Medistri

Providing Sterilisation & Laboratory Services for the World's Most Innovative Healthcare Companies.

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# Medistri’s Packaging Validation - Medistri

## 🚀 Medistri’s Packaging Validation

The validation of packaging stems from the need to ensure the quality of products across the many steps in your distribution cycle: from shipping to storage. It is indeed an increasingly common requirement for many product categories, including a strong emphasis on the packaging quality requirements for medical and pharmaceutical industries.

Packaging validation is a process in quality assurance used to ensure that a product's packaging can consistently protect and maintain its integrity, safety, and efficacy from production through to its final use. This is especially important in the pharmaceutical and medical devices industry, where packaging must meet regulatory standards to prevent contamination, degradation, or damage during shipping, storage, and handling.

Packaging Validation for medical devices & pharmaceutical goods is segmented into three categories:

1. Environmental Conditioning.
2. Transport Simulation (also known as Transit Testing).
3. Integrity Testing (also known as Sterile Barrier Integrity Testing).

Once you’ve performed the first two test categories, we finish the packaging validation process with Sterile Barrier Integrity Testing in our laboratory. This last series of tests allows you to ensure that your packaging’s sterile barrier has not been compromised during the previous tests.

Medistri’s packaging validation ensures that your products are protected to the highest standards, meeting strict regulatory requirements and enduring real-world conditions to prevent contamination and damage.

This thorough process supports compliance, reduces risks, and strengthens customer trust. Here are some of the advantages:

- Shortened packaged development time and confidence in product launch.
- Protection of products and profits with reduced damage and product loss.
- Increase customer satisfaction.

ISO 11607-1 specifies the requirements related to the compliance of the packaging for sterilised medical devices, including materials, sterile barrier systems and packaging systems.

- Sterile barrier system: “The minimum packaging that prevents the entry of microorganisms and allows the sterile presentation of the product in the place of use”.
- Protective packaging: “A material configuration designed to prevent damage to the sterile barrier system and its contents from the time they are assembled until they are used”.
- Packaging: “A combination of the sterile barrier system and the protective packaging".

Should you fully validate your packaging system or should you simply test one particular characteristic of your sterile barrier system, Medistri laboratory is accredited and highly experienced for the most common test method provided in ISO 11607-1.

🎯 To learn more about Medistri’s Packaging Validation Services, visit on our website here or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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