Writing Effective Test Scripts and Validation Protocols for the Bio/Pharmaceutical Industry

Definition of Test Script - **A test script is a document that contains a series of instructions to be performed to determine if the utility/system, equipment, or process functions as expected. It defines the actions to be performed, expected results, and the acceptance criteria.**

Definition of Validation Protocol - **A validation protocol is a document that is written, pre-approved, and then executed to confirm specific attributes of the installation, operation or performance of a utility/system, equipment or process. The confirmation occurs by observing, testing, and documenting actual results (which are recorded next to the pre-approved expected results).**

Simply put, a validation protocol may consist of several test scripts

Scripts may be written and used to confirm the following:

- Unit/Module Testing
- Integration Testing
- System Testing
- User Acceptance Testing

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Key Features of an Effective Test Script

1) Pre-requisites (i.e. required data, configuration)

2) Instructions or Reference (i.e. SOP) For Test Script Execution

3) Test Script Page
    a. Run # (if applicable)
    b. Location (if applicable)
    c. Environment (if applicable)
    d. Objective
    e. Acceptance Criteria
    f. Test Section
        i. Step #
        ii. Procedural Information
        iii. Expected Results
        iv. Actual Results
        v. Meets Expectations (Y/N)
    g. Comments Section
    h. Performed By Section
    i. Reviewer Section

4) Pre-approval Page (for stand-alone script)
    a. with at least 2, preferably 3 signatures
    b. one Quality Assurance signature

5) Overview Page (for stand-alone script)
    a. Environment (i.e. Development, Test or Production - for computer systems)

6) Signature Log (for stand-alone script)

7) Deviation Form (for stand-alone script)

8) Deviation Log (for stand-alone script)

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Key Features of Well-Written Test Scripts and Protocols

1. Written to confirm user requirements, functional and design specifications

2. Written with an audience's (tester's) skills and abilities in mind

3. Written so that test execution involves generating and attaching at least one printout demonstrating the success of the test.

4. **Written so that the test steps (procedural information) is clear, concise, and unambiguous**

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No-Nos For Test Scripts and Protocols

1. Those that have been executed prior to approval.

2. Those that are reviewed by the person that executed them. (They may be reviewed by your peer, your supervisor or a QA representative)

3. Those that are reviewed by the writer's subordinate. (They may be reviewed by your peer, your supervisor or a QA representative)

4. Failure to explain (document) why the actual result does not meet the expected result.
    a. There may be a typographical error in the test script
    b. There may be a script generation error – the test procedure does not work as written.
    c. There may be a script generation error – the expected result is incorrect.
    d. There may be a system error (script is correct, system does not work properly).

5. Failure to train testers how to record actual results (writing "as expected" adds no value)

6. Those that have typed in actual results and initials and date.

Two Examples For Compliant Test Script Pages Are Provided Below

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