



Package Integrity Readiness Checklist

This checklist helps engineers and quality professionals evaluate the readiness of medical device packaging for validation and routine production. Based on best practices from Life Science Outsourcing (LSO).

Checklist Items

- ✓ Verify seal design and uniformity across all package types.
- ✓ Conduct visual inspection of all sealed packages for defects or anomalies.
- ✓ Perform concurrent testing using multiple methods (e.g., dye penetration, bubble leak).
- ✓ Ensure comprehensive validation documentation is maintained through revalidations over time.
- ✓ Review test selection and confirm each method's applicability to your specific packaging materials.
- ✓ Confirm alignment with applicable standards such as ISO 11607-1/2 and ASTM F2096.
- ✓ Maintain process controls for sealing, packaging, and sterilization to ensure repeatability.
- ✓ Review recent validation and quality records to confirm ongoing compliance.
- ✓ Establish corrective action procedures for any detected packaging integrity issues.
- ✓ Schedule periodic reviews of packaging validation strategy and equipment calibration status.

For consultation or validation plan review, contact LSO's Medical Package Testing Team. Regular use of this checklist helps prevent failures, maintain compliance, and ensure patient safety.