__ 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.

__ Visually detectable quantities, if available.
__ Suitability of cleaning agents to surface finish.
__ Relevant information regarding the materials of construction of product contact surfaces from which the transferred product has been cleaned previously, including surfaces that are more problematic than others to clean.
__ Evaluation of cleaning limits for the transferred product at the receiving site against existing cleaning limits matrices for receiving site, if applicable
__ Information on cleaning deviations related to the cleaning process and resulting investigations at sending site, if relevant to the cleaning procedure used at the receiving site.
__ Cleaning Process change control reports / documentation, if relevant to receiving site
__ Whether cleaning validation for Biopharma products will occur prior to, or concurrently with process validation batches.

Analytical Method Qualification and / or Validation Considerations:
When transferring analytical sampling and test methods, it should be determined what the analytical method is utilised for (e.g. quality of product, EHS purposes, etc.), as well as the current validation status.

Some methods (e.g. related to operational efficiency only) may not require validation. One can then prioritise which methods may require a more formalised analytical transfer and/or validation. A comparison of the originating and receiving laboratory instruments and capabilities would likely need to be performed.

The following information should be provided to the receiving site:
__ The analytical sampling and test method, including description of method, reagents and instrumentation used at the sending site laboratory.
__ Method development and validation documentation and reports. If methods require validation and there is no validation documentation available, or the method was not originally validated to current standards, the method may need to be revalidated.
__ Information about critical analytical method parameters and / or procedural steps, deviations related to the method, and resulting investigations at the sending site.
__ Procedures to prepare analytical standards that are not readily available, for example, API Impurities or Intermediates.
__ Microbiological method validation (e.g. Endotoxin, Bioburden) if applicable.

Process Validation Considerations:
Processes used in the manufacture of API or Drug Product require validation. The timing and strategy for validating the process at the receiving facility will typically be influenced by the following factors:

__ Prerequisite activities such as facility, equipment, and system qualification, cleaning validation strategy and analytical method validation requirements.

__ When required information is contained in other GMP documents (e.g. site Validation Master Plan, SOPs, etc) it does not have to be repeated in the VP. The other documents may simply be referenced in the relevant section of the VP. Where additional detail specific to the project is required, this information should be discussed in the VP.
__ Confirmation that critical inter-related systems at the receiving site, such as utilities, environmental control systems, equipment, etc are qualified, or are identified as requiring qualification or validation.
__ Schedule of critical validation activities, which may be by reference to a separate document, plan, or schedule
__ The sequence of validation of different systems and processes, along with any interdependencies should also be outlined. If some activities must be completed before a given validation can be initiated these should be identified.
__ Reference to programs that support validation and qualification activities, such as: change control, SOPs, document retention, calibration, preventative maintenance, periodic review and training.
__ The VP should specify what activities may be needed outside of the normal quality systems that are specific to support a given tech transfer validation. For example, if special training is required to execute a given tech transfer validation, this may be specified in the plan.
__ Related document references, such as procedures, the site Validation Master Plan and/or guidelines used in the validation and qualification activities of the technology transfer.

Validation Project Plan Report

Upon successful completion of the validation and on approval of the supporting validation reports, a Validation Project report may be written and approved by the signatories of the plan (or their designee).

This report summarises conclusions from:

__ Process validation batches and references the process validation report.
__ Systems Qualification and respective report references
__ Cleaning Validation Strategy as outlined in the protocol
__ Analytical Method Qualification and / or Validation and reference to the reports

The report should also state whether or not the process is acceptable for regulatory submission and commercialisation.

