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Title: <b>Self-Inspection Program</b>	Implementation Date:	Version Number 1.0

The Lead Auditor convenes the Self-Inspection Team.

#### **4.4 Audit Team**

The Audit team supports the Lead auditor during the Self-inspection preparation, performance, reporting and monitoring of follow-ups, based on the Lead Auditors needs.

#### **4.5 Auditee/Area Leader**

The Auditee/Area Leader ensures appropriate members of the department management team being available to accompany the Self-inspection team for the duration of the Self-inspection. The Area Leader is also responsible that sufficient resources are made available to support the Self-inspection preparation, performance and follow-up activities. The Auditee/Area Leader is responsible for the initiation and the implementation of corrective actions related to identified Self-inspection findings.

### **5. Procedure**

#### **5.1 General**

All activities, which may have impact on the quality, safety and efficacy of products manufactured and distributed from the site, will periodically undergo a Self-inspection.

The Self-inspection program ensures that regular inspections of all these areas and systems are conducted on an annual basis.

The Self-inspection schedule is issued beginning of every year and details the departments, the systems and the processes subjected to be audited as part of the yearly Self-inspection program. Planned Self-inspections which could not be carried out due to any circumstance as requested by the yearly self-inspection schedule must trigger a deviation with a detailed investigation why the planned inspection could not been done and a corrective action to assure the coverage of the missed audit subject.

All non-compliance observations will be tracked to ensure identified corrective actions are on track or completed.

Audits additional to the planned Self-Inspections, such as for-cause audits and pre-approval inspections may be added to the schedule during the year when required or on demanded.

The Lead Auditor and the Audit Team members must have received formal auditing training or have appropriate Audit experience within the GMP and GDP regulated industry.