Validation : Packaging Operations

- US-FDA and EMEA Regulatory compliance
 - 'equipment must be suitable for its intended use'.
 - need to validate packaging machines / their various component
- Validation process: technically complex, time consuming, costly

Key Elements :

- Qualification of equipments: all relevant sub-systems are thoroughly tested and documented to provide the information that is essential for successful validation.
- Validation of a Product Packaging operation
- PQ: verification of facility, utilities, equipment performance, components, trained personnel and processes
 - Evaluation of variance & Assessment of impact on Critical Product Quality attributes
- Cleaning validation : Part of Packaging Validation

Pharmaceutical Packaging Validation

PT Brinkman

Pharmaceutical Packaging Validation:

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