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LEVERAGING PATIENT-CENTERED DESIGN TO DELIVER LARGE VOLUME DRUGS

In this article, Maggie Tsai, Marketing Product Manager, BD Medical – Pharmaceutical Systems, describes using a patient-centred design approach to deliver larger volume drugs in a space where current delivery devices are being challenged.

THE NEED FOR CUTTING-EDGE DRUG DELIVERY

Many market factors are driving the need for advancements in drug delivery devices. Pharmaceutical companies are developing more innovative injectable therapies. The injectable drugs market is set to grow at a 14% compounded annual growth rate to reach US$43.3 billion (£28 billion) in 2017.[1] In the injectable drug delivery market, self-injection devices such as auto-injectors are the fastest growing segment.[1] Many new drugs must be delivered in higher volumes and at higher viscosities than has traditionally been the case, challenging the limits of current delivery devices. At the same time, there is an effort to reduce overall healthcare costs by moving patient care out of the hospital / clinic into the home setting. As a result, drug delivery devices must be patient friendly and intuitive to use in order to drive acceptance and adherence to these innovative drugs.

IMPORTANCE OF FINDING THE RIGHT DEVICE PARTNER

Collaborating with a device partner with the experience and technical competence to help guide pharmaceutical companies through the device development process could maximise product success in the market. Factors such as human factors engineering, integrated design and development, preclinical and clinical capabilities, and regulatory expertise and support could play an important role. Such factors and criteria could minimise downside risks, reduce time to market, and drive commercial success.

OPTIMISING PATIENT OUTCOMES THROUGH DEVICE DESIGN

With the migration of patient care to a nonclinical setting, the patient is now responsible for his/her therapy. Because the patient may not be as skilled as a health care provider or caregiver, the design of the device needs to be intuitive and patient friendly. Other complications of larger volume delivery include longer injection times and the need to wear the device during this period. Partnering with a device company that has expertise in human factors engineering could help drive product acceptance and preference. Large volume device designs that may enhance usability and total patient experience include button

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force optimisation, feedback indicators and safety features. Understanding the impact and incorporating these features into the product design could enhance patient compliance and improve outcomes.

INTEGRATED DESIGN AND DEVELOPMENT

Many of the biologic drugs in development are sensitive and may require a primary container that reduces the risk of surface interactions and meets the technical requirements of the drug. Factors such as biocompatibility, gliding forces and container closure integrity could impact the performance of the system. According to Diane Doughty, PhD, Scientist II at Medimmune, "Knowledge from prefilled syringe development (silicone oil level, product contact materials, and extractables and leachables, for example) can help in the design of wearable injectors." [2] A device partner who has the technical expertise and knowledge of the interactions between the drug, primary container and delivery device for higher volume subcutaneous injections could minimise risk during the development process and optimise robustness of the system.

CLINICAL & REGULATORY EXPERTISE

In order to enable a successful commercialisation, a device partner should have the proper toxicology, clinical and regulatory expertise with global experience. Collaborating with a device company who has the resources and expertise for clinical data collection as well as the capabilities to conduct clinical trials could help navigate through these uncharted territories. Such resources include protocol and clinical method development, investigator and/or patient recruitment, and statistical analysis.

A device partner could also manage downside risk by offering regulatory consultation and support for registration of combination products. The increasing scrutiny within the regulatory environment increases the need for strong partnerships and functional experts on the device and pharmaceutical company side. Since specific guidance has not been fully developed yet for wearable, large volume delivery devices, a device partner who has a breadth of experience in regulatory submission and maintenance could help effectively advise recommendations, which would support commercial success of the product.

BD'S BROAD AND INNOVATIVE PORTFOLIO

BD Medical – Pharmaceutical Systems offers a broad portfolio of innovative drug delivery systems to meet the current and evolving needs of the pharmaceutical industry. BD's wide range of products includes glass and plastic prefillable syringes (Figure 1), safety and shielding systems (Figure 2), self-injection devices (Figure 3), and needle technology. "BD is leveraging its unparalleled experience to offer innovative solutions for the pharmaceutical industry to meet the emerging needs of large volume and high viscosity drugs," commented company Worldwide President Peter Nolan. "Such solutions include primary container technologies (for example, BD Neopak™ 2.25 mL glass prefillable staked syringes), 2.25 mL safety and shielding systems, and self-injection systems with potential to deliver up to 15 mL (for example, BD Libertas™ Patch Injector)."

BD LIBERTAS™ PATCH INJECTOR

The BD Libertas™ Patch Injector, as shown in Figure 4 (overleaf), has been designed from deep insights on patient attitudes, beliefs and perceptions about devices and with BD's human factors, ergonomic design and clinical capabilities.[3]

The product is a single-use, prefillable disposable, injection system for hands-free use during drug delivery and applicable to multiple therapies. Target delivery ranges cover drugs with volumes up to 5 mL (with additional preliminary assessment on volumes up to 15 mL) and high viscosities up to 50 Cp.

KEY CHARACTERISTICS OF LIBERTAS™ INCLUDE:

- Ready to be used by patient (i.e. no patient assembly)
- Prefillable syringe technology developed for biotech drugs
- Needle advantages like hidden needle before and after injection and passive needle retraction
- Feedback indicators, including a large window that can allow easier visual drug inspection and monitoring of injection progression (Figure 5, next page).

Figure 1: BD prefillable syringes.

Figure 2: BD Safety shielding systems.

Figure 3: BD's self-injection portfolio.

Figure 4: The Libertas™ Patch Injector.

Figure 5: Viewing window for drug inspection and monitoring of injection progression.

BD Libertas™ Patch Injector was designed and optimised through an iterative design approach that puts the patient at the center and uses patient feedback (see Figure 6).

More than 1,000 patients of various demographics and experience levels have been interviewed over the product development process.[4] The feedback provided inputs to enhance product features and design of the BD Libertas™ Patch Injector, including the elimination of an assembly step for the patient, a separate status indicator window, and an intuitive activation button shape perpendicular to the skin.

"The BD Libertas™ Patch Injector is a patient-friendly device. The design simplifies the patient injection experience and gives the patient comfort and confidence to ensure compliance," says Peter Quinn, Patch Injector Platform Leader.

BD'S STRATEGIC VALUE-ADDED SUPPORT

With in-house preclinical and clinical capabilities, BD is leading the collection of data to understand the physiological limits of large-volume and high-viscosity drug delivery, and establishing *in vivo* technical feasibility for large-volume and high-viscosity delivery while optimising the function of prototypes. In addition, BD partners with its pharmaceutical customers during the development process to guide development and optimisation for their unique formulations and delivery requirements. As a result, BD is able to understand boundary conditions for delivery feasibility better and develop critical insights for system performance success.

On the regulatory front, BD is actively involved in forums where guidance and standards for large-volume delivery devices is being developed. BD's deep understanding of emerging regulatory challenges across the globe, and its breadth of experience in regulatory submission and maintenance, could help pharmaceutical customers navigate through registration requirements and guidance documents.

SUMMARY

Large-volume, wearable injectors are an emerging class of delivery technologies that enable convenient delivery in alternative healthcare settings. There is a need for pharma companies to offer solutions that enable delivery of larger volume and high-viscosity drugs while encouraging patient confidence through an intuitive and easy-to-use device. To drive a successful product launch, it is important to find a device partner that has the experience and technical competence to guide pharmaceutical companies through the device development process.

A device partner should leverage and apply patient and therapeutic insights to inform product design, have the technical expertise to ensure integration and performance of the drug delivery system and support the development process through clinical studies and regulatory