Packaging Process Documentation Transfer for Drug Products

Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion
This document provides document on the transfer of documents during the activities that take place as a result of the Technology Transfer for approved commercial packaged Drug Product (DP) processes.

It also provides document on what documentation needs to be considered as part of the packaging transfer process activities within a GMP site. A list of information to consider as part of the packaging transfer knowledge information package is included in the example. If the documentation received from the sending site is robust and complete, it may allow the receiving site to leverage the qualification and validation strategy from the sending site.

A Packaging technology transfer of an existing DP packaging presentation to a different site often involves a change in registration documentation for the product, to include the new location. Therefore, validation requirements for packaging and support systems at the receiving site should be considered at an early stage of the packaging technology transfer process. The Site Validation Master Plan should also be updated accordingly. Validation requirements for processes, cleaning, analytical methods, and systems (equipment, facilities, utilities etc) should be documented in Site Quality Standards.

Once the project transfer team is in place, the success of the transfer process will depend on how effectively and successfully the knowledge and documentation is transferred between the sending and receiving sites. The knowledge information to be transferred will depend in part on the complexity of the process that is being transferred. Refer to following example for a list of the information that is recommended to be compiled by the sending facility during the packaging transfer. The application of the list needs to be conducted on a case by case assessment of the process to be transferred.

Where information suggested in this document is not available to provide to the receiving site, an evaluation should be performed to determine the significance of the information gaps. This situation 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 or obtained. Depending upon the nature of unavailable information, it may be possible for some technology transfer activities to proceed in parallel with the collection or generation of the unavailable information. If the information is determined to not be critical, then the technology transfer may be able to proceed without obtaining it.

When only the packaging process is transferred, the documentation from the sending site should be focused mostly on product quality documentation and product history. When the packaging equipment is also included as part of the transfer, the documentation to be transferred will include equipment documentation such as calibration, qualification, cleaning certificates, SOPs, maintenance logs, etc.

The documentation received will be used to define the qualification and validation strategy to be followed by applying a scientific risked-based approach. As an example of how important it is to receive a complete package, refer to the following example:

Example:

