INSIDE STORY

As medical device companies are innovating new products, close attention needs to be paid to the creation of safe packaging systems that will protect medical devices during shipment and transport. Developing an appropriate test plan for package performance testing is of utmost importance with the globalization of the medical device industry. In addition, packaging systems need to comply with Food and Drug Administration (FDA) or international health and safety regulations. To find out more about the expertise required to develop a testing plan for package performance testing, MDB recently spoke with Sunny Modi, Director of Package Testing for Eurofins Medical Device Testing in Lancaster, PA.

***MDB:* What are the expectations from the FDA and the European Union (EU) countries on medical device packaging?**

Sunny Modi: The Medical Device Regulations (MDR) for many EU countries provide general guidance on how to design, manufacture, and package medical devices to minimize the risk posed by contaminants, pathogens, and residues to patients. In addition, the medical device must remain sterile and not adversely affected during transport and storage, and the integrity of the packaging systems must be clearly evident to the final user. Similarly, the FDA under 21 CFR Part 820 on labeling and packaging control states, "Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution" (21CFR820.130). The FDA expects the manufacturer to prove the overall integrity and safety of the packaging system. The packaging system is subject to rigorous validation processes that include full validation of the packaging process, accelerated and/or real-time shelf-life testing, package strength testing via mechanical performance of the packaging materials, verification of the sterile barrier system, and finally performance testing via distribution testing.

***MDB:* What are distribution testing, shipping studies, transit testing, and packaging simulations?**

Modi: These terms are commonly used to describe the testing of packaging materials, components, and shipping containers. Furthermore, these tests measure the effectiveness of the packaging systems and medical devices when exposed to various real-world conditions and demands, such as the mechanical and climatic stresses from being filled, moved, stored, or transported. However, there are multiple standards (ASTM, ISTA, and ISO) available to test the system and evaluate the responses of a particular design or material when exposed to different stresses. According to the ASTM D4169-16, distribution simulation "provides a uniform basis for evaluating, in a laboratory setting, the ability of shipping container(s) to withstand the different distribution environments" (ASTM D4169). "This is accomplished by subjecting shipping container(s) to a test plan consisting of different anticipated mechanical hazards" (ASTM D4169).

***MDB:* What tests are included in the most common distribution simulation?**

Modi: The most common series of tests include manual handling, vehicle stacking, loose load and vehicle vibrations, low pressure/high altitude testing, and concentrated impacts. These tests are further defined based on the modes of transportation that will be used to deliver the medical devices to their final destination.

***MDB:* Prior to performing distribution simulation, what other conditioning should be considered?**

Modi: Preconditioning of the samples at multiple environments will affect the performance characteristics of the packaging system, as different conditions are likely to exist between the origin and final destination points. These climatic changes play a vital role in the durability and performance of the packaging system during warehousing and transportation. As the packaging system goes through various degrees of humidity and temperature cycles, the structural properties of the material change, leading to potential material and sterility failures.

***MDB:* After the distribution simulation is complete, how should the packaging system and medical device be evaluated?**

Modi: At a minimum, a visual inspection of the packaging system should be completed to look for gross damages to the shipper, the carton, or the medical device. In addition, if a sterile environment is needed, then sterility testing on the medical device or seal integrity testing on the packaging system should be performed. Seal integrity testing would include bubble emission, dye penetration, or seal strength testing. Finally, the functionality of the medical device should be evaluated by checking for mechanical properties, or verifying the device operates as listed in the Instructions for Use (IFU).

To learn more about Eurofins Medical Device Testing, visit www.eurofins.com/medical-device.