- Validation scheduling plan (may be a separate document);
- Review or requalification period for systems / processes, where applicable

This may be documented as part of the validation strategy document, or separately.

Validation Planning

A validation planning document should be considered for use for larger scale projects that encompass multiple systems and processes. A planning document may be a separate document or combined with other documents such as testing or change control documents.

The planning document should contain, or at least reference, the following information, as applicable:

- A description of systems (e.g., system boundaries, system level impact assessments) and/or processes included in the project;
- The validation approach that will be followed;
- Key roles and responsibilities;
- Testing strategy;
- Project documentation requirements; and
- Sequence of activities and execution.

Testing Documentation

Documentation, such as protocols or test scripts, should be developed that specifies how the validation study will be conducted. Testing documentation should contain or reference the following information, as applicable:

- Title and unique identification number;
- References to related documents such as the validation planning document and SOPs;
- Objectives and scope of the study;
- Prerequisites (e.g. qualified equipment for process validation or Installation Qualification with no major deviations prior to Operational Qualification)
- Clear, precise definition, or reference to same, of the system or process to be validated, for example:
- Summary and/or process flow diagram of critical processing steps included in the study;
- The Master Manufacturing instructions or Device Master Record to be validated (i.e., that to be used in preparation of validation lots or batches);
- The critical process parameters (CPPs) for the process steps being validated;

- List of document modifications and test deviations.

All test results, along with any test deviations, should be recorded and documented in a manner permitting objective pass/fail decisions to be made, regarding the success or failure of the validation.

Actual values obtained should be stated and reported in appropriate significant figures (where applicable). Calculations should be shown, including application of rounding rules.

All fields of a test document should be completed. If a field is intentionally left blank, the field should be lined-out, initialed and dated and indicated as "Not Applicable" or "N/A".

Where appropriate, primary data should be placed in tables and/or plotted. Primary data and other attachments, including videotape and any type of electronic data storage medium, should follow good documentation practices. Attachments should be referenced in the relevant section of the test documentation.

The attachment itself should also be identified appropriately, for example, by protocol or report section, test number or attachment number. It is recommended that where there are multiple pages/items within an attachment that the number submitted is also recorded in the test documentation and/or on the attachment.

When transforming or plotting data, an individual other than the executor should verify the accuracy of the data transcribed. For data that is plotted, a printout of the data tables from the software used to generate the plot should be attached to the report. The data table printout may be signed instead of the graph.

The results of the test execution should be reviewed by QA and the system owner, at minimum, typically as part of the validation report.

Validation Reporting

Reports should describe the results from the planning and testing and should be approved by QA and the process/system owner, at minimum. The content of the report should include, or reference, the following:

- The planning or test document, including scope;
- Summary of the results obtained;
- Analysis of the results, where appropriate. For a process, this may include:
- Review of critical process parameters from validation batch/lot production records;
- Comparison with previously produced batches (commercial, development, or biobatches), where applicable;
- Summary and resolution of any manufacturing, laboratory or testing deviations observed;
- Report conclusions, including clear statement of validation status of system/process; for example:

