

STANDARD OPERATING PROCEDURE
International Pharmaceutical Excipients Auditing, Inc.

Title Auditor Qualification		Revision 2	SOP Number 2
Originator Irwin Silverstein	Approved By IPEA Management Committee	Date Approved 7/8/2011	Page Page 1 of 4

PURPOSE:

This procedure establishes the qualifications of auditors and the training necessary prior to their performing excipient GMP audits.

SCOPE:

This procedure applies to all auditors who issue audit reports for IPEA.

RESPONSIBILITIES:

1. **IPEA Executive Management:**
 - a. Review the credentials of candidate auditors to assure they meet IPEA minimum requirements;
 - b. Provides assurance the content of auditor training is appropriate;
 - c. Verify that the candidate satisfactorily completed the auditor training, including audit report preparation;
 - d. Maintain the list of Qualified Auditors;
 - e. Periodically review the performance of auditors and provide feedback;
 - f. Periodically re-approve Qualified Auditors or designate an alternate; and
 - g. Evaluate the need for Senior Auditors and Trainer/Auditors.
2. **Trainer/Auditor:** Conduct the training of candidate auditors and supervise the auditor qualification audit.

REFERENCES:

1. The Joint IPEC-PQG Good Manufacturing Practices Audit Guide for Pharmaceutical Excipients 2007.
2. ISO 19011, Guidelines for Management Systems Auditing.
3. QDoc 8, Auditor Fee Schedule

DEFINITIONS:

1. **See Glossary**

PROCEDURE:

1. A candidate for Qualified Auditor preferably has at least a Bachelor degree in a scientific discipline or other suitable education in combination with either:
 - a. Prior training as an auditor such as American Society for Quality Certified Quality Audit (CQA) or ISO 9000 Lead Auditor certification; or
 - b. A record of having performed GMP audits or quality audits of excipient manufacturers.
2. The candidate receives training from IPEA that is appropriate to their prior audit experience. The following is presented as a guideline for the depth of training:
 - a. Candidates who meet the requirements under 1a successfully complete a comprehensive excipient audit course such as the Three Day IPEA Excipient Auditing Workshop. In addition, the candidate submits a sample audit report for evaluation.

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Title Auditor Qualification		Revision 2	SOP Number 2
Originator Irwin Silverstein	Approved By IPEA Management Committee	Date Approved 7/8/2011	Page Page 2 of 4

- b. Candidates who have prior training as described in 1b successfully complete, at a minimum, the Three Day IPEA Excipient Auditing Workshop or equivalent.
 - c. Candidates who have significant prior audit experience as described in 1b, successfully complete the One Day IPEA Excipient Audit Workshop.
 - d. The CEO or COO can qualify an auditor based upon their previous experience and expertise in performing excipient GMP audits without having participated in an excipient audit workshop. Such candidates include those who have participated in the training of excipient auditors for IPEA.
3. Successful completion of the courses listed under item 2 is determined by the course instructor(s).
 4. The candidate auditor works under the supervision of a Senior Auditor, Trainer/Auditor, or a person deemed to be so qualified by IPEA Executive Management (EM). The candidate auditor is supervised until EM has found the candidates audit skills and their audit reports satisfactory.
 - a. The audit supervisor (Trainer/Auditor) observes the candidate auditor for:
 - i. Personal attributes
 - Ethical
 - Open minded
 - Diplomatic
 - Observant
 - Perceptive
 - Versatile
 - Tenacious
 - Decisive
 - Self-reliant
 - ii. The audit supervisor evaluates the candidates knowledge and skills to:
 - Apply audit principles, procedures and techniques
 - Plan and organize
 - Meet time schedule
 - Prioritize and focus on matters of significance
 - Collect information
 - Understand the appropriateness and consequences of using sampling techniques for auditing
 - Verify the accuracy of information
 - Confirm audit evidence is sufficient and appropriate to support audit findings and conclusions

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International Pharmaceutical Excipients Auditing, Inc.

Title Auditor Qualification		Revision 2	SOP Number 2
Originator Irwin Silverstein	Approved By IPEA Management Committee	Date Approved 7/8/2011	Page Page 3 of 4

- Assess factors that can affect the reliability of the audit findings and conclusions
 - Record audit activities
 - Prepare audit reports
 - Maintain confidentiality
 - Communicate effectively
5. EM informs the candidate Qualified Auditor that they are now approved to conduct excipient GMP audits without supervision.
 - a. IPEA executes the audit contractor agreement with the Qualified Auditor.
 - i. Payments to the auditor are made in accordance with the Auditor Fee Schedule (QDoc 8).
 - b. Their name is added to the list of Qualified Auditors maintained by IPEA.
 6. EM annually reviews the Qualified Auditors to determine their qualification to become a Senior Auditor. EM reports to the IPEA Management Committee auditors deemed qualified to be a Senior Auditor. The Management Committee reviews the auditor's qualifications and by majority vote, approves their elevation to Senior Auditor.
 7. EM proposes to the IPEA Management Committee on an as needed basis, Senior Auditors for approval to Trainer/Auditor. The Management Committee reviews the Senior Auditor's qualifications and by majority vote, approves their elevation to Trainer/Auditor.
 8. Qualified and Senior Auditors are evaluated annually. Evaluation involves discussion of the auditor performance including:
 - Audit report,
 - Participation on audit teams, and
 - Proper classification of observation.

Suggestions may be made for the maintenance and improvement of their knowledge and skills. A summary of the discussion is kept on-file for follow-up at the next evaluation.
 9. EM re-approves Qualified and Senior Auditors every 3 years. EM or designated alternate may use the following as the basis for re-approval:
 - a. Observation of the Qualified Auditor
 - i. This is the preferred approach especially where the Qualified Auditor has only conducted 3 audits in the 3-year interval.
 - b. Review of audit reports
 - i. If the Qualified Auditor has conducted at least 6 audits in the 3-year interval and their audit reports were found to be comprehensive and well written this may be used in lieu of (6ai).

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Originator Irwin Silverstein	Approved By IPEA Management Committee	Date Approved 7/8/2011	Page Page 4 of 4

The performance of Trainer/Auditors is monitored by Executive Management on an ongoing basis. They are re-approved every 3 years based upon observation of their training of auditors.

HISTORY OF REVISIONS

Revision No.	Effective Date	Description of Changes
0	Jan 1, 2007	New Procedure
1	Jun 19, 2009	Removed reference to ITS and added many details
2	Jul 8, 2011	Minor edits