



DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Qualification of Trainer and Auditor	Effective Date:
Supersedes: Nil	Review Date:
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



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)	
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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 (QA)		Approved By (Quality Head)	
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8. History

Version No.		Effective Date	
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