

QUALITY ASSURANCE DEPARTMENT

### STANDARD OPERATING PROCEDURE

Department: Quality Assurance SOP No.:	
Title: Qualification of Trainer and Auditor	Effective Date:
Supersedes: Nil	<b>Review Date:</b>
Issue Date:	Page No.:

# 1. **Purpose** : To define a procedure for qualification of trainer and auditor.

2. **Scope** : This procedure is applicable to the persons of individual department who can be qualified as internal auditor and trainer.

### 3. References , Attachments & Annexure:

3.1 References: NA

# 3.2 Attachments:

- 3.2.1 Attachment 1: Certificate Of Qualified Trainer for Training
- 3.2.2 Attachment 2: Certificate of Qualified Auditor for Internal Audit

### 3.3 Annexure:

3.3.1 Annexure 1: List of Qualified Auditors & Trainers

### 4. Responsibilities:

# 4.1 **Quality Assurance Head:**

4.1.1 To identify competent trainer and auditor of each department.

## 4.2 Quality Head:

4.2.1 To authorize the person as qualified trainer and auditor.

# 5. Distribution:

5.1 Quality Assurance

# 6. Abbreviations and Definitions of Terms:

#### 6.1 Abbreviations : NA

6.2 **Definitions of Terms:** NA

# 7. Procedure:



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# 7.1 **Procedure for Trainer and Auditor Qualification:**

- 7.1.1 Competent person shall be identified in each department for imparting training and as an auditor.
- 7.1.2 These identified persons shall be qualified as trainer in their respective area and as auditor to other area.
- 7.1.3 Trainer and Auditor shall be qualified on the basis of following criteria:
  - 7.1.3.1 Minimum Qualification shall be a Bachelor/Master degree in Pharmacy/Science/job related discipline with relevant experience of minimum one year in the desired work area in any SPIL location and a total of minimum two years experience for both as Trainer and Auditor.
  - 7.1.3.2 The above requirement for qualified trainer and auditor in specific cases when employee is of Executive and above rank can be overruled by QA Head/Quality Head based on previous experience of the person.
  - 7.1.3.3 The Auditor must have knowledge of regulatory requirement.
  - 7.1.3.4 Total work experience in years.
  - 7.1.3.5 Area of work during past and present tenure.
- 7.1.4 Quality head/QA head shall qualify the trainer and auditor based on information provided by personnel and administration department as per point no. 7.1.3.
- 7.1.5 Training and Internal Audit in any department shall be conducted by authorized trainer and auditor.
- 7.1.6 A xerox copy of certificate shall be issued to each trainer and auditor as per attachment- 1 & 2.
- 7.1.7 Original certificate shall be retained with QA.



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# Attachment – 1

# **Certificate of Qualified Trainer for Training**

CERTIFICATE

**This Is To Certify That** \_\_\_\_\_\_\_ is fulfilling all pre-requisite for being an qualified trainer, Hence has been Certified as **Qualified Trainer** in of ......

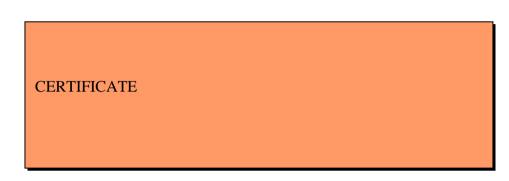
Prepared By (QA)	Approved By (Quality Head)	
$(\mathbf{Q}\mathbf{A})$	(Quality IIcau)	



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# Attachment – 2 Certificate of Qualified Auditor for Internal Audit



This Is To Certify That \_\_\_\_\_\_ Has under gone Training for Internal Audit and is fulfilling all pre-requisite for being an Internal Auditor, Hence has been Certified as INTERNAL AUDITOR of .....

Prepared By (QA)	Approved By (Quality Head)	
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### Annexure – 1 List of Qualified Auditors & Trainers

# List of Qualified Auditors and Trainers for period of

S.No.	Name of Employee	Employee Code	Dept.	Date of Joining	Qualified as

Prepared By	Approved By	
(QA)	(Quality Head)	

# 8. History

Version No.		Effective Date	
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