

Where a protocol error is identified, it is recommended that the deviation procedure makes a clear distinction between typographical and other minor errors where the intent of the protocol is still clear, and errors that require correction to allow the test to be executed. It is considered acceptable to hand-amend (per applicable site documentation practices) typographical and other minor errors that have no impact on the test method or acceptance criteria. Where correction is required to allow the test to be executed, including determining whether the test passes or fails, then a deviation should be raised.

### ***Document the deviation***

The deviation should be documented according to the applicable procedure or protocol. This should include assignment of a reference number to the deviation, the test section (and run number, where applicable), the test step (where applicable), a description of the deviation and the signature and date of the person recording the deviation.

Although errors may be grouped by type, repetitive protocol errors are the most practically grouped in this way. When deviations are grouped, care should be taken to ensure that the link between each individual issue identified, its investigation, and corrective actions is clear. In addition, all issues will need to be resolved (or transferred to a tracking system) to allow closure of the deviation.

### ***Investigation***

An investigation should be conducted to determine the root cause of the deviation. In many cases, this will not require any in-depth analysis. However, for system or process failures, a formal investigation including appropriate technical representatives may be required. Such a detailed investigation should be conducted according to applicable procedures.

The investigation may be used to identify the type of deviation; this can be documented descriptively on the form or by using check boxes. Examples of types of deviations could include:

- *System/Process Error* -An actual problem with the functionality of the system or a technical problem with the process, whereby the system or process does not meet the acceptance criteria when the test step is executed.
- *Protocol Error* -The test step instructions require addition, deletion, modification and/or clarification due to missing/incorrect/ambiguous test instructions. Or the acceptance criteria require addition, deletion, modification and/or clarification due to missing/incorrect/ambiguous acceptance criteria.
- *Other* -A deviation occurs that is not related to the test method, acceptance criteria or system, for example, operator error.

Protocol errors that require correction in order to allow the test to be executed as intended may include missing test instructions or incorrect acceptance criteria. In these cases, the