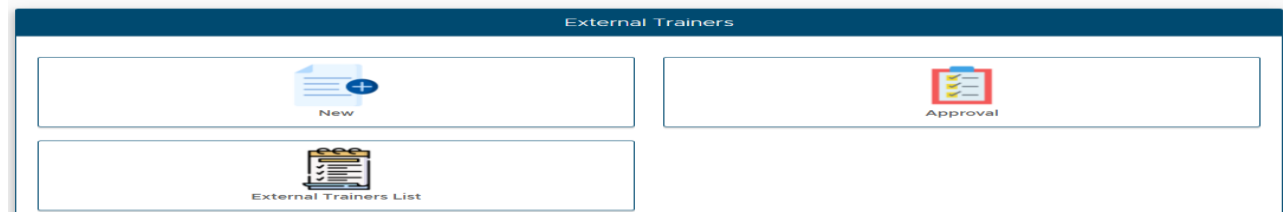
The Training Module Dashboard is a grid of 13 tiles. The tiles are arranged in four rows: the first three rows have three tiles each, and the fourth row has one tile. The tiles are: Trainers, Training Need Identification, Training Schedule, Training Attendance, Training Evaluation, Individual Training Record, Training Log / Record, Training Feedback, Induction Training, Self Certification, Retraining Training, Daily Training, and Trainers Certification.

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



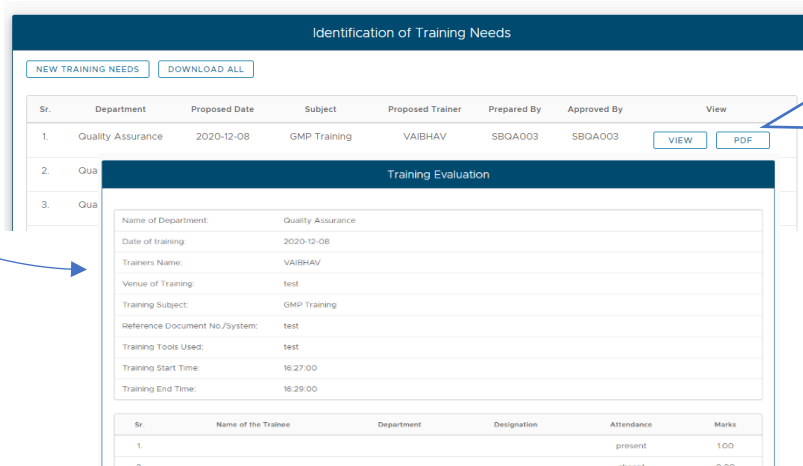
The Trainers Master Dashboard is a simple layout with two tiles: Inhouse Trainers and External Trainers.

- 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.



The External Trainers Dashboard is a simple layout with three tiles: New, Approval, and External Trainers List.

✓ Training Need Identification



The Training Need Identification form is a complex form with multiple sections. The first section is 'Identification of Training Needs' which includes a table with columns: Sr., Department, Proposed Date, Subject, Proposed Trainer, Prepared By, Approved By, and View. The second section is 'Training Evaluation' which includes a form with fields for: Name of Department, Date of training, Trainers Name, Venue of Training, Training Subject, Reference Document No./System, Training Tools Used, Training Start Time, and Training End Time. The third section is a table with columns: Sr., Name of the Trainee, Department, Designation, Attendance, and Marks.

-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:	<input type="text"/>
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:

Training Time:

Venue:

Training Attendance Record


Name of Department:	Quality Assurance
Date of training:	2020-12-22
Trainers Name:	VAIBHAV
Venue of Training:	Corporate
Training Subject:	GMP Training
Reference Document No./System:	DFGHe
Training Tools Used:	<input type="text"/>
Training Start Time:	--:--
Training End Time:	--:--

Sr.	Name of the Trainee	Department	Designation	Attendance
1				<input type="button" value="PRESENT"/> <input type="button" value="ABSENT"/>
2				<input type="button" value="PRESENT"/> <input type="button" value="ABSENT"/>
3				<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	Training Date:	2020-12-17
Trainers Name:	VAIBHAV	Venue:	Corporate
Subject:	GMP Training	Reference Document:	enduluth

Evaluators Name: Duration: Total Marks:

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

No Records Found!

Training Evaluation

Venue of Training:	test
Training Subject:	GMP Training
Reference Document No./System:	test
Training Tools Used:	test
Training Start Time:	10:29:00
Training End Time:	10:29:00

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

- 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

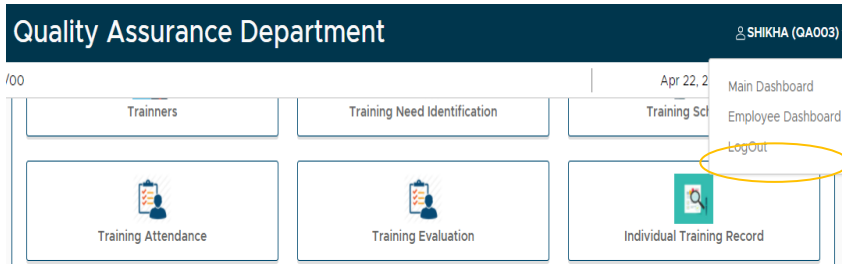
Individual Training Record

Department:	<input type="text"/>	Employee Name:	<input type="text"/>	Designation:	<input type="text"/>	No. of Trainings Attendends:	<input type="text" value="0"/>
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Sr.	Date	Subject	Venue	Duration	Trainers Name	Attendance	Marks	Feedback

Quality Assurance

✓ Self-Certification



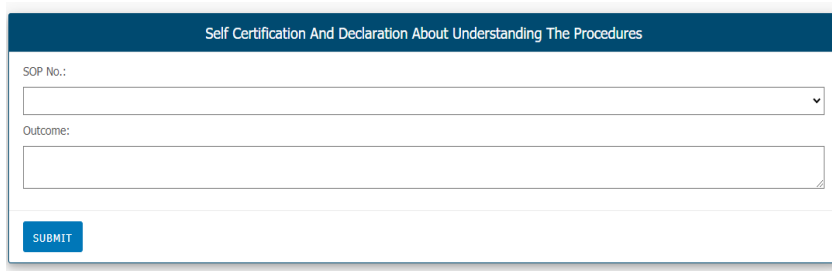
- for self-certification go to employee dashboard first

- Open SELF CERTIFICATE fill the form.

