

Helping Patients Stay on their Medication Regimen with Integrated Drug Delivery Systems

The increase in self-administered drugs is part of an even larger shift towards a more patient-centric approach to the production of integrated delivery systems. Because of this renewed focus on the patient, drug delivery system manufacturers are continually re-evaluating the processes by which they improve existing systems and how they develop new ones. As a result, delivery system manufacturers have become an invaluable partner to pharmaceutical companies.

Around the world, patients with chronic diseases are seeking new freedom from frequent doctor's office visits by self-administering their critical medications at home. Yet with these new home-based administration plans, it can sometimes be more difficult to comply with a prescribed treatment regimen than when injectable medicines are administered by a nurse or physician.

Drug delivery systems can help make self-administration a less painful, more streamlined and simplified process and help patients realize the freedom they desire. For most patients, an easy-to-use, integrated drug containment and delivery system can be key to enabling the consistent routines that bring about compliance with care plans. When delivery systems are intuitive and efficient, they stand a better chance of encouraging compliance with their treatment protocol because the impact on daily routines lessens.

Conversely, drug delivery systems deemed inconvenient, intimidating or complicated can negatively affect a patient's emotional attitude and motivation to sustain adherent behavior. And in many cases, looks count, too: discreetness of the drug delivery system can be very important to patients. New integrated delivery systems can enable use without calling undue attention to the administration process, creating distractions to others or feelings of stigmatization. Such a shift from a product-centric focus to a patient-centric focus can help manufacturers design a product that encourages compliant behavior.

Putting patients first in drug containment system design

No matter what type of delivery system is selected for a particular injectable drug product, there are several elements that must be carefully considered when designing a drug delivery system. The primary goal of any drug delivery system is to ensure that a patient safely receives a proper dose of a prescribed medication. In years past, if a delivery system 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 should be minimized by providing proper training to the patient or caregivers.

Now, the industry is rethinking that stance, and the priority is engineering usability into the drug delivery system to help patients achieve better outcomes. In order to design a drug delivery system that meets the needs of both the drug and the patient, the pharmaceutical manufacturer and its packaging and delivery system partner must consider the interface between the drug, container, delivery system and patient.

Understanding patients informs usability

Effective drug therapy 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 administration. Drug manufacturers should take into account four main facets of integrated drug



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Figure 1: Electronic wearable injector designed to easily integrate into a patient's lifestyle

delivery that, when planned early in the development process with a packaging and delivery system partner, can lead to better outcomes:

Primary Container Format - The selection of a drug's primary container is an important consideration for drug efficacy and stability. Vials may be necessary for initial use, but a syringe or cartridge system may provide a desirable solution for the patient when the system reaches the market. Custom systems may also help to differentiate the product, and should be considered early in the development process.

Drug/Container Compatibility - Hand-in-hand with the type of primary container is making sure the container material can be safely and effectively paired with the drug product. Is the elastomeric material compatible with the drug? What are the levels of extractables and leachables? Will a barrier film or coating be required for the elastomer? Choosing the proper drug container material can help prevent chemical incompatibility issues that could impact a drug's purity, stability or efficacy. While glass is suitable for many

pharmaceutical products, high pH drugs or otherwise sensitive drug products may require vials or syringes made from alternative materials such as cyclic olefin polymers. The filling, handling and secondary assembly processes must also be considered as an integral part of providing the overall delivery system.

Container/Delivery System Interface - Once the primary container system has been selected, efforts must be made to ensure that it works with the delivery system. Dimensional tolerances and functionality should be tested to ensure proper activation and gliding forces. If the interface between the primary container and the delivery system is not effectively understood, the performance of the combined system may suffer.

For example, when considering the use of a glass prefillable syringe in an auto-injector, manufacturers must

ensure that the stress placed on the glass does not cause breakage or that the force in the auto-injector is enough to overcome variability in dimensions, functional performance and siliconization effectiveness to ensure complete dosing.

Patient Interaction - Perhaps the most essential consideration is how the patient will use the drug delivery system. Even the most innovative drug can only provide the appropriate therapeutic benefit if it can be delivered effectively and the patient adheres to the necessary treatment regimen.

Simply designing a drug delivery system that patients/users "can" use, is no longer sufficient. Delivery systems should be designed for affinity, and encourage patients to "want" to use them. Even then, effective training, onboarding, and ongoing adherence are critical to ensuring effective outcomes.

Forward-thinking partners make the difference for patients

West's SmartDose platform is a single-use, electronic wearable injector that was designed to easily integrate into a patient's lifestyle. The discreet, wearable technology adheres to a patient's body, usually on the abdomen, and is designed to minimize discomfort. The SmartDose platform currently incorporates a polymer-based drug container (made from Daikyo Crystal Zenith cyclic olefin polymer) with a drug delivery system that can be pre-programmed to deliver high volumes of sensitive drug products, making it easier for patients to self-

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Figure 2: Electronic wearable injector

administer medication outside of the clinical setting.

West is currently collaborating with HealthPrize Technologies, LLC-a

leader in digital solutions for patient engagement and medication adherence-to enable connectivity between a variety of injection systems and their adherence programs, to help motivate patients to

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comply with their prescribed treatment regimen. Connected health innovations like this help to boost motivation by incorporating game-like technology that enables short-term rewards for patients, by tying rewards and education to the drug administration process.

A drug can only truly have the desired patient benefit if it is taken as prescribed, delivered effectively and maintains performance over time. Together, drug delivery system and drug manufacturers can work seamlessly as partners to provide innovative solutions that help mitigate risk, improve patient outcomes, and enhance value through unique integrated delivery combinations. ■