5 Guideline

5.1 Reporting of individual deviations

There must be a local procedure to describe the steps to be followed to investigate and document deviations and to prevent premature batch release.

The local system must ensure that all deviations are adequately addressed according to the seriousness of the deviation and that the appropriate corrective and preventative actions are taken. The originating area and

Quality Assurance must agree the corrective and/or preventative actions. Deviations must be classified and investigated according to their seriousness as, Level 1, 2 and 3. Appendices 1 and 2 identify the minimum reporting requirements and the key steps in the lifecycle of a deviation.

For Level 1 deviations, the root cause must be identified wherever possible and a formal root cause analysis should be done if the root cause cannot be readily identified. If, following analysis, the root cause cannot be identified, the most probable root cause should be identified. The identified root cause, or the most probable root cause should be used as the basis for defining preventative actions to prevent recurrence.

For Level 1 and 2 deviations, a formal investigation should be performed and the root cause identified. Level 3 deviations are at minimum usually only documented in routine batch or test related documentation and records.

The process and timing in which agreement and approval are achieved may vary depending on the level of the deviation. The exact approach should be described in local procedures. For example, for a Level 3 deviation a retrospective review by QA in connection with batch release is acceptable. However, for a Level 1 deviation, corrective and preventative actions should be agreed with QA as soon as reasonably practicable after the incident.

5.1.1 Deviation Reporting

Electronic or paper records of all deviations must be kept, together with a record of the investigation (if applicable) and remedial action taken. The degree of documentation required may vary according to the level of the deviation. For example, minor deviations (Level 3) can be recorded in batch or other GMP documentation, whereas more significant deviations (Level 1 and 2) are usually recorded using a specific proforma. Batch related deviations must be referenced and/or filed with the relevant batch records.

The following minimum requirements must be included in the deviation documentation, as appropriate:

6.2 Appendix 2

Deviation Lifecycle