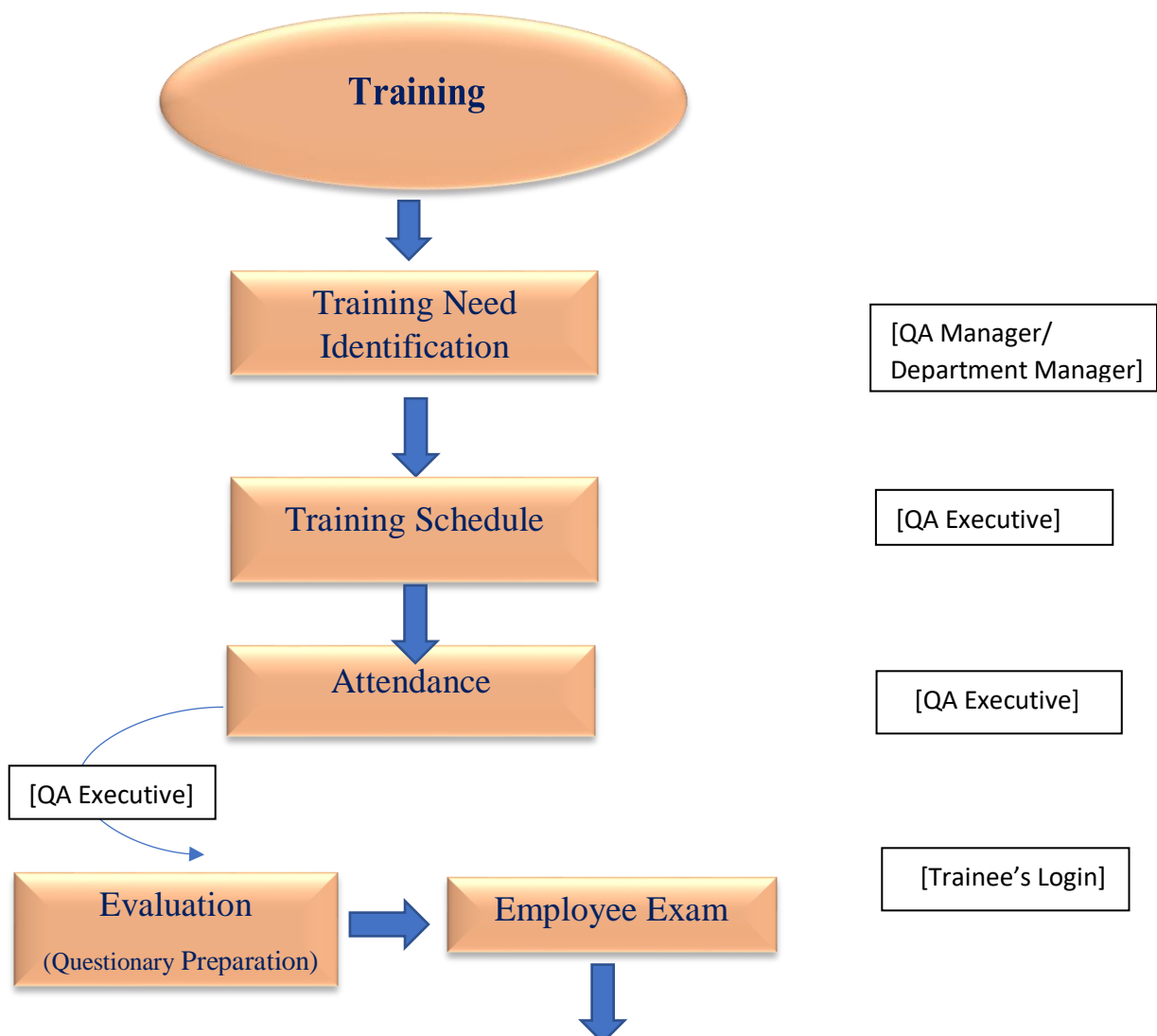
- Submit

-Get Approval from QA Manager.

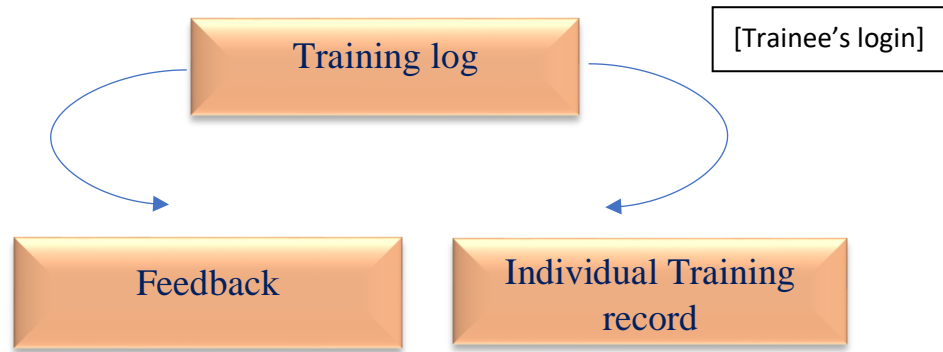
- Record will be maintained at Self Certificate log.



Flow Chart of Training:



Quality Assurance



[Trainee's login]

Stability Management

The dashboard includes the following options:

- Initiate Stability
- Stability Sampling
- Stability Charging
- Schedule of Study
- Stability Interval Allocation
- Testing
- Summary Report
- Deviation
- Stability Chamber Log
- Stability Calendar
- Stability Trend

Form fields: Packing, Market, No. of Batches to be charged (0), Batch Type.

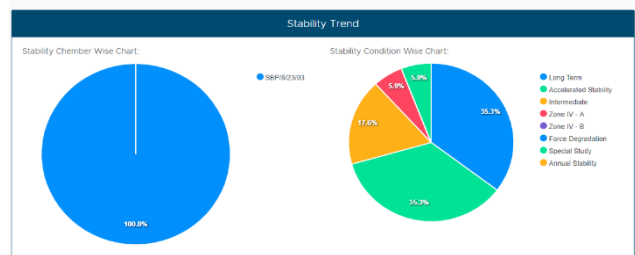
Action	Condition	Intervals	Total Intervals	Sample Qty Single Analysis	Total Sample Qty
<input type="checkbox"/>	Long Term	0, 3, 6, 9, 12, 24, 36, 48	8		Specification Not Available
<input type="checkbox"/>	Accelerated Stability	0, 3, 6	3		Specification Not Available
<input type="checkbox"/>	Intermediate	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

Buttons: SUBMIT, CLOSE

- 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

Buttons: Sampling Allocation, Proceed Sampling.

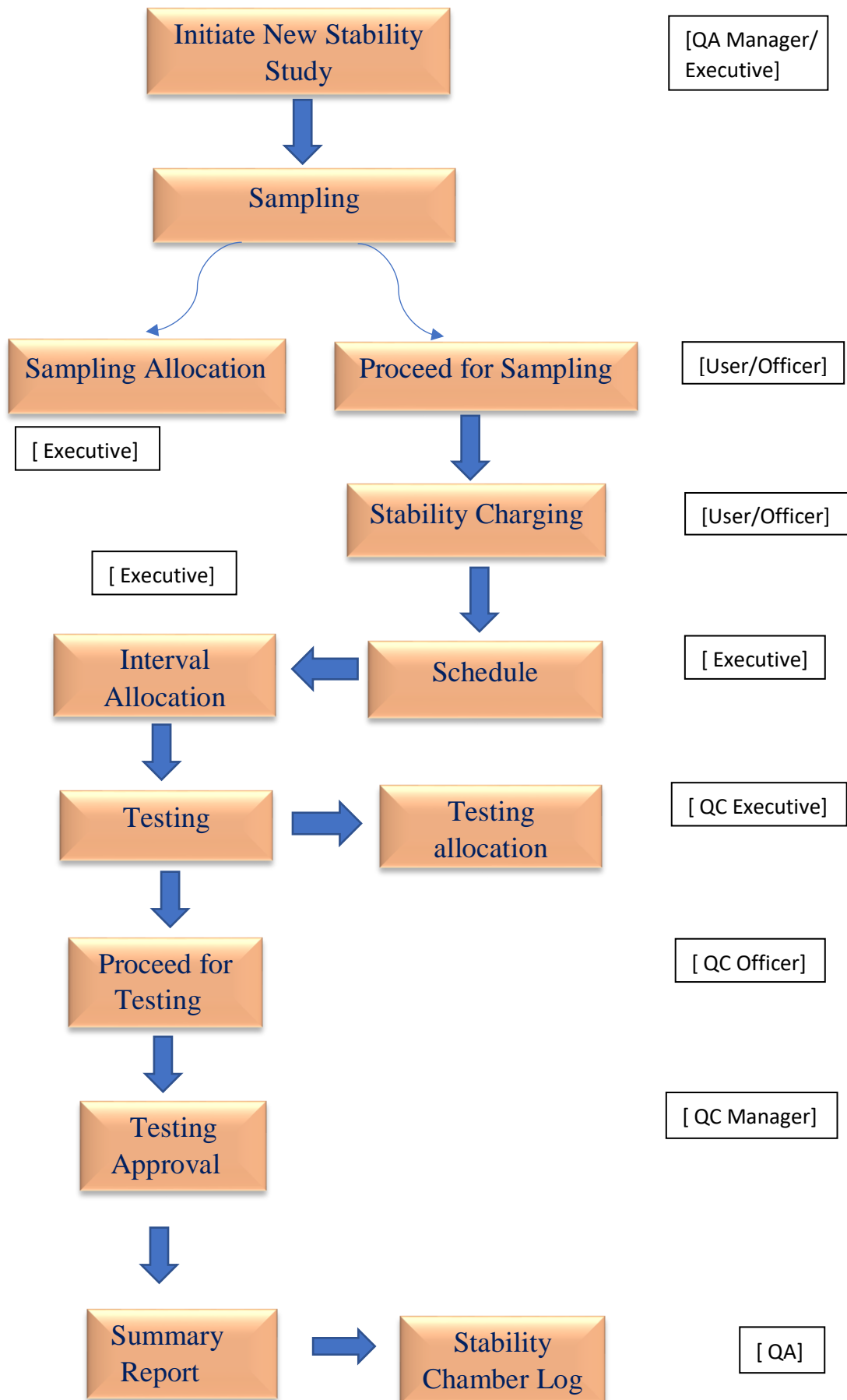
Stability No.	Dosage Form	Product	No. of Batches	Date of Initiate	Initiated By	View Protocol
No Records Found!						



