Summary - Validation Activities during Technology Transfers

Technology transfers of existing APIs or DP processes to a different site often involve a change in registration documentation for the product, to include the new location. This will likely prompt a regulatory inspection at the receiving site and/or regulatory scrutiny (e.g. of analytical methods, critical process parameters, etc) of the registration documents. Therefore, validation requirements for production and support systems at the receiving site should be considered at an early stage of the technology transfer process. The Site Validation Master Plan should also be updated accordingly.

- Regulatory Process Description
- Process Flow Diagrams
- Product Specifications
- In-process testing methods and limits
- Qualification and Validation Documents specific to the transferred process
- Change History for the process
- Analytical Methods
- Stability Requirements
- Critical Quality Attributes and Critical Process Parameters
- Annual Product Review reports
- Cleaning Evaluation Reports (inc. appropriate limits and cleaning methods)

Multi-product facilities may consider the potential benefits of single use consumables to reduce the burden of cleaning and the risk of cross contamination. This may be especially relevant for products manufactured using Biopharmaceutical and classical fermentation processes. The receiving site should perform an assessment to determine what equipment may be dedicated and what will be designated for multi-product use.

Providing the documentation of key information relating to the process is fundamentally important to the successful transfer of the process. In addition to the documents provided as part of the knowledge information package, the following list of documents and considerations are typically needed for the receiving site to successfully validate the incoming process:

- Existing Regulatory documents, including Annual Product reviews and change supplements.

- Raw material, reagents, solvents, Intermediate and Final product specifications. The validation impact (if any) of changes in raw material suppliers. For example, if a critical drug product raw material such as the API is changed, this may prompt revalidation of the DP process.

Read More