

## From the Blog

### Packaging Validation

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As medical devices and pharmaceutical products move toward market entry, packaging is no longer assessed as a logistical element alone. For products placed on the market as sterile, packaging becomes a regulated system that must be validated to demonstrate that sterility, integrity, and product safety are maintained until the point of use.

Packaging validation provides objective evidence that the selected packaging system performs as intended under defined and reproducible conditions. Without this evidence, sterile claims, shelf-life justifications, and product release at the Go-to-Market stage cannot be sustained.

#### Why Packaging Validation Matters at Market Entry

At market entry, manufacturers are expected to demonstrate that packaging performance goes beyond design intent. The packaging system must be proven capable of maintaining its protective and sterile function after exposure to environmental and mechanical stresses representative of real-world distribution and handling.

Packaging validation is therefore directly linked to regulatory approval and sterile labeling. It forms a critical component of the technical documentation reviewed during conformity assessments, audits, and inspections.

#### Regulatory Framework: ISO 11607

Packaging validation for terminally sterilized medical devices is governed by ISO 11607. This standard defines requirements for packaging systems, including sterile barrier systems and protective packaging, and establishes expectations for validation and routine control.

ISO 11607 requires manufacturers to demonstrate that the packaging system is fit for its intended use and capable of maintaining sterility throughout the product lifecycle, from sterilization through to the point of use.

#### Medistri's Go-to-Market Approach to Packaging Validation

At Medistri, packaging validation is treated as an integral component of the Go-to-Market pathway. Our laboratory supports manufacturers with accredited testing methods aligned with ISO 11607 and validation strategies designed to integrate packaging, sterilization, and shelf-life considerations.

By structuring validation activities and documentation in line with regulatory expectations, we support efficient market entry while reducing the risk of late-stage findings or rework.

To learn more about Medistri's Packaging Validation Services, please visit our website [here](#) or contact us at [contact@medistri.com](mailto:contact@medistri.com).

– The Medistri Team

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#### A Structured Validation Approach

Packaging validation follows a structured sequence designed to simulate real-world distribution and storage conditions. Environmental conditioning exposes the packaging system to defined temperature and humidity ranges representative of storage and transport environments. Transport simulation then applies mechanical stresses reflecting handling, shipping, and distribution scenarios.

Once these steps have been completed, sterile barrier integrity testing is performed to confirm that the packaging system has not been compromised. This final verification step is essential, as it demonstrates that sterility has been maintained despite cumulative stresses applied during validation.

This approach is typically structured around three complementary activities:

- Environmental conditioning
- Transport simulation
- Sterile barrier integrity testing

#### What Packaging Validation Demonstrates

A completed packaging validation provides documented and traceable evidence that the packaging system consistently maintains its protective and sterile function. At the Go-to-Market stage, this evidence supports sterile claims, shelf-life justifications, and regulatory submissions.

From a regulatory perspective, packaging validation demonstrates:  
Control over packaging-related risks  
Consistency of packaging performance under defined conditions