Integrated Drug Containment and Delivery Solutions

Choice of the right containment and delivery system for a drug can make a product stand out from the competition – particularly in a crowded market.

For a newly diagnosed patient suffering from a chronic condition such as diabetes or an autoimmune disease, the thought of a daily injection can be frightening. Failure to use a delivery device or system correctly, such as an insulin pen or auto-injector, could result in a life-or-death emergency, or affect their ability to manage their condition effectively. For the pharmaceutical manufacturer, such a failure could result in a massive backlash that may result in loss of market share, costly product recalls or worse.

The primary goal of any drug delivery system is to ensure that a patient receives a proper dose of a prescribed drug. In years past, if a device failed or was used incorrectly, patient error was most often the culprit. While providing detailed instructions is important for any pharmaceutical manufacturer, failure to follow directions is no longer a viable excuse when a patient or care-giver is unable to operate a device or delivery system successfully.

Effective drug therapy and treatment requires more than simply having an effective molecule. Rather, it is the combination of a safe drug within a suitable container and/or delivery system, as well as...
an understanding of patient needs as it relates to adherence. By working closely with a packaging and delivery system manufacturer that has generated partnerships with companies such as assembly equipment manufacturers, filling companies, human factors experts and design companies, pharmaceutical manufacturers can select, design and/or develop an appropriate integrated drug containment and delivery system. In this way, the chances of moving a product to market quickly can be maximised with an optimal drug and packaging combination that can be used by the patient or a care-giver as effectively as by a healthcare professional.

**The Rise of Integrated Delivery Systems**

Historically, pharmaceutical manufacturers have focused – and rightly so – on the efficacy and safety of a drug product. However, if the drug is to achieve its therapeutic objective, then its primary container and delivery system must be both compatible with the drug and stable over time, as well as foster adherence from the patient. A drug can only truly have the desired patient benefit if it is taken as prescribed, delivered effectively (often by a patient or care-giver), and maintains performance over time.

Many years ago, a pharmaceutical manufacturer needed only to make a drug available for use with a vial and syringe. As needs evolved, so too did delivery techniques. Patients who required daily dosing or those with special considerations, such as haemophiliacs, needed new ways to mix and inject drugs that lowered the risk of needle-stick injuries and increased adherence to therapeutic regimes. Mixing and transfer devices helped create a needle-free preparation environment for haemophiliacs. For chronic users of fixed-dose medications, including diabetics, injection systems such as pen injectors, pumps and multi-dose cartridges helped to ease the burden of regular dosing.

Today’s injectable therapies can take many forms. Liquid drugs may use a traditional syringe and vial, a prefilled syringe or a delivery system such as an auto-injector, pen device or patch injector. Lyophilised drug products that require reconstitution with water for injection, may require a kit containing a transfer device, syringe or needle, and containers of the drug and water. As the trend toward self-care continues, and patients take an even greater role in decisions regarding their treatment, easy-to-use delivery systems will be essential. Increasingly, the market is evolving toward the use of sophisticated, patient-friendly delivery systems with increased capabilities for use in the home environment. Since there is a strong correlation between the ease of drug product administration and patient adherence, manufacturers must shift from a product-centric to a patient-centric focus when designing an effective drug delivery system. Such a move can help to differentiate the product in the market, while fostering patient adherence and encouraging brand loyalty.

A successful integrated system must combine the following four key elements:

1. The needs of the patient, care-giver and healthcare professional – clinical benefit, as well as ease-of-use and ability to adhere to a treatment schedule, should be considered

2. The drug – a drug product must provide effective treatment in an appropriate form that enables effective delivery with an optimum delivery rate and frequency

3. A primary containment system – the drug must be held in a container that maintains effectiveness, safety and optimum quality over a period of time

4. A delivery device or system – the drug should be compatible with the containment system and designed to enhance the drug delivery experience for the patient or care-giver

**Delivering a Unique System**

So how does a pharmaceutical manufacturer deliver a unique system that meets compliance requirements and the needs of both the drug and the patient, while offering differentiation to their product in a crowded market? First, consider the interface between the drug and the container itself. Selection of a material that can be used during the drug discovery phase and travel through to a self-injection platform is an ideal solution for containment. Effective containment should maintain stability, efficacy and quality over time while meeting appropriate regulatory and quality
Patients at the Forefront

To make a truly effective product, the patient must be at the forefront of the delivery system design. Any potential failures of use must be predicted and designed out. Human factors testing allows manufacturers to support delivery system development from a range of critical perspectives. From a regulatory standpoint, such testing accounts for important human factors inputs that regulatory agencies expect to see as part of the development process for any delivery system. These same inputs also ensure that risks from user-based errors are identified early in the development process, and provide critical user information to the development team for risk mitigation measures. The full development process should constantly assess the effectiveness of the integrated delivery system, and risks should be mitigated.

The process by which a testing team engages users should also yield valuable information regarding a user’s physical and emotional needs and desires, and the lifestyle challenges faced in managing the disease. Understanding how to analyse and effectively utilise this information serves as a strong foundation for guiding the design process to develop delivery systems that are not only intuitive and easy to use, but also encourage experiences that enable positive emotional connections between the user and delivery system.

Recognising how the patient interacts with the delivery system is essential to ensuring success in the market. Even the most innovative drug can provide the appropriate therapeutic benefit to the patient only if it can be delivered effectively and the patient adheres to the necessary treatment regimen. Patients may choose one product over another based on dose frequency, pain associated with dosing, or ease-of-use or mobility of the delivery system. Thus, packaging can differentiate a product, particularly if a pharmaceutical manufacturer commercialises a drug product designed to treat a condition that has a significant amount of competition from other products already on the market. An excellent example of a drug product that is designed to suit patient preference is Merck Serono’s Rebif® (interferon beta-1a); the product is used to treat relapsing forms of multiple sclerosis and is available in a range of patient options, including prefilled syringes and self-injection systems, all designed to improve the patient experience.

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Other options include designs that centre on more traditional containers, such as vials or prefillable syringes. Auto-injectors have long been recognised as a convenient method for delivering drug products, especially for patients who may have dexterity or needle phobia issues. Auto-injector systems can be combined with prefillable syringe systems made from cyclic olefin polymers to help prevent breakage.
Increasing Quality Can Combat Rising Costs

New designs are evolving around the needs of today’s growing pharmaceutical and biopharmaceutical markets. Many of these technologies may increase the price of the drug product, and pharmaceutical companies are being challenged to justify those additional costs, particularly with regard to the delivery system or device. Integrated systems that encourage ease-of-use may aid in increased sales, higher revenues, customer loyalty and retention of market share. However, to truly justify the cost, it may help to go further back in the manufacturing process.

As previously mentioned, material selection can make a difference in the quality of the product. Mouldable cyclic olefin polymers can be used throughout a product’s life cycle, which can diminish the many rounds of testing required to ensure that the drug is stable in different containment systems. Other quality issues such as rejection rates and breakage can be mitigated through the use of high-quality polymers. Often, the extra cost associated with these materials can be justified through quality improvement and increased sales, as well as a faster move to market.

Conclusion

Whether seeking to create a custom integrated delivery solution or to package a drug product in an existing delivery option, such as an auto-injector, pharmaceutical and biotech companies should seek out a partner with expertise and experience in providing packaging solutions. Packaging manufacturers who are focused on providing quality solutions will have the knowledge and partnerships in place to ensure that all four key elements of an integrated design are met. New and innovative drug delivery systems can optimise the quality of life for patients by effectively managing the interrelationship of the four primary components: the drug, the end-user, the primary container and the delivery system. Together, packaging and pharmaceutical manufacturers can work seamlessly as partners to provide innovative solutions that help mitigate risk, encourage patient adherence and enhance value through unique integrated delivery combinations.

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