

- ___ Regulatory Process Description
- ___ Process Flow Diagrams
- ___ Equipment List
- ___ Bill of Material
- ___ Master Batch Records or Manufacturing Instructions
- ___ Cleaning Procedures or Instructions
- ___ Raw Material Specifications (where appropriate)
- ___ Intermediate Specifications (where appropriate)
- ___ Product Specifications
- ___ In-process testing methods and limits
- ___ Cleaning Agents used, including solubility data.
- ___ Qualification and Validation Documents specific to the transferred process
- ___ Change History for the process
- ___ Access to Regulatory Documents
- ___ Analytical Methods
- ___ Stability Requirements
- ___ EH&S requirements
- ___ Critical Quality Attributes and Critical Process Parameters
- ___ Annual Product Review reports
- ___ Cleaning Evaluation Reports (inc. appropriate limits and cleaning methods)

Where information suggested in this guidance is not available to provide to the receiving site, an evaluation should be performed to determine the significance of the missing information. This may be more common with older processes. If the information that is not available is considered to be critical to the technology transfer, then it is recommended that the necessary data be generated/obtained.

Depending upon the type of missing information, some tech transfer activities may be able to proceed in parallel with the collection/generation of the missing information. If the information is determined to not be critical, then the tech transfer may be able to proceed without obtaining it.

Considerations for System Validation (e.g. Equipment, Facilities, Utilities, Automation, Computers)

Considerations related to Systems Validation may include:

- ___ A documented risk analysis should be performed comparing the requirements of the transferred process with the existing systems such as facilities and equipment. Validation requirements for systems such as facility modifications, qualification of new equipment, or equipment transferred from the originating facility can be outlined in a revision to the existing facility validation master plan, or in a Tech Transfer Validation Project Plan.
- ___ A System and Component level impact assessment, if necessary, to determine Direct Impact Systems and Critical Components that may require qualification as a result of the incoming process.