

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PR	OCEDURE
Department: Quality Assurance	SOP No.:
Title: Department Organogram and Job Description	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure Standard Operating Procedure for preparation of Department Organogram and Job Description.

2.0 SCOPE:

This SOP shall be applicable to all responsible Personal at

3.0 RESPONSIBILITY:

- **3.1** Head concerned department/designee shall be responsible for:
 - **3.1.1** Preparation of Job Description and department Organogram.
 - **3.1.2** To assign and approve the Job Description of all concerned staff of the department.
- **3.2** Head Quality Assurance shall be responsible for:
 - **3.2.1** Approval of Job Description of Head of Department.
 - **3.2.2** Approval Department Organogram and Organization chart.
 - **3.2.3** Assigning and Approval of the Job Description of the concerned staff.

4.0 ACCOUNTABILITY:

4.1 Head QA shall be accountable for ensuring compliance of this Standard Operating Procedure.

5.0 **DEFINITIONS**:

5.1 JOB DESCRIPTION: A Job Description or JD is a document that describes the general tasks, or other related duties, and responsibilities of a position. It may specify the functionary to whom the position reports, specifications such as the qualifications or skills needed by the person in the job. Job descriptions are usually narrative, but some may comprise a simple list of competencies; for instance, strategic human resource planning methodologies may be used to develop competency architecture for an organization, from which job descriptions are built as a shortlist of competencies.



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6.0 **PROCEDURE:**

6.1 **Preparation of Department Organogram:**

- **6.1.1** All department shall prepare the department Organogram as per hierarchy keeping department Head on top and then reporting people in descending order as per Annexure-I and shall be forward to Head Quality for Approval.
- **6.1.2** In Department Organogram, only name of the section In-charge shall be mentioned and below only Designation of the designation holder shall mentioned.

6.2 **Preparation of Organization Chart:**

6.2.1 QA shall prepare Organization chart of the Organization as per Annexure-II and shall be approved by Head Quality.

6.3 **Preparation of Job Description (JD):**

- **6.3.1** All departments shall prepare the Individual Job Description as per Annexure-III.
- **6.3.2** Concerned Department Head shall assign the job responsibilities to new joinee which shall be signed by new joinee/designee in absence as an acceptance of JD.
- **6.3.3** Job Description of new joinee shall be prepared along with TNI and after completion of training Job Description (JD) shall be made effective by QA and controlled copy of JD shall be issued to concerned department.
- **6.3.4** In case of relocation of an employee or assigning work other than mentioned in JD then first JD shall be revised and training shall be given on job related topics/subject, after satisfactory evaluation of an employee JD shall be made effective.
- **6.3.5** Job Description (JD) shall be numbered as per below numbering system:

JD/XX/ZZZZ

Where,

- $JD \quad Stands \ for \ Job \ Description$
- **XX** Stands for various department codes i.e., QA-for Quality Assurance, QC-for Quality



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Control, PD- for Production, WH-for Warehouse, EN-for Engineering, HR-for Human Resource, IT-for Information Technology.

ZZZZ – stands for last four digit of employee code.

- **6.3.6** Revision number of JD shall be changed after any modification or change in job responsibility of an Employee.
- **6.3.7** Job Description of the Head-Quality shall be prepared by QA and authorized by **CEO** of the Organization.
- 6.4 All Job Description, Department Organogram and Organization chart shall be revised whenever required.
- **6.5** Issuance, Retrieval and Archival of Organogram, Job Description and Organization chart shall be done as per Procedure for Documentation and Data Control.
- **6.6** In-charge concerned department shall ensure that the Job Description is available with the individual training file of the concerned staff.
- 6.7 Head Quality shall report to Chief Executive Officer.

7.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
F	Format
QC	Quality Control
HR	Human Resource
QA	Quality Assurance
WH	Warehouse
PD	Production
EN	Engineering
JD	Job description
Pvt.	Private
Ltd.	Limited



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8.0 ANNEXURES:

Annexure No.	Title of Annexure	Format No.
Annexure –I	Format for Organogram	
Annexure –II	Format for Organization Chart	
Annexure-III	Job Description	

9.0 **DISTRIBUTION:**

- Master Copy
 Quality Assurance Department
- Controlled Copy No. 01 Quality Assurance Department.
- Controlled Copy No. 02 Quality Control Department.
- Controlled Copy No. 03 Production Department.
- Controlled Copy No. 04 Human Resource Department (HR).
- Controlled Copy No. 05 Engineering Department.
- Controlled Copy No. 06 Warehouse Department (Store).
- Controlled Copy No.07 Information Technology Department

10.0 REFERENCES:

In-House & 21CFR part 210 & 211 and cGMP Guidelines

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		



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Annexure-I

QUALITY ASSURANCE

ORGANOGRAM

Prepared By Sign/Date Approved By Sign/Date



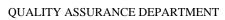
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Annexure-II

Format of Organization Chart

Prepared By Sign/Date Approved By Sign/Date





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	rtment Organogram and Job Description	Effective Date:	
persedes		Review Date:	
sue Date:		Page No.:	
		nexure-III Description	
Name of	Employee:	JD No.:	
Departn	ient:	Employee Code:	
Designat	tion:	Date of Joining:	
Qualific	ation:	Experience:	
Revision	Number:	Supersedes No.:	
Effective Date of JD:		Reporting To:	
Effective	e Date of JD:	Reporting To:	
Your job	responsibilities are listed below for your	• 0	
Your job	responsibilities are listed below for your	understanding and acceptance. In case of any system up	
Your job gradatior S.No. In case o intimatio	responsibilities are listed below for your in future, you will be simultaneously re-tree Responsible for	understanding and acceptance. In case of any system up rained to understand the new implementation.	
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