

STANDARD OPERATING PROCEDURE
International Pharmaceutical Excipients Auditing, Inc.

Title Audit Process Overview		Revision 2	SOP Number 1
Originator Irwin Silverstein	Approved By IPEA Management Committee	Date Approved May 27, 2011	Page Page 1 of 5

PURPOSE:

This procedure provides an overview of the IPEA Audit Program.

SCOPE:

This procedure describes the IPEA audit process beginning with the audit request and concluding with the approval of the audit report by the audit sponsor.

RESPONSIBILITIES:

1. **Audit Sponsor Representative:** Coordinate financial arrangements with IPEA.
2. **Audit Site Representative:** Coordinate audit arrangements with IPEA.
3. **IPEA Administrator:** Complete all IPEA documentation and financial requirements for IPEA.
4. **IPEA VP and Chief Operating Officer (COO):** Assure audit program requirements are met and review completed draft audit report.
5. **Qualified Auditor:** Arrange, prepare, conduct, and document the audit in accordance with IPEA procedures.

REFERENCES:

1. SOP 2, Auditor Qualification
2. SOP 11, Conflict of Interest
3. SOP 16, Appeals, Complaints and Disputes

DEFINITIONS:

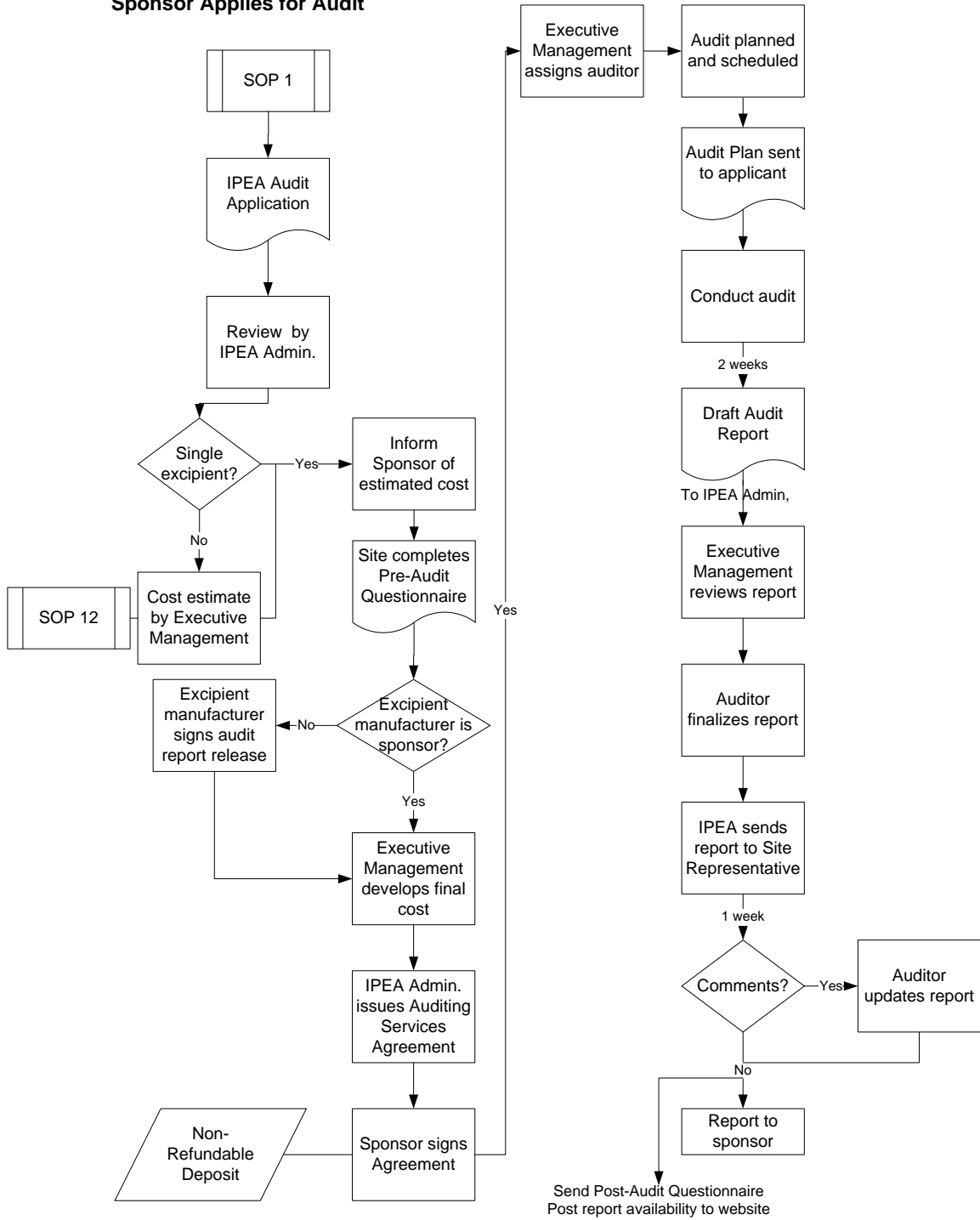
See Glossary

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Sponsor Applies for Audit



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PROCEDURE:

1. An audit request is initiated by completion of the IPEA Audit Application available on the IPEA website (www.ipeainc.com/application.php). Alternatively the request for an audit can be made via phone, email, fax, etc. to IPEA. The IPEA Administrator will provide an Audit Application to the requestor. The Audit Application may then be completed and returned to IPEA.
2. The IPEA Administrator reviews the Audit Application to determine the scope of the audit. Where the audit is of a single excipient, the IPEA Administrator will provide the estimated cost to the Audit Sponsor, subject to modification as noted below. Otherwise the request will be forwarded to IPEA Executive Management for a cost estimate that will be provided to the IPEA Administrator.
3. The IPEA Administrator informs the Audit Site Representative to complete the Pre-Audit Questionnaire or asks the site for their Excipient Information Package (EIP) for the excipient.
4. The IPEA Administrator sends the completed questionnaire or EIP to IPEA Executive Management for review to confirm that the audit can be conducted during a one day visit and that travel to the site is expected to be ½ day or less.
 - a. If there is any concern that the audit cannot be completed within one day, the IPEA Executive Management will discuss the scope and complexity of the proposed site audit with the Sponsor.
 - b. Where the decision is reached that the audit requires additional time, the IPEA Administrator is informed of the updated cost estimate and a revised agreement is developed.
 - c. Where travel time to the site exceeds ½ day, cost for the additional time is added at ½ the auditor rate.
5. Where the Audit Sponsor is not the excipient manufacturer, the Audit Report Authorization (Form 09) is sent to the Audit Site Representative for their approval. If the site does not approve the sale of the report, the price for the audit service will increase by the amount stipulated in Form 09.
6. IPEA Executive Management issues a final cost estimate.
7. The IPEA Administrator develops an agreement for the audit based upon the cost estimate as noted in step 6 as well as the agreement by the Audit Sponsor and Audit Site to release the Audit Report for sale. This final cost (exclusive of travel expenses) is communicated to the Audit Sponsor by the IPEA Administrator.
8. The Agreement is sent to the Audit Sponsor Representative for signature. The Representative returns the signed agreement and arranges for payment of the deposit.
9. IPEA Executive Management assigns an auditor to conduct the audit. The IPEA Administrator notifies the Sponsor and the Audit Site Representative of the auditor and provides their Curriculum Vitae upon request. The Sponsor or Audit Site Representative can request a replacement auditor if they believe the audit does not meet the requirements of the conflict of interest procedure (SOP 11).
10. The IPEA Qualified Auditor:

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- a. Finalizes the schedule for conducting the audit with the Audit Site Representative, and
 - b. Informs the IPEA Administrator and IPEA COO of the audit schedule as well as the Audit Sponsor Representative where the sponsor is not the excipient manufacturer.
11. The Qualified Auditor conducts the site audit as scheduled. If there is a delay in conducting the audit, the new audit date is communicated to the IPEA Administrator.
 12. Within 2 weeks of the completion of the site audit, the Qualified Auditor drafts an Audit Report and submits it to the IPEA Administrator or directly to IPEA Executive Management for review.
 13. IPEA Executive Management completes the quality review of the Audit Report within 1 week and returns the Audit Report to the Qualified Auditor, with a copy to the IPEA Administrator.
 14. The Qualified Auditor addresses any comments made by the IPEA Executive Management review and then sends the completed draft Audit Report to the IPEA Administrator.
 15. The IPEA Administrator sends the Audit Site Representative the draft report and notifies the representative that the Audit Report should be reviewed and any comments received within 1 week. The audit site approval or comments are to be sent to the IPEA Administrator. If the audit site has not provided IPEA with their comments within 2 weeks, IPEA will issue the report.
 - a. If the audit site has comments requiring a change to the audit content, the IPEA Administrator forwards the audit report to the Qualified Auditor to address the site comments. The Qualified Auditor sends the updated report to the IPEA Administrator who then forwards the updated report to IPEA Executive Management to confirm and approve the changes made is appropriate.
 - b. If the Qualified Auditor disagrees with the changes requested by the audit site, the Qualified Auditor discusses the request for change with the Audit Site Representative. If the conflict cannot be resolved, further steps are described in accordance with SOP 16.
 16. The audit site can provide IPEA with a correction action plan that will be appended to the audit report.
 17. The completed Audit Report is sent to the Audit Sponsor Representative via overnight mail. If the Audit Sponsor or Audit Site Representative requests an electronic copy of the report, it is sent in PDF format with a footer that states "Official copies of this report are uniquely numbered by IPEA. Otherwise IPEA cannot guarantee authenticity."
 18. The IPEA Administrator sends the:
 - a. Post-Audit Questionnaire (Form 10) to the Audit Sponsor for completion, or

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- b. To the Audited Site Representative for completion where the Audit Sponsor is not the excipient manufacturer.
19. The Audit Report is listed on the IPEA website.

HISTORY OF REVISIONS

Revision No.	Effective Date	Description of Changes
0	Jan 1, 2007	New Procedure
1	Feb. 18, 2009	Delete all references to ITS and update the process flow
2	May 27, 2011	Minor edits