

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

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## Packaging Optimisation for Sterilisation - Medistri

### Packaging Optimisation for Sterilisation

The design of a medical device's packaging is a critical component that should be addressed during the early stages of the product's development phase. Packaging plays a vital role not only in maintaining the sterility of the medical device but also in ensuring its safe delivery from the manufacturing process to the point of use with patients. This makes it essential to consider packaging as a priority from the outset.

Neglecting the packaging design during the initial phases of development can lead to significant and costly challenges later on. For example, delays during the Sterilisation Validation stage are common when packaging requirements are not addressed early. Additionally, last-minute adjustments to packaging can result in increased costs, extended timelines, and unforeseen bottlenecks in the production process. To avoid these issues, manufacturers should integrate packaging considerations into their product development strategy. This proactive approach ensures smoother operations, better resource management, and a more efficient path to market.

To develop effective and compliant packaging for medical devices, the following factors must be taken into account:

1. The packaging must provide a robust and durable barrier to protect the medical device throughout its lifecycle, from manufacturing to final use.
2. Optimising packaging costs without compromising quality is essential to maintaining overall product affordability.
3. Packaging should be intuitive and user-friendly for healthcare professionals, ensuring ease of use in critical settings.
4. Packaging must meet stringent regulatory requirements for each market where the medical device will be distributed.
5. Packaging materials and design should facilitate efficient sterilisation processes, reducing potential complications during validation.
6. Packaging must ensure product quality across all stages of the distribution cycle, including shipping and storage. This involves testing for strength and integrity to meet the demands of the medical and pharmaceutical industries.

Once the packaging design is finalised, the next step is to ensure that it can withstand the rigours of real-world use.

Packaging validation involves a series of comprehensive tests to confirm that the packaging is fit for the purpose, compliant with regulatory standards, and capable of maintaining the integrity of its contents throughout the distribution cycle. This seamless transition ensures that the design phase flows naturally into a robust validation process, safeguarding both the product and the end user.

Medistri offers comprehensive validation services to ensure your packaging meets the highest standards of quality and compliance. Key standards include:

- **ISTA Packaging Standards:** Developed by the International Safe Transport Association, these standards focus on the expectations of safe transport services and provide protocols for packaging validation.
- **ASTM Packaging Standards:** These internationally recognized guidelines cover packaging quality and testing requirements, developed through collaboration between consumers, manufacturers, and scientists from over 140 countries.

Medistri performs a full range of packaging tests, including:

- Transport Simulation Testing.
- Atmospheric Preconditioning and Conditioning.
- Mechanical Handling Tests (e.g., Compression, Impact, and Vibration Tests).
- Sterile Barrier System Integrity Testing (e.g., Accelerated Ageing, Dye Migration, and Burst Tests).

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, visit our website [here](#) or directly contact our team at [contact@medistri.swiss](mailto:contact@medistri.swiss).

- The Medistri Team

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