EagleMedical
PACKAGING, STERILIZATION, INC.

PATH

Packaging Accelerated TimelineHelp

KEY QUESTION:

" What would your project look like if you could shorten your development timeline by six to nine months and save up to $1MM in development cost?"

– R.E. Morgan, Eagle Medical, Inc.

Getting to market quickly is imperative to maximizing revenues with any new product. Unfortunately, the medical device industry presents many challenges to new entrants. Not only must the product be verified as safe and efficacious, but when labeled sterile it also must arrive in validated packaging that maintains sterility, protects the device from damage, and allows the end user to aseptically present the product to the clinician. Additionally, the entire process must be documented within an established QMS. The packages must be robust, with a microbial barrier not prone to punctures or tearing, and rigorously tested for the ability to withstand distribution and maintain shelf-life stability prior to use. Distribution simulation and shelf-life testing take time. If you're starting from scratch, this protracted process can delay the approval of your product if not considered early in the design process. As technology advances and the market for medical implants and other devices increases around the world, companies must comply quickly with strict regulations that have uncertain timelines to have any chance at penetrating a highly competitive market. There really is no time to waste.

Eagle Medical is proud to announce PATH™, the Packaging Accelerated Timeline Help program. This innovative offering will dramatically reduce your time to market while ensuring your device packaging will protect your product and comply with international standards and requirements. You'll receive a complete representative data set that allows you to easily adopt the packaging and process into your existing QMS. The resulting nine-month contraction in launch schedule equates to $250,000 to $1 million in savings, and provides the significant competitive advantage of being first to market.

What About ISO 11607?

The ISO 11607 document contains FDA and Internationally accepted standards for validating sterilized medical device packaging. ISO 11607-1:2019 refers specifically to materials, sterile barrier systems, and packaging designs, while ISO 11607-2:2019 focuses on requirements for sealing, forming, and assembly methods. Together, these two sections address the validation of all aspects of medical device packaging with the intent to ensure physical protection and sterilization from initial packaging, through transport and storage, and up to the point of use.

These steps are time consuming and arduous. "Pre-validated" packaging has been promoted by various companies in recent years as a way to shorten packaging development timelines. Unfortunately, the so-called pre-validated packaging currently offered to the medical industry is insufficient. Most contract packagers provide validated *empty* packaging material, which offers no guarantee that the sterile barrier will survive the distribution and delivery process with anything other than *air* inside. Perhaps the empty package meets all specifications, but it certainly behaves differently when your product is inside, which could result in a puncture or tear that renders the product useless due to sterility compromise. Furthermore, when you're creating and testing a new package, there is a chance it could fail validation at any point in the process. You could be 20 weeks into a 26-week process when testing reveals that your packaging fails after aging, which sadly resets the development clock and would present an existential threat to many start-ups.

What Is True-Validated®?

The PATH™ True-Validated® system is different. PATH True-Validated packaging is *completely* validated in accordance with ISO 11607-1:2015 and medical industry standards. PATH True-Validated packaging will shorten your path to market by eliminating the need to source materials, design and build packaging, validate processes, and test your package before you complete your regulatory submission. This system includes both inner and outer sterile barrier, suitable for implants, providing for aseptic transfer to the clinician in the medical setting and also includes a single pack product box and labeling. With PATH True-Validated packaging, you get complete data sets based on actual distribution testing after sterilization. As the OEM, you will receive a solution backed by reports, charts, and protocols, providing a clear PATH to reduce your time to market by about 50%.

The savings can equate to about

nine months

of burn-rate reduction, which ranges from about

$250,000 to $1 million,

depending on the project and your company.

Partnering with Eagle Medical Packaging

At Eagle Medical, we offer FDA-compliant assembly, packaging, sterilization, and validation services for clients in the medical device industry. Our Quality System is ISO 13485:2016 certified, and assembly and packaging is performed in cleanrooms compliant with ISO 14644-1 CLASS 7 (Class 10,000). By leveraging our experience and our strategic industrial partnerships, we will reduce the timeline and costs associated with your project. Having worked with a wide variety of medical companies over the past 30 years, from start-ups to Fortune 100 manufacturers, we have the experience necessary to efficiently execute your medical packaging plan. Please continue to eBook #2 or Contact us to learn more about our innovative medical industry packaging solutions and how our True-Validated packaging can help you win the race to market.

About Us

Eagle Medical Inc. offers efficient and FDA-compliant assembly, packaging, and in-house Hydrogen Peroxide Gas Plasma (HPGP) specific, as well as contract irradiation (gamma and e-beam) sterilization services for the medical device industry. Validation services for manufacturing processes, packaging, and sterilization are customized to product-specific requirements. The company is dedicated to industrial sterilization requirements and meeting the highest of industry standards: FDA registered; ISO 13485:2016 certified; Audited in accordance with ISO 14937:2009 and compliant with ISO 14644-1 Class 7 (Class 10,000) cleanrooms.

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