

- 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;