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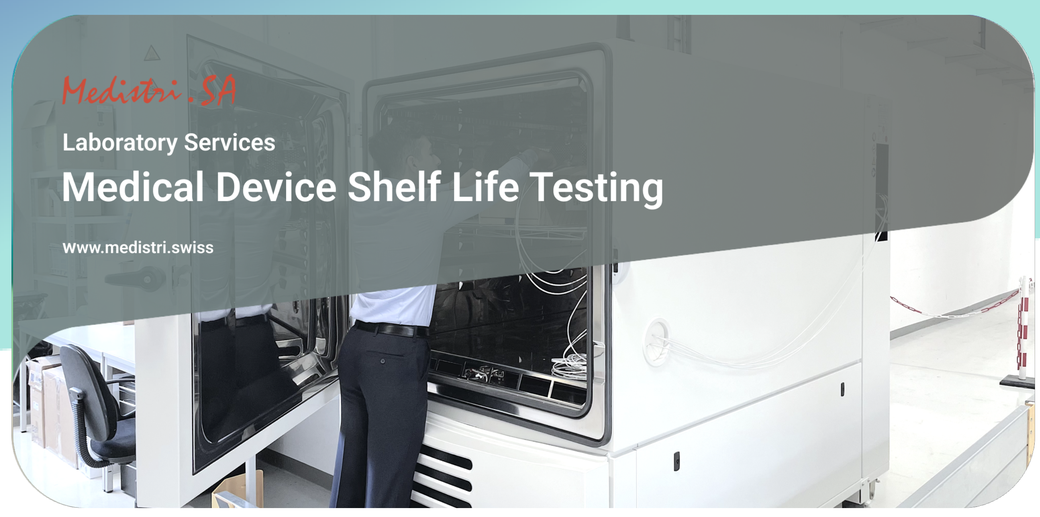

Medical Device Shelf Life Testing - Medistri

🚀 Medical Device Shelf Life Testing

Medical devices are labeled with an expiration date that is supported by testing shelf-life data. Medical device manufacturers wishing to gather data on the shelf life of their products may subject their devices to long-term stability studies or accelerated aging studies. There are many different endpoints that can be used to assess the shelf life of a medical device, including sterility or package integrity, so it is important that endpoints and test methodology are decided upon before testing is begun.

Establishing the right shelf-life study for your medical device is a complex projects that involves different types of tests.The United States Pharmacopoeia (USP) defines shelf life as “the extent to which a product retains, within specified limits and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of manufacture.”

It is the duration in which a product’s characteristics can be expected to remain stable. It is important to separate “shelf-life” from a product’s “useful life”. “Shelf-Life” describes a stability expectancy prior to use. The “Useful-Life” is the duration of a product’s viability during the time of use or the number of uses.

Medistri performs accelerated aging while performing real-time aging tests to generate shelf-life data for medical device manufacturers. This data is used in the product’s design-history files, technical dossiers and 510(k) submissions.

Accelerated ageing tests are essential in determining the expected lifespan of materials and products in a shorter period of time. These tests are conducted to simulate the natural ageing process under extreme conditions, such as high temperature and humidity, to predict the performance and durability of the materials and products.

Accelerated ageing tests according to ASTM F1908 are essential in assessing the performance and durability of materials and products. These tests provide valuable data that can be used to predict the lifespan of products and ensure that they meet the required standards.

✔ By conducting these tests, manufacturers can develop high-quality products that meet the needs and expectations of their customers.

Real-Time Ageing Tests are a great way to test the durability of a product. They can also be used to test how quickly an object will deteriorate, or even how long it takes for certain chemicals to break down. It's important that you follow all safety precautions when performing a real-time ageing test.

Real-time ageing tests are a type of accelerated weathering test. They use light sources and other equipment to simulate the effects of natural weathering on your product over time.The purpose of these tests is to determine how well your product will hold up in real-world conditions, so it can be sold with confidence as it its defined quality and usability features.

Real-time ageing tests provide an instant result which allows you to make quick decisions about your product's shelf life or suitability for sale. This means that you can avoid selling products that will soon become unusable or dangerous for consumers.

ISO 11607-1 and ISO 11607-2 are standards that outline the requirements for medical device packaging and shelf life testing.

ISO 11607-1 specifies requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems, and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use. It establishes the requirements and methods for testing the sterile barrier systems and packaging systems, to ensure they remain terminally sterilized from factory to end user.

ISO 11607-2 specifies requirements for the development and validation of processes for packaging medical devices that are terminally sterilized. It outlines validation requirements for forming, sealing, and assembly processes.

These processes are crucial to ensure that sterile barrier system integrity can be maintained until opened by the users of sterile medical devices. It sets out the process requirements on a manufacturer when creating a sterile barrier system for their medical devices.

At Medistri, we can help preventing any adverse health effects or damage that may occur due to the use of expired devices through shelf life testing, guaranteing the safety and efficacy of medical devices and, ultimately, ensuring that medical devices' quality remains intact and patients are protected.

🎯 To learn more about Medistri’s Medical Device Shelf Life Testing, visit on our website here or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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