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WEST'S SMARTDOSE PLATFORM: A WEARABLE ENGINEERED WITH BOTH PATIENT & PHARMA PARTNER IN MIND

In this article, Tom McLean, Vice-President, Delivery Systems, R&D, West Pharmaceutical Services, discusses the company's wearable technology platform. SmartDose is a customer-driven, patient centric device that was recently selected by Amgen for the Pushtronex™ system.

For patients with chronic conditions, the use of biologic therapies is on the rise. These drugs present several challenges for both drug manufacturers and patients. In particular, many biologics are highly concentrated, so a prescribed dose may be very viscous or require large volumes of the medication to be injected slowly over time. This can make it difficult to deliver a consistent dose, potentially impacting patient adherence to a given therapy.

Additionally, there has been a rise in popularity of wearable self-injection systems for biologics. Instead of scheduling a doctor's appointment for certain treatments, a wearable device allows patients to self-administer injectable medication without assistance from a trained medical practitioner. For some patients, an integrated delivery and administration system may be helpful when trying to comply with prescribed treatment regimens.

The market demand for biologics coupled with the growth of self-administration required the drug delivery sector to develop innovations, such as the West SmartDose® technology platform, to administer these very important therapies. SmartDose, shown in Figure 1, is a single-use, electronic wearable delivery system that adheres to the patient's body, usually on the abdomen, and is pre-programmed to deliver high volumes of viscous medications. It was designed with the goal of minimising discomfort, fostering an improved patient experience and offering accurate and timely drug delivery.

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Earlier this year, Amgen (Thousand Oaks, CA, US) selected the SmartDose technology platform for a single, monthly 420 mg dose delivery option for Repatha® (evolocumab). While this is the latest collaboration, the success of SmartDose is the product of many

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Figure 1: West's SmartDose® technology platform.

years of innovative research, design and implementation, based on input from both patients and pharmaceutical customers. It promotes greater adherence, which benefits all parties involved.

THE PATIENT-CENTRIC SHIFT

Historically, the primary focus of pharmaceutical manufacturers has, appropriately, been on the efficacy and safety of their drug product. However, with more drugs coming onto the market as combination products – drug products paired with delivery devices – pharmaceutical companies are paying closer attention to the design, function and efficacy of integrated delivery systems as well.

A successful system will combine the needs of the patient, which can evolve throughout the treatment journey, with those of the drug, its primary containment system and delivery system.

The best way to incorporate meeting patient needs into a platform's design is to gain a considerable amount of user feedback before even prototyping a delivery system. It is also critical to understand how they feel about their journey from diagnosis through ongoing treatment, and how to make a delivery system that will both enhance the therapeutic experience as well as improve medication adherence.

This kind of development costs more than traditional approaches, and may take a bit more time at first. However, when built into the overall timeline of drug development, we believe this approach pays dividends by yielding medications with delivery systems that patients not only can use, but want to use. This helps promote patient adherence and ultimately contributes to improved chronic disease management and outcomes.

In the research conducted when developing the SmartDose technology platform it became clear that delivery systems that patients deem inconvenient can negatively affect their emotional attitude and motivation to sustain adherent behaviour. As a result, SmartDose was developed with extensive human factors testing and analysis to understand the interaction between the patient and the delivery system. The two most common human factors were:

- **Pain:** Patient concerns related to discomfort were certainly valid, as the device requires needle insertion for an extended period while affixed to the body using an adhered patch. As such, it was designed to minimise 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 not to have medication administered by visible delivery mechanisms. Special consideration was taken with SmartDose technology to ensure that it is easily concealed to avoid calling undue attention to the device or creating feelings of stigmatisation.

CUSTOMER-DRIVEN DESIGN

In addition to taking a patient-centric approach, it is also important to focus on

the specific needs of our pharmaceutical customers when pairing a drug with a delivery system. In designing the SmartDose technology platform, input from pharmaceutical companies was key to ensuring the system met their requirements.

One of the more important customer-facing features of SmartDose technology is its adaptability. Its design allows the dosage amount and length of time to be adjusted to the drug maker's specifications. If a pharmaceutical customer needs a 3 mL dose delivered over 30 minutes or a 2 mL dose delivered in five minutes, the SmartDose technology platform can accommodate the unique properties of the drug. Beyond the actual delivery the aesthetic features such as colour scheme can be customised to maintain branding.

West's dedication to working with its customers to deliver new solutions also requires paying close attention to emerging trends, such as cold chain storage. Some new therapies require the drug to be stored in sub-freezing temperatures prior to use. To ease impact on shipping and cost, West has traditionally kept the drug and device separate.

"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 include a prefilled option, with the objective of reducing user steps while maintaining sterility."

However, there is increased demand for a prefilled version of the SmartDose technology platform that would require the device to be stored in the same cold environment as the drug. As a result, we are exploring engineering and design methods that would allow for cold storage without impacting the mechanical components of the SmartDose technology platform.

