Quality Assurance is responsible for ensuring that the deviation has been completed in accordance with all cGMP requirements and Quality guidelines and that the completed deviations do not impact product quality or data integrity.

5.0 PROCEDURE

5.1 Validation Deviations

A validation deviation is a planned or unplanned excursion from an expected result or approved procedure. When an actual result is different from the expected result or the procedure is changed from the authorised procedure whether planned or unplanned, or for any unexpected event, it is considered a deviation.

A critical deviation is a deviation as described above, which directly or indirectly results in compromise of the product, system or data integrity.

A non-critical deviation is a deviation as described above resulting from a misunderstanding of the requirement, function, or procedure, or an unexpected result or change to the procedure that does not impact the product, system or data integrity.

All deviations must be assessed to determine their impact on the following as required:

- Product, system and data quality and integrity
- Design, functional, or product specification
- Protocol(s)
- SOP's
- System documentation and Drawings
- Testing already completed
- Training programs
- User requirements
- Validation plan

Once the impact on these aspects have been determined, resolutions or justification shall be established and documented on a deviation form (for all deviations) and, for critical deviations, in a Quality Assurance Report – Deviation (QAR) (in addition to the deviation form.). Refer to appendix 1 for deviation form format.

A blank deviation form must be attached to each protocol and copied as required to record deviations. In general a separate form should be completed for each deviation, however related deviations may be grouped on one form. All completed deviation forms must be attached to the protocol.

A typographical error is not considered a deviation and may be hand corrected with an appropriate comment. All hand corrections to approved protocols must be counter signed by QA.

All completed deviation forms should be appended to the validation protocol. The deviation forms will be numbered sequentially and will be referenced in the protocol at the page where the unexpected result or change in procedure was recorded.

5.2 Types of Validation and Deviations

5.2.1 Process Validation

If a deviation occurs during process validation performed on a commercial batch, it must be assessed to determine if it is a critical or non-critical deviation as defined in

5.3.1.2 Test Script/Test Procedure Number:

The section of the protocol/procedure where the deviation occurred must be referenced in the deviation form for traceability back to the test.

5.3.1.3 Description of Deviation:

The description of the deviation concisely and clearly details the deviation from the protocol/procedure. There should be sufficient information in this section to allow the approvers a clear understanding of the actual results/requirements versus the required results/requirements. This section should not contain any information on resolution or justification of the failure. The person who raised the deviation must initial and date this section.

5.3.1.4 Type of Deviation (Critical/Non-Critical):

The type of deviation must be defined by circling the classification on the form. Define the type of deviation as per the definition in section 5.1. If the deviation requires a change control, QAR or commitment, the number should be referenced in this section.

5.3.1.5 Deviation Close Out

A deviation may be closed out by resolution and retesting, if required, or by justification for acceptance of the deviation:

5.3.1.5.1 Resolution:

The resolutions section should be completed only if the deviation has been resolved and should detail the resolution and any retesting required on the resolution. Any retesting should be attached to the deviation form.

The resolution section should indicate if the deviation resolution has been accepted and must be initial and dated by the person completing the deviation.

5.3.1.5.2 Justification for Acceptance of Deviation

If the deviation cannot be resolved or does not require resolution but is still considered acceptable a justification for acceptance of the deviation must be detailed in this section. The justification should be clear and concise and provide enough information to allow approvers a full understanding of the deviation and its acceptance including corrective actions. The justification section should indicate if the deviation has been accepted and must be signed by the person completing the deviation.

In general if resolved, a justification is not required and likewise if justified, resolution is not required. In some situations resolution is not required prior to release of the equipment/system/product e.g. a drawing update for equipment. In this case a justification for delaying the resolution must be documented. The commitment should be referenced in the deviation form and the validation report detailing the responsible person and timeline for resolution. If a change is required as a result of a deviation, the change control number should be reference on the deviation form.

5.3.1.6 Deviation Approval

All deviations must be approved by:

