1.0 Purpose

To provide the information needed to ensure that all deviations are documented and managed effectively. For compliance to cGMP (21 CFR 211.100(b) and 211.111) and the sake of continuous improvement, these deviations are recorded in the form of a *Deviation Report* (DR) *(Q13-PR-100-F024)*.

2.0 Scope

A Deviation is a non-permanent departure from approved quality procedures, policies, processes or where there have been unusual or unexplained events which have the potential to impact product quality, system integrity or personal safety. Deviation applies to a one-time, temporary event.

3.0 Responsibility

The Quality Unit is responsible for ensuring that all Deviation Reporting activities including, but not limited to, the recording, approval, monitoring and control are carried out in accordance with this procedure. When applicable, QA will oversee that deviations are fully investigated in a timely manner in order to determine root causes and the associated actions to prevent recurrence.

4.0 Safety Considerations

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

A deviation should be raised when there is a deviation from methods or controls specified in manufacturing documents, material control documents, standard operating procedures, and from the occurrence of an event and/or observation suggesting the existence of real or potential quality related problems.

6.1 Deviation Classification - Deviations are classified as either Planned or Un-planned and Major or Minor. A DR is to be used for recording all deviations.

- Planned – is a described and pre-approved deviation from current operational document/system, covering a temporary specified period of time or number of batches. Planned deviations shall be approved before execution.
- Un-planned – an unplanned or uncontrolled departure from the designed systems or procedures at any stage of manufacturing, packaging, testing, holding and storage.
- Major – a critical event that affects product quality which is addressed through an investigation and CAPA
- Minor – a non-critical event that does not affect product quality

6.2 Recording and Authorization of DR – the DR should be completed by area manager and/or process engineer (or designee) and submitted to the Quality Unit for approval.

In the case of a planned deviation, the DR must be approved by QA before execution.

In the case of an unplanned deviation, the Quality Unit must be notified immediately upon discovery of the unplanned deviation. QA will verify if the deviation is major or minor; if determined to be major, QA will oversee the conduct of an investigation and evaluate resulting corrective actions.

QA will assign Deviation Report #, evaluate the deviation, determine if an investigation is required, ensure the corrective actions are effective and close the deviation upon completion of all activities, preferably within 30 days. If a deviation cannot be completed within 30 days, an interim report should be generated detailing the reason for the delay and the progress to date. QA will note any trends relating to procedures, materials, equipment or testing processes from previous deviations.

Completed Deviation Reports that have been closed by the Quality Unit will be filed in the *Deviations Report* binder for the current year and then maintained in the cGMP Library for a period of 3 years.

7.0 Reference Documents

Deviation Report (DR) *(Q13-PR-100-F024)*

8.0 Change Information

New Document