

**STANDARD OPERATING PROCEDURE**  
**International Pharmaceutical Excipients Auditing, Inc.**

Title <b>The Surveillance Certification Audit</b>		Revision <b>0</b>	SOP Number <b>32</b>
Originator Irwin Silverstein	Approved By IPEA Management Committee	Date Approved <b>Oct. 12, 2011</b>	Page Page 1 of 3

**PURPOSE:**

This procedure describes the Surveillance Certification Audit.

**SCOPE:**

This procedure applies to all applicants certified to excipient GMPs.

**RESPONSIBILITIES:**

1. **Lead Auditor:** responsible for issuing a draft report whose contents are in conformance with this procedure.
2. **Qualified Auditor:** responsible for supporting the Lead Auditor in the conduct of the audit.
3. **Report Reviewer:** responsible for confirming that the contents of the report conform to this procedure.

**REFERENCES:**

1. SOP 9, Certificate of Excipient GMP Conformance
2. SOP 17, Post Certification Review
3. SOP 20, Conducting the Certification Audit
4. SOP 24, Documenting the Certification Audit

**DEFINITIONS:**

See Glossary (SOP 0)

**PROCEDURE:**

1. In preparation for the surveillance site audit, the Lead Auditor prepares an audit plan based upon the information provided since certification or recertification as required by SOP 17, the prior audit, and corrective action plan. The audit plan contains:
  - a. **Purpose:** The surveillance audit is conducted to confirm the site Quality System continues to conformance to the current Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients.
  - b. **Scope:** The audit plan identifies the excipient ingredients to be assessed during the site visit. The plan lists all grades of the excipient produced at the facility. Where applicable, the plan groups excipients by type such as when the manufacture of multiple excipients use different chemistry, differ in their composition, or are produced in different facilities or equipment. The plan provides for review of corrective actions from the previous site audit, surveillance or complete audit.
  - c. **Audit Standard:** The audit plan documents the version of the IPEC excipient GMP guide to be used for the assessment.
  - d. **Schedule:** The audit plan lists the proposed timing of activities beginning with the agreed arrival time through the time the visit is to be completed.

**STANDARD OPERATING PROCEDURE**  
**International Pharmaceutical Excipients Auditing, Inc.**

Title <b>The Surveillance Certification Audit</b>		Revision <b>0</b>	SOP Number <b>32</b>
Originator Irwin Silverstein	Approved By IPEA Management Committee	Date Approved <b>Oct. 12, 2011</b>	Page Page 2 of 3

The schedule should include time for an opening, daily wrap-up, and closing meeting.

- e. **Audit Team members:** Lists the auditors assigned to audit the facility.
2. The Lead Auditor provides the audit plan to the site representative and confirms the audit dates. The Lead Auditor discusses with the site representative safety issues that the auditors should be aware of prior to their visit.
3. A Pre-Audit Meeting is conducted upon entry into the facility. The site should have been informed of the surveillance audit and the audit plan so that the site can have appropriate personnel present. The Pre-Audit Meeting is led by the Lead Auditor and should review the following items:
  - a. Identify the audit host and escorts for each area to be visited.
  - b. Site safety measures and other restrictions (i.e., cameras, cell phones)
  - c. The audit schedule
  - d. Audit purpose and scope
  - e. Confirm lunch arrangements
  - f. Establish timing of a daily meeting and audit closing meeting
  - g. Review audit findings, ratings, and possible audit outcomes
  - h. Post-audit activities including report preparation, site review of the draft report including the rating of findings, site addendum of corrective measures to the report, and responsibility for follow-up of the corrective measures.
  - i. Auditor requests to see selected procedures.
4. It is advisable to review the site process flow diagram to identify those manufacturing areas where a visit is most appropriate. Such areas involve operations that can have an impact on excipient quality such as manufacturing, packaging, and bulk storage. It is also advisable to identify that point in the manufacturing process where the site has determined excipient GMP principles should be applied.
5. Once the Pre-Audit Meeting has been conducted, the flow diagram has been reviewed, and the schedule for visiting the various areas of the facility has been established, the inspection commences.

Note: The auditor must report to IPEA Executive Management any activity or situation that presents a significant risk to consumers, that compromises good manufacturing practices at the facility, or may prevent continued certification of the site.

- a. The surveillance audit extends the quality system review from previous audits. Generally the surveillance audit will assess the continued implementation of GMP through review of subordinate procedures, records, and practices.
6. The audit is documented as directed in SOP 24.
  - a. The initial surveillance audit report contains only new observations in the Details Sections.

**STANDARD OPERATING PROCEDURE**  
**International Pharmaceutical Excipients Auditing, Inc.**

Title <b>The Surveillance Certification Audit</b>		Revision <b>0</b>	SOP Number <b>32</b>
Originator Irwin Silverstein	Approved By IPEA Management Committee	Date Approved <b>Oct. 12, 2011</b>	Page Page 3 of 3

- b. The surveillance audit report lists the findings from the prior audit report in the Executive Summary along with verification that the site corrective actions have been implemented.
  - c. The surveillance audit report adds new findings in the Executive Summary.
7. The draft surveillance audit report is review by IPEA Executive Management and is sent to the site and/or company representative for verification of factual accuracy. The company notifies the Lead Auditor of any factual errors or omissions. The company provides a Corrective Action plan for all findings noted in the Executive Summary within 30 days of receipt of the draft surveillance audit report.
  8. After addressing the comments from the site, the Lead Auditor forwards the completed Surveillance Certification Audit report and site Corrective Action plan to the IPEA office for filing.

Note: The Surveillance Certification Audit report is not released to pharmaceutical companies. The Certification Audit or Recertification Audit report, as applicable, is available for purchase.

**HISTORY OF REVISIONS**

<b>Revision No.</b>	<b>Effective Date</b>	<b>Description of Changes</b>
0	Oct. 12, 2011	New Procedure