Summary - Packaging Process Documentation Transfer for Drug Products

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.

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.

Evaluate if the qualification documentation provided by the sending site will meet site requirements. If not, the receiving site can develop a plan to address the missing information. If documentation is acceptable then evaluate if any additional testing is required from an operation range stand point. If an operational range needs to be extended then OQ testing will be required. If the product and process requirements are satisfied no additional OQ testing is required.

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