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From the Blog

Packaging Validation

September 7th 2026

Before a sterile medical device can be placed on the market, its packaging system must be validated under conditions representative of sterilization, storage, transport, and handling.

A packaging validation strategy defines how this evidence will be generated. At the Go-to-Market stage, this means identifying the configurations to be tested, the conditions to be simulated, and the methods required to demonstrate that the sterile barrier remains intact.

Defining the Validation Strategy
Packaging validation should reflect the final product and the conditions it will encounter throughout its intended lifecycle. The strategy may consider the packaging materials and configuration, product characteristics, sealing process, sterilization method, distribution conditions, and claimed shelf life.

These parameters define the conditions under which the packaging system must perform and provide the basis for selecting the appropriate validation activities.

Selecting Representative Configurations
Medical devices may be available in several sizes, weights, or packaging configurations. A validation strategy must therefore define which configurations will be included in testing.

Where representative or worst-case configurations are used, their selection should be justified based on the characteristics that may affect packaging performance. Product weight and dimensions, packaging geometry, material combinations, seal characteristics, and sensitivity to mechanical stresses can all influence this assessment.

Preparing for Market Entry
Packaging validation generates part of the technical evidence required to support a sterile medical device at market entry. For an efficient Go-to-Market pathway, packaging activities should be planned alongside sterilization validation and shelf-life studies. Aligning these activities early helps define testing requirements, establish appropriate configurations, and avoid additional validation work late in the development process.

The resulting documentation provides traceable evidence that the packaging system has been evaluated under defined conditions and is suitable for its intended use.

Packaging Validation at Medistri
Medistri supports packaging validation programs for medical devices and pharmaceuticals. Our teams work with manufacturers to define testing strategies according to the product, packaging system, sterilization process, and intended distribution conditions, generating the documentation required to support Go-to-Market activities.

To learn more about Medistri's Packaging Validation Services, visit our website here or contact us at contact@medistri.com.

– The Medistri Team

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Environmental and Distribution Conditions
Packaging systems are exposed to different stresses before reaching the point of use. Temperature and humidity variations, vibration, compression, impact, and handling can affect both the packaging and the sterile barrier.

Environmental conditioning is used to expose packaged products to defined climatic conditions. Transport simulation then reproduces mechanical stresses associated with the intended distribution cycle. The conditions applied should be selected according to the product, packaging configuration, and expected distribution environment.

Sterile Barrier Integrity
Following conditioning and transport simulation, the packaging system is tested to confirm that its required characteristics have been maintained. Depending on the packaging system, testing may include seal strength, package integrity, and methods used to identify channels, leaks, or other defects.

The results provide documented evidence of packaging performance after the stresses defined in the validation protocol.

Packaging and Shelf Life
The packaging system must also maintain its required performance throughout the claimed shelf life of the product. Aging studies can be incorporated into the validation strategy to evaluate packaging performance over time. Accelerated aging may be used to generate supporting data within shorter development timelines, while real-time aging continues under defined storage conditions.