

PACKAGING VALIDATION PROCESS

1. Drafting a Validation Plan

2. Installation Qualification

3. Operational Qualification

4. Performance Qualification

5. Drafting Validation Report

6. Formal Validation Approval

7. Process Control and Monitoring

8. Process Changes and Revalidation

PACKAGING VALIDATION REPORT

1. Validation Plan

- Type of Validation
- Location
- Responsibility
- Packaging Device Descriptions
- Material Descriptions
- Sterilization Process (if applicable)
- Qualification Steps
- Plan approval

2. Installation qualification

- Qualification Details: Place/Time/Product
- Packaging Device Details
- Installation Condition(s)
- Calibration Schedule
- Safety Features (if applicable)
- Operation Work Instruction
- Critical Process Parameters (temperature/Pressure/Time/Speed)
- Maintenance Schedule and Procedure
- Training
- Validation Conclusions

3. Operational Qualification

- Qualification Details: Place/Time/Product
- Batch number and Batch Size
- Critical Process Parameters and Control Limits
- Sampling Plan and Rationale
- Process Outputs (Product specifications)
- Validation Conclusions

4. Performance Qualifications

- Qualification Details: Place/Time/Product
- Batch number and Batch Size
- Critical Process Parameters (Medium or Average Value)
- Sampling Plan and Rationale
- Process Output Results
- Validation Conclusions