BREAKING DOWN THE BARRIERS OF PACKAGING

Fusing healthcare package design, development and validation into one streamlined experience.

SUBMITTED BY PACKAGING COMPLIANCE LABS

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Packaging Compliance Labs (PCL) is a medical device and pharmaceutical packaging engineering partner that provides design, development and validation services to the healthcare manufacturing industry.

Founded by Matthew Lapham and Ryan Erickson in 2014, PCL has brought a top notch laboratory and engineering team to the Michigan area. This has not only helped boost the already strong biomedical presence in Grand Rapids, but also bring business into the Michigan economy that would've otherwise gone elsewhere. With clients from around the nation and world, PCL has developed a system to help companies accelerate to market by breaking down the barriers of packaging.

Many companies aren't knowledgeable about the complexities of packaging. PCL works with medical device manufactures to ensure the packaging equipment and sterile packaging used for their products meet criteria established by the U.S. Food and Drug Administration (FDA).

The company is backed by a full service ISO 17025 accredited testing lab equipped with ASTM and ISTA test methods for healthcare packaging validation. Additionally, the PCL engineering team has developed a proven process for packaging design & development with expertise in getting clinically-safe and cost effective packaging solutions to market. This system, known as the "Speed to Market Program" runs through the core of every project to help clients make data-driven decisions and build confidence in successful product launches.

Many medical device manufacturers are increasingly relying on expert contract labs to meet the ever-tightening federal regulations for sterile packaging, as well as to avoid making substantial investments in their own testing equipment. PCL is relying on that trend to accelerate its own growth.

Within the biomedical industry of Michigan and around the world, the need for FDA adherence is becoming more and more vital. An example of this in the field, has been the recent change in spinal medical device FDA requirements. Recently, the FDA has changed the requirements on these devices, so that they must be sterile in packaging. Prior to this requirement the infection rate on spinal surgeries was between 1 and 12 percent, causing problems for patients, surgeons, and hospitals. Increased rates of infection can raise post-operation costs for hospitals and diminish surgeons' reputations, leaving healthcare providers clamoring for change.

The demand is matched with updated standards required by the FDA. Within the bio-industry of Michigan, this means that proper packaging validation for medical device companies becomes more important. The combination of more strict requirements and complete packaging validation tests could potentially lower post-operation infection rates significantly and improve regulatory compliance. With a lower infection rates, hospitals will be able to boast a more successful surgery performance outcomes, and therefore attract more spinal surgeons and patients to the immediate medical area.

While this transition to sterile packaging for spinal devices will help the infection rate, it does not fully solve it. The reality is that it will take many years for non-sterile packages to phase off of hospital shelves. In many case, spinal devices can sit for years inside a hospital supply room before being used. This means that the recirculated devices will still be available until they are either used or retired.

To determine these shelf life times, medical device companies utilize accelerated aging tests to test the durability and usability of a device over time. By ensuring the lifespan of a spinal product, hospitals know exactly when to retire unused devices. This practice saves lives by avoiding unsterile, outdated, and decayed products from being used in the surgery room.

Although it will take time, it is easy to understand the importance of this change in the spinal device industry. As the medical field advances, especially in Michigan, it is vital to ensure the safety of these devices after they enter into the real world hospital environment. PCL and their engineering team works with spinal and other device manufacturers to ensure their product packaging is safe and sterile so it is completely effective not only upon arrival, but during the course of its hospital shelf life.

PCL has made it its mission to service the ever-expanding medical industry in Michigan and beyond. Vice President, Ryan Erickson, commented, "Michigan was left with a void from the automotive industry that the medical industry has now begun to fill." Parallel with the growth of the medical industry, PCL also grows to fit the needs for medical package testing and engineer consulting. Matthew Lapham, President, predicts to double their engineering team by the end of next year, and has plans to increase their lab by 5,000 square feet in November 2016. Together, Matt and Ryan plan to help Michigan fill an unmet need with successful medical products packaged and delivered to hospitals all over the world. In so doing, PCL views itself as an essential driver to growing Michigan's reputation as a hub for medical device manufacturing. ■

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