Standard Operating Procedure

Title: External Audit Procedure

Department	Quality Management		Document no	QMS-155	
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Prepared by:		Date:		Supersedes:	
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1.0 DOCUMENT OWNER

Technical/Quality Manager

2.0 PURPOSE

This objective is to describe the method for regular audits of suppliers, distributors, service providers, and contract laboratories for the GMP manufacturing facility. The purpose of the procedure is to ensure that the suppliers comply with the current Code of GMP and/or other GMP Quality Standards and that action is taken to correct any deficiencies.

3.0 SCOPE

This SOP covers audits of:

3.1 Suppliers and distributors of printed packaging components, primary, secondary and tertiary packaging materials, raw materials, and bulk materials.

3.2 Service Providers for example but not limited to calibration services, documentation storage providers, sterilization services, and warehouses.

3.3 Contract Laboratories for example but not limited to those used to test raw materials, finished goods, intermediate products, microbiological samples, and validation samples.

3.4 This SOP does not cover audits for contract manufacturers or those suppliers that are under global purchase agreements.

4.0 RESPONSIBILITY

4.1 Supplier status shall be determined based on the audit rating of the scheduled audit conducted by the Quality Assurance Associate or delegate.

4.2 The Quality Manager has the responsibility of ensuring that the audit program is conducted to schedule and to the requirements of this SOP. Other unscheduled audits may be required to be added during the year either because they are proposed new sub-contractors / suppliers or due to quality problems that have arisen. This is at the discretion of the Quality Manager.

4.3 It is the responsibility of the Quality Assurance Associate or delegate to publish and manage external audit schedule.

4.4 Members of the Quality Assurance group together with other suitable GMP staff should conduct audits. One person on each audit team should have completed the GMP supplier auditor course. Other audit training and experience may be considered in lieu of this training. A list of auditors should be available in “Approved Site Auditors” list.

4.5 Maintenance of audit files is the responsibility of the Quality Assurance Associate or delegate.

4.6 New supplier, new materials from an already approved supplier, or new supplier-manufacturing site shall be assessed and approved by means of the following:

5.2.3 Send out audit agenda as specified below to the supplier. A template of the audit agenda, questionnaires etc. can be downloaded from www.gmpsop.com website. Vendor Audit questionnaire.

5.2.4 Confirm Audit agenda.

5.2.5 Collect pre audit questionnaire (to be sent back to site before the audit date).

5.2.6 Review Audit Guideline (provides a checklist of the area of focus).

5.2.7 Prepare document list (to request which documents are required to have ready on the date of the audit).

5.2.8 Review previous audit reports, noting findings and comments for review during the audit. Additional resources for preparing for the audit may include relevant standards, material test reports, registration documentation and supplier specifications, etc.

5.3 Conducting the Audit

5.3.1 Conduct the audit according to the guidelines as specified in "Site Quality Auditor Training Program Manual". Also refer to "Audit Open / Close meetings guideline".

5.3.2 Commence the audit with an opening meeting during which the audit method, scope, timetable, resources will be confirmed.

5.3.3 Note all observations and recommendations for reference at the closure meeting.

5.3.4 Discuss all action items that will be included in the audit report with the subcontractor / supplier / manufacturer management at the closing meeting.

5.3.4.1 Review observations with reference to internal GMP standards where applicable.

5.3.4.2 Agree on corrective action and time frames for closure of observations.

5.4 Audit Reporting

5.4.1 A supplier audit report shall be drafted by the auditor for Quality Manager 's approval and issued within 30 working days of the audit.

5.4.2 The audit report shall be written in a way that the body of the report is free from proprietary, speculative, or potentially controversial comments and stating only actual facts observed during the audit.

5.4.3 The audit report shall be written in accordance with the given format as indicated in Section

5.4.4. An agreed closure date from the audit closure meeting shall be entered in the audit report. If a closure date has not been established a closure date will be assigned based on the classification of the action, by the Lead Auditor.

5.4.4 The report format shall include, but not be limited to the following information:

a. Supplier name, address, type of operation, name of product or service supplied and principal contact;
b. Date of audit and date of last audit, if applicable;
c. Purpose of audit;
d. GMP auditor and audit participants;
e. Audit findings;
f. Supplier audit rating;
g. Executive Summary (for GMP use only); and
h. Recommendations for possible corrective actions for each finding.

extra manufacturing steps) may apply. A periodic re-evaluation of the supplier performance should be conducted.

III. **Unacceptable** - The materials or services specified cannot be purchased from the supplier.

5.4.13 Where the supplier audit rating is Conditionally Acceptable, the supplier is required to develop an action plan to address the action items in the report. The action plan should specify the actions that will be taken to address the ASC and major observations and have a timeline for completion. The action plan should be completed by the supplier and sent back to GMP Site within 30 days of the issue of the report.

5.4.14 When a Supplier Status or Supplier Audit Rating has been downgraded, within one (1) working day of the status change, The Lead Auditor shall notify the Quality Manager & Logistics-Procurement Manager.

In the event of the only available supplier receiving an Unacceptable Audit Rating, and no alternative exists other than to use that supplier, the following actions shall be completed to upgrade the Supplier Audit rating:

A corrective audit action plan shall be prepared by the supplier and submitted to and review and approved by Site Quality Team.

Upon completion of the items listed in this action plan, the supplier shall notify the Lead Auditor and a follow up audit shall be conducted, and;

After a successful follow up Supplier Audit, a new audit rating shall be assigned of either acceptable supplier or conditionally acceptable supplier.

5.5 Commitments and Corrective Actions

5.5.1 Raise all action items (ASC, Major and Minor) in GMP tracking system as an Action (child of the Event).

5.5.2 Supplier corrective actions require documented evidence of the completion of the action.

5.5.3 File report in a master file together with correspondence and the responses from the supplier.

5.6 Audit Follow-Up

5.6.1 All action plans shall be reviewed and approved by Lead Auditor and Quality Assurance Associate or delegate. All queries found shall be followed up with Supplier for clarification.

5.6.2 The Lead Auditor or delegate shall be following-up with Supplier on open action items on a regular basis to ensure close out of action items within the agreed timeframe.

5.6.3 When all the action items have been addressed according to the agreed action plan consult with the Quality Manager or delegate to determine if the audit can be closed.

5.6.4 Conditionally acceptable suppliers require a follow-up audit. Restrictions must be communicated to relevant personnel (Logistics, QO) to ensure that the supplier will only be used on a conditional basis.

5.6.5 When audit action items have been closed by the supplier written acknowledgement will be sent to the Supplier that the audit has been satisfactorily closed.

5.6.6 Close audit action items in GMP tracking system.

5.7 Reviews

Contravenes written instructions or procedures without proper justification or authority.

Allows process control loss so that the process outcome is not consistent or predictable.

Minor Action Item - Item observed is not yet serious but could become a problem if not corrected in a timely manner. Supplier Management follow-up is required to assure that a systematic problem does not exist.

Many minor deficiencies or the same type that could become a major deficiency.

