1.0 Purpose

The purpose of this procedure is to provide a process and documentation requirements for the effective, organized and structured conduct of internal audits.

2.0 Scope

This procedure applies to the internal audit of all systems that comprise Giles' Quality System. The internal audits will inspect actual practice against established policies, procedures and forms.

3.0 Responsibility

cGMP Coordinator is responsible for:

- Organizing the internal quality audit program including appointing a team to carry out each audit and verifying their independence of the area being audited.
- Ensuring that corrective actions are closed in a timely fashion, within determined close-out dates whenever possible.

Auditor/Audit Team is responsible for:

- Arranging a suitable time for the audit with the area manager.
- Reviewing area audit checklist and relevant quality procedures.
- Completing audit and audit report

Area Manager is responsible for:

- Cooperating with the audit team.
- Progress corrective actions to completeness.

4.0 Safety Considerations

Applicable safety requirements for each audit area will be observed.

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

5.0 Materials/Equipment

N/A

6.0 Procedure

- **Planning and Scheduling**

  The cGMP Coordinator or Designee is responsible for planning and scheduling internal audits using the *Internal Quality Audit Schedule (Q12-PR-100-F008a)*. Each main activity comprising the Quality System is audited at least once a year. In addition to the annually scheduled audits, the Quality Unit may select certain activities for more frequent auditing, depending on their status, importance and past compliance history. The audit schedule lists all the activities that allow an objective assessment of the Quality System and compliance to 21 CFR 211, identifies locations where these activities are taking place, and assigns an audit date to each activity/location.

- **Audit Team**

  Personnel assigned to carry out an audit should be independent of those having direct responsibility for the audited activity. When possible, a QA representative assisted by another trained auditor will conduct the audits. Training will be conducted by a certified ISO 9001 auditor. All team members must be accompanied by the certified ISO 9001 auditor during their first audit. Refresher training will be conducted annually. Personnel from other departments are also encouraged to familiarize themselves with auditing techniques and cGMP requirements so as to participate in the internal auditing program assisting auditors.

- **Preparation for Audit**

  The cGMP Coordinator or Designee will notify selected audit team members of their audit assignment using the *Internal Quality Audit Assignment* check sheet *(Q12-PR-100-foo8b)*. The *Internal Quality Audit Assignment* check sheet will be given to the lead auditor to complete.

  Auditors prepare for the audit by reviewing the appropriate *Internal Quality Checklist (Q12-PR-100-F008c-k), Quality Manual* and applicable regulations (21 CFR 210/211, 820, ICH Q7, Q10). Any findings from previous audits on the area will be reviewed so as to follow-up on any outstanding corrective actions or the effectiveness of implemented corrective actions.

  The lead auditor will contact the manager responsible for the area being audited at least one week in advance with the proposed audit date. The manager concerned is to respond with a confirmation or propose an alternative date.

- **Conducting the Audit**

  Using the *Internal Quality Checklist,* the auditors seek objective evidence demonstrating whether the audited activities comply with the requirements of the documented Quality System.

Findings, positive and negative, are recorded by the auditors during the audit on the audit checklist. The audit findings are to be discussed with the area representative to ensure the auditor and representative are in agreement with the auditor's findings.

When non-compliance is noted, it is to be brought to the attention of, and discussed with, the responsible manager. Before the end of an audit day, each noncompliance noted during the day is documented on the *Audit Non-compliance Report (Q12-PR-100-F008l)*. Auditors fill out only the first part of the form, describing the noted non-compliance. The form is then handed over to the responsible manager who completes the second part to propose a corrective action.

At the conclusion of the audit, the *Internal Quality Checklist, Audit Non-compliance Report* and *Internal Quality Audit Assignment* check sheet are to be turned into the cGMP Coordinator or Designee for review.

Audit assignments are issued at the beginning of the month and are scheduled to be completed within 30 days of their assignment. Based upon conflicts that may arise due to the work schedule of the auditor(s) and/or the area(s) to be audited, the due date of the audit may be extended up to two weeks.

- **Corrective Action and Follow-up**

A copy of the *Audit Non-compliance Report* will be forwarded to the responsible manager. The agreed corrective action implementation due date should take into account the severity (major, minor) of the non-compliance and the time needed to complete the corrective action. A standard target date should be within 1 month of the audit.

If the severity of the non-conformance is ranked *major*, then a CAPA Investigation will be initiated through the *Corrective and Preventative Action System (Q13-PR-100-014).*

The lead auditor will schedule a follow-up audit to confirm implementation and effectiveness of the corrective action. Findings will be noted on the bottom section of the *Audit Non-compliance Report.* In the event of the actions being incomplete, a new date will be agreed upon and the reason for incomplete actions noted.

The report/corrective action is closed only when the auditor is satisfied with their findings.

- **Effectiveness**

The following criteria shall be reviewed to determine the effectiveness of the internal audit system:

  - Time to complete the audit
  - Effectiveness of the audit (objective evidence)
  - Trends in findings

Internal Quality Audit documentation shall be filed by the Quality Unit in the cGMP library and retained for a period of four years.

7.0 Reference Documents

Internal Quality Audit Schedule (Q13-PR-100-F008a)
Internal Quality Audit Assignment Report (Q12-PR-100-F008b)
Internal Quality Audit Checklist (Q12-PR-100-F008c-k)
Audit Non-compliance Report (Q12-PR-100-F008l)

8.0 Change Information

New Document

Audit Life Cycle