Flow Chart of Stability Study:

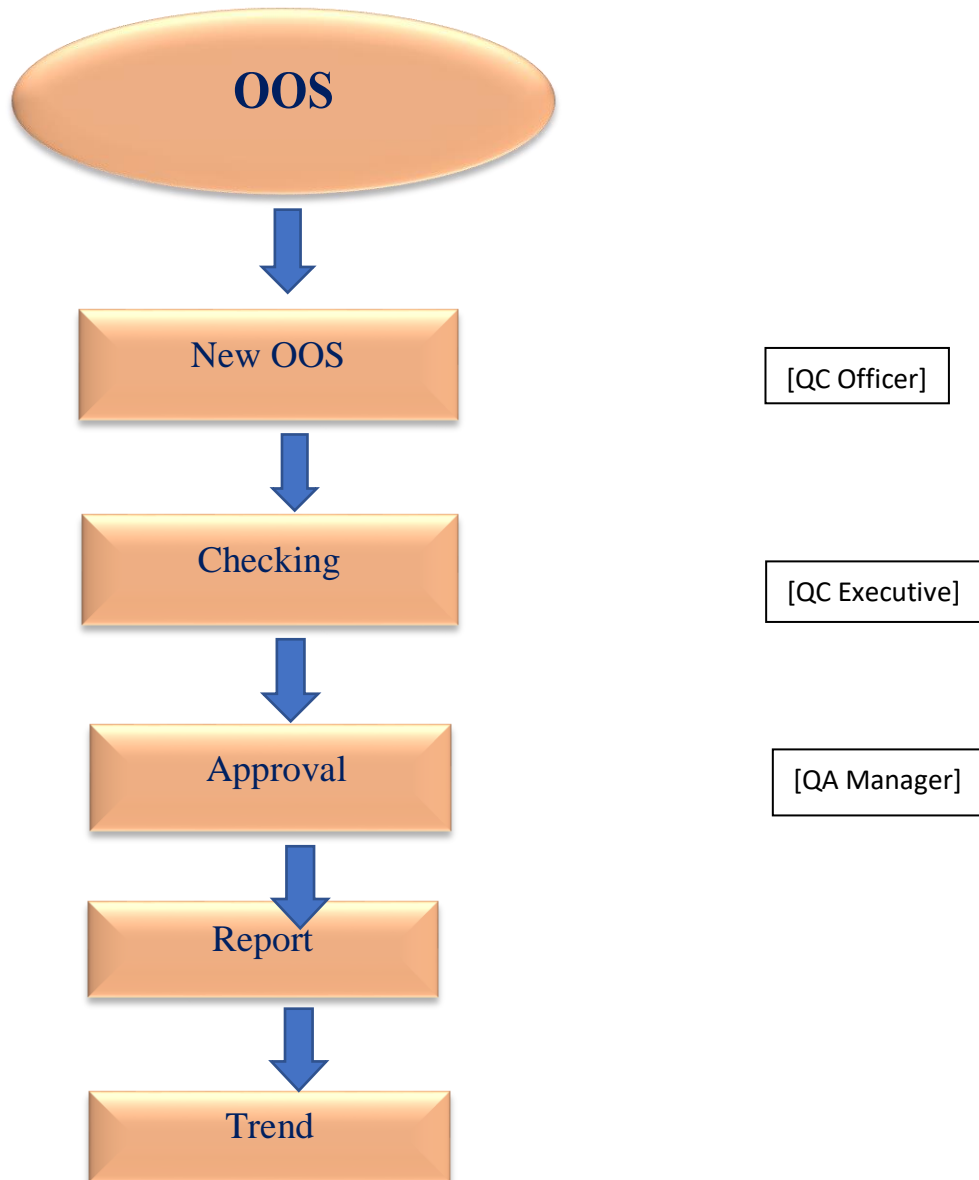


Quality Assurance



Quality Assurance

- OOS:



- Risk Management:



Quality Assurance

The screenshot shows a web form titled "Risk Identification". It contains several input fields and dropdown menus. At the top, there are two dropdowns for "Department:" and "Section:". Below these are three more dropdowns: "Risk Identification For:", "Usages For Stage / Step:", and "Risk Identified:". There are two text input areas: "Description of Risk:" and "Justification of Risk:". At the bottom, there are four dropdown menus arranged in two pairs. The first pair is for "Is it going to impact on Product Quantity?" and "Impact Strength:". The second pair is for "Is it going to make risk to Human Life?" and "Human Life Risk Strength:". At the very bottom, there are two buttons: "SUBMIT" (blue) and "CLOSE" (red).

- 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