A notable example of the customer-facing engineering of the SmartDose technology platform can be seen in Amgen's decision to utilise the delivery system for the company's single, monthly dose delivery option of Repatha, marking the first use of SmartDose technology with a commercialised product. The combination of Amgen's innovative treatment with West's patient-focused technology platform is an example of how West closely collaborates with its pharmaceutical and biotechnology partners to deliver advanced, integrated solutions for drug delivery and containment.

Amgen is one of a number of pharmaceutical partners that have considered West and the SmartDose technology platform to assist in the development of an innovative delivery solution. There are multiple active programs at various stages of pre-commercial development utilising SmartDose.

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 include a prefilled option, with the objective of reducing user steps while maintaining sterility. The newer version will include:

- Additional design flexibility based on the use of a customised Daikyo Crystal Zenith® container, commercially available plungers with Flurotec® barrier film technology and rigid needle shields
- Optimised manufacture, filling and sterilisation for manufacturers to help ensure cost effectiveness and leverage established filling equipment.

IMPROVING ADHERENCE

The end result of the innovative engineering research necessary to strike the perfect balance between what is best for both the patient and customer, ideally, is increased patient adherence and outcomes. According to estimates from the WHO, adherence is still a very real issue globally, with adherence to chronic medication therapies remarkably low – about 50%.

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. To combat the adherence issue, injectable drug administration systems should be intuitive, efficient and non-

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PATIENT-CENTRICITY IN WEARABLE TECHNOLOGY TRAINING

A recent study conducted by Noble® (Orlando, FL, US), a leader in onboarding and device training, and analysed by Auburn University (Auburn, AL, US), found that more than 60% of patients self-reported that they did not thoroughly read the required steps outlined in a self-injection system's Instructions for Use document prior to beginning drug treatment, potentially leading to administration errors and impacting compliance with prescribed therapies.

Research from both Noble and West has revealed that patient-friendly drug delivery systems and comprehensive education around self-injection are needed to improve the patient experience. To address this adherence challenge, West and Noble have worked together to offer a multisensory-based educational and training program for the SmartDose® technology platform to pharmaceutical and biotechnology customers. West brings its expertise in human factors testing and analysis to the design and development of drug delivery systems, and Noble incorporates a similar approach into the development of the SmartDose patient onboarding support materials which include a smart training device and packaging, Instructions for Use and more. Through this collaboration West and Noble aim to help improve the patient experience, reduce errors and anxiety and potentially increase adherence to prescribed injectable therapies that utilise the SmartDose platform.

This collaboration with Noble complements West's established relationships with other technology innovators such as Insight Product Development (Chicago, IL, US) and HealthPrize Technologies to enhance its patient-centric approach to the SmartDose drug delivery system.

disruptive to the patient's daily routine.

After all, a drug can only have the desired patient benefit if it is taken as prescribed and delivered effectively. SmartDose integrates innovative features that may help to encourage patient compliance, including:

- **Ease of use:** Because injectable medications are administered completely by the patient with SmartDose technology, the process needs to be so intuitive that only minimal instruction is required. To this end, SmartDose is equipped with an easy-to-load cartridge that contains the drug, a user-friendly activation button on the front of the device and LED indicator to let the patient know that the dose delivery is in progress.
- **Dose notification:** Perhaps the most critical aspect of the SmartDose platform is how it addresses the possibility that 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.

Additionally, in 2014, West collaborated with HealthPrize Technologies (South Norwalk, CT, US) to develop a connected health offering that is designed to improve and reward medication adherence with unique technologies in a gamified environment. In our first offering, patients can manually scan barcodes or otherwise enter data about their medication compliance into a smartphone/tablet app or on an Internet browser from a computer. Patients are then rewarded for compliance, and other forms of engagement.

In the near future, using the app will be even more automated, streamlined and interactive by enabling West's drug delivery systems, including SmartDose, to signal the smartphone with data points about each instance of medication self-injection. For example, the app would automatically, in real time, confirm that a particular dose was used, the needle protection system was deployed, that the entire dose was injected, and other details.

CONCLUSION

In developing SmartDose, West has further broadened its ability to balance the safety and well-being of patients and the technical demands of our pharmaceutical partners. As the wearable drug delivery market expands, West will continue to develop and engineer innovative platforms to ensure greater patient adherence and outcomes and assist drug companies to bring safer and more efficacious new therapies to market.

SmartDose® is a registered trademark of Medimop Medical Projects Ltd., a subsidiary of West Pharmaceutical Services, Inc. West seeks partners for its SmartDose® injector technology platform. This platform is intended to be used as an integrated system with drug filling and final assembly completed by the pharmaceutical/biotechnology company. Repatha® is a registered trademark of Amgen Inc.

ABOUT THE AUTHOR

Tom McLean leads West's Delivery Systems R&D Organisation where his responsibilities include the development of delivery system products from concept through product design verification and validation. Mr McLean holds Six Sigma Black Belt Certification and Six Sigma Master Black Belt Certification. He received a B.S. in Mechanical Engineering from Purdue University (West Lafayette, IN, US).

Empower Your Patients

The SmartDose® technology platform is an innovative drug delivery system that allows your patients to leave their treatment center—and its costs and interruptions—behind.

Learn more from our experts at **www.smartdose.com** or call **800-345-9800**

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