Considerations for Choosing the Right Wearable Drug Delivery System

For patients with chronic conditions, the use of injectable biologic therapies is on the rise. Biologics, while providing considerable therapeutic benefit, can also present several challenges for both drug manufacturers and patients. In particular, many biologics are highly viscous and others require large doses to be injected slowly over time. This can make it difficult to deliver a consistent dose every time, potentially impacting medication adherence.

According to estimates from the World Health Organization, patient compliance with chronic medication therapies is remarkably low – about 50 percent internationally.[i] This is a major health issue, as non-compliance can lead to a number of complications, including poor clinical outcomes, increased costs for many healthcare stakeholders (including the patients themselves) and lost revenue for pharmaceutical companies.

Treatment options are not the only evolving elements in the care of chronic diseases. Ongoing management of chronic conditions is increasingly shifting from doctors' offices and hospitals into the patient's home in an effort to provide patients with more independence and control over their treatment while helping to stem growing healthcare costs. This, coupled with increased use of biologics, is making it important to provide patients with novel approaches to drug delivery.

One of the most promising options is wearable drug delivery technology. Wearable systems combine the drug, its primary containment system and delivers the prescribed dose electronically. For most patients, an easy-to-use, integrated delivery and administration system can be key to creating the reliability that can help to bring about compliance with treatment plans. A truly successful wearable delivery system must also consider the needs of the end-user during the different stages of a patient's journey.

West Pharmaceutical Services' SmartDose® technology platform, for example, was designed to easily integrate into a patient's lifestyle. The SmartDose technology platform is a single-use, electronic wearable injector that adheres to the patient's body, usually on the abdomen. Discreet, intuitive and designed to minimize discomfort, SmartDose technology currently incorporates a polymer-based drug container (made from Daikyo Crystal Zenith® cyclic olefin polymer) with a drug delivery device that can be pre-programmed to deliver high volumes of viscous or sensitive drug products over time, making it easier for patients to self-administer medication outside of the clinical setting.

Delivery System Design

The priority when designing a wearable drug delivery system—and any drug delivery system, for that matter—should always be the safety and effectiveness of the system and its drug product. To accomplish this, it is critical for biopharmaceutical companies to have a thorough knowledge of the potential interactions between a drug and its packaging. This is especially important for sensitive biologics, which require sophisticated packaging and delivery systems. As more and more drug

manufacturers ramp up production of biologics, the issue of how to best package and deliver these compounds will continue to rise in importance.

In order to design a drug delivery system that helps to address the needs of both the drug and the patient, pharmaceutical manufacturers must consider the interface between the drug, container, delivery device and patient. It is also critical to "start with the end in mind" and consider the ultimate method, location and person involved in the preparation and administration of the medicine.

For the development of any delivery system—and certainly in the development of the SmartDose technology platform—the following considerations are key:

- **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**: Going hand-in-hand with selecting the type of primary container is making sure the container material can be safely and effectively paired with the drug product. While glass is suitable for many pharmaceutical products, high pH drugs or otherwise sensitive products may require vials or syringes made from alternative materials such as cyclic olefin polymers.
- **Container/delivery system interface:** Once the primary container 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 glide force. If the interface between the primary container and the delivery system is not effectively understood, the performance of the combined system may suffer.
- **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 a prescribed treatment regimen. Simply designing a device that patients/users "can" use is no longer sufficient—devices should be designed for affinity. It starts from a thorough understanding of patient needs, including the fact that these needs may change during the journey from diagnosis through ongoing treatment. These same inputs also ensure that risks from user-based errors are identified early in the development process and provide critical user information for risk mitigation measures.

Understanding Patient Needs

In the research conducted while developing the SmartDose technology platform, it became clear that when patients deem a system inconvenient, there can be a negative effect on the emotional attitude and motivation to sustain adherent behavior. As a result, the SmartDose technology was developed with extensive human factors testing to address potential obstacles to compliance:

- **Pain**: Patient concerns related to discomfort were certainly valid, as the device requires needle insertion for an extended period of the time while affixing to the body using an adhered patch. As such, it was designed to minimize discomfort throughout the duration of the dosage and to be easily removed once the dosage was complete. There is also an automatic needle protection feature that can help prevent needlestick injuries.

- **Discreteness:** Many patients prefer a delivery mechanism that is not visible to others. Special consideration was taken with the SmartDose technology platform to ensure that it is easily concealed to avoid calling undue attention to the system, creating distractions to others or creating feelings of stigmatization.
- **Ease of use**: Because injectable medications are administered completely by the patient with SmartDose technology, the process needed to be so intuitive that only minimal instruction is required. To this end, the SmartDose technology platform currently allows for the patient to load the cartridge containing the drug. A user-friendly activation button on the front of the device and LED indicator lets the patient know that the dose delivery is in progress.
- **Dose notification:** A critical aspect of SmartDose technology is its patient-focused design elements that address the possibility a user did not receive the full dose, or did not receive their medication at all. To account for this possibility, the device is equipped with a microprocessor that is designed to offer immediate feedback via a dose confirmation window and audible cues indicating whether the prescribed medication was delivered.

Choosing the Right Partner

It is important for drug manufacturers to have a clear understanding of the role packaging should play in the drug development process as well as how it fits into the regulatory and quality environment. By working with a packaging provider with an intimate knowledge of the regulatory and quality requirements related to pharmaceutical drug products, drug manufacturers can make more informed decisions about which container and delivery systems are most effective for a particular drug. Additionally, manufacturers can increase their ability to create a device that can help to establish the drug product as a leader in the market. New technologies and innovative materials provide ideal lifecycle management solutions and can help ensure high quality solutions for drug purity and patient safety.

For example, West worked closely with Amgen to ensure compatibility between the SmartDose technology platform and the monthly single dose administration of Amgen's Repatha®--the first combination product that incorporates SmartDose® technology for use in the United States. The combination of Amgen's innovative treatment with West's technology platform exemplified the close collaboration West has with its pharmaceutical and biotechnology partners to deliver advanced, integrated solutions for drug delivery and containment.

West assists pharmaceutical and biopharmaceutical customers every day in the development of innovative delivery solutions, and there are multiple active programs at various stages of pre-commercial development utilizing SmartDose technology. Additionally, West is currently in the process of expanding the SmartDose technology platform to ensure continued leadership and innovation in this area. The next generation products will include a prefilled option, with the objective of reducing user steps while maintaining sterility.

Partnering with a company like West that can provide expertise in the field of drug packaging and delivery systems should be an important part of the launch plan for any biologic to be delivered in a wearable system. By developing a thorough understanding of the drug's intended use and the patient's needs, packaging manufacturers can lend their expertise to drug manufacturers to develop a delivery system that differentiates the drug in the market and helps to ensure that the patient's needs are met. Having a sophisticated drug delivery system, as well as advice from a partner with experience and understanding of the drug packaging industry and end user needs, will help meet the needs of patients, but also may help get products to market faster.

Looking ahead, it's imperative that the pharmaceutical industry remains focused on better understanding the interaction between patients, their medication and the drug delivery system, as this relationship may have a substantial impact on patient outcomes. As patients and healthcare providers are increasingly looking to technology in pursuit of improved wellness – especially to manage chronic diseases – providing new, innovative approaches will be critical to truly impacting the way patients receive their care and the effective treatment of chronic conditions.

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[i] World Health Organization. (2003). *Adherence to long-term therapies: evidence for action.* Retrieved August 5, 2015 from http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf