

Establishing Shelf Life of Medical Devices

Introduction

The FDA defines shelf life as the term or period during which a device remains suitable for its intended use. Fitness for use can be impacted by both maintaining sterility of the package and the performance characteristics of the device. There are many naturally occurring events that can impact how long a manufactured device maintains its fitness for use. An expiration date identifies the end of shelf life. It is important to understand that the stability of the sterile barrier as well as the stability of the product itself both impact shelf life and should be tested separately.



Shelf Life Defined

The United States Pharmacopoeia (USP) defines shelf life (i.e. stability) 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 important to note that a medical device’s “shelf life” is not the same as its “useful life,” as the latter refers to the duration of actual use.

Assessing Risk

Shelf life is a concept that needs to be integrated into the product development process. A risk-based approach should be used to determine the potential impact for using a device that may no longer be fit for use. Some devices will experience degradation over time and the risk of that degradation to the device's fitness for use must be assessed when determining specifications and tolerances for manufacturing and components.

Variables to Consider

There are many things that can influence the shelf life of a medical device. While the FDA does not have specific requirements it does recommend categories of factors that should be considered. These include:

Storage Conditions. This includes the impact of temperature, humidity, air pressure, air-borne contamination, visible light and radiation.

Intended Use. Some medical devices use materials that degrade over time because the intended use of the device justifies their selection.

Components. Some devices contain components that may have unique expiration features, such as batteries.

Method of Manufacture. Manufacturing processes may introduce variables that impact the shelf life of the device.

Packaging. Some devices are affected by contact with its packaging and different



packaging concepts may impact devices differently.

Transportation. Shipping stresses including shock, vibration, and temperature.

Sterilization. The affect of the sterilization method on both the package and the device.

A Procedure for Testing Shelf Life

A written procedure for establishing a shelf life is needed to avoid mistakes and to provide design documentation. A good procedure should include the following sections:

1. A description of organizational responsibilities for the phases of shelf life testing.
2. A finished device sampling plan including the number of finished devices collected, frequency of sampling, sample selection criteria, and lots to be sampled.
3. Raw material component and packaging evaluation plan that determines how raw materials and packaging impacts the shelf life of the device.
4. A plan for the storage of shelf life samples including storage conditions.
5. Accelerated aging parameters with results supported by real time testing.
6. A plan for the simulation of shipping stresses.
7. Follow-up procedures that outline the steps taken as a result of the shelf life testing. For example, setting limits on the time sensitive raw materials can be stored and methods of stock rotation.

Testing Requirements

Shelf life is impacted by both internal and external events. Internal events include degradation of the device itself due to component interactions. External events include shipping and storage events that can impact its fitness for use including breakage and damage to the sterile barrier system.

Sterile Barrier System

A stability study must be conducted on the sterile barrier system. Samples (without product as long as the product does not interact with the sterile barrier system over time) typically undergo both accelerated and real-time testing to establish the shelf life of the seal. Accelerated testing is allowed for market launch but must be followed up by real-time data. Both accelerated and real-time aging should be done on packages that have undergone worst case sterilization. The sterile barrier system is tested for integrity and strength. Integrity is typically done with a visual inspection of the seal as well as a dye test. Strength of the seal is tested with a tensile test.

The Product

The stability of the product is determined by its fitness for use as determined by the design engineers. Product testing can take many avenues including material strength testing as well as visual inspection and functional testing. The product stability tests should be conducted on packaged product that underwent worst case sterilization and simulated distribution.

The Testing Strategy

J-Pac recommends that stability studies for devices be conducted separately from SBS



stability studies. There are several reasons for this position:

- Initially, most stability studies are conducted on an accelerated aging basis. The temperatures that are appropriate for SBS materials may not be applicable to device materials. For example, an adhesive coated Tyvek lid sealed to a thermoformed PETG Tray can be safely subjected to an accelerated aging temperature of 55C. This elevated temperature may not be acceptable for the device materials that are packaged in the tray/lid. An aging temperature of 55C may cause unacceptable changes to the device materials that it would not be exposed to in normal distribution. This jeopardizes the otherwise successful stability study on the SBS.
- When devices are included with the SBS during stability studies, they often interfere with many of the tests that are conducted on the SBS at each aging interval.
- When stability studies are conducted on SBS, the aging intervals often go out to five years and beyond in anticipation of a variety of devices that may be packaged in them in the future. Devices often have a functional shelf life, which is much less than that. These device limitations would unnecessarily shorten the dating claims for future products using the same SBS materials.
- Once a SBS stability at a particular sterilization modality is established, it is not necessary to repeat it when using that SBS material sterilization modality combination for a new device/product packaging system. In this case, the MDM would build the device aging samples, may or may not place them in an SBS, sterilized the samples to the maximum exposure, age them and at the aging intervals only evaluate the devices for their aging stability.

MDM's that include devices in their SBS stability studies often end up linking that particular device with the specific SBS used. They then feel it is necessary to repeat the stability study on the same SBS materials if a different device is packaged in it. This is not true. It is much better to keep SBS stability studies independent from any specific device.

Conclusion

In establishing shelf life of sterile medical devices engineers must consider both degradation of the sterile barrier system as well as the product itself. A risk-based approach should be used in establishing the criteria for device components, manufacturing and storage based on their impact to safety and performance. The FDA recommends several variables to consider including storage, manufacturing, and shipping conditions. MDM's should document their methods for establishing shelf life in the form of a standard procedure. The best testing strategy is usually to separate product performance testing from the testing of the sterile barrier system.

Additional Resources



ISO 11607-1:2006/(R) 2010 *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems* and **ISO 11607-1: 2006/A1: 2014** *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging, Amendment 1*

ISO 11607-2:2006/(R) 2010 *Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes* and **ISO 11607-2: 2006/A1: 2014** *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing, and assembly processes, Amendment 1*

ANSI/AAMI/ISO TIR16775: 2014, *Technical Information Report, Packaging for terminally sterilized medical devices-Guidance on the application of ISO 11607-1 and ISO 11607-2.*

Guide FDA, 1991, *Shelf Life of Medical Devices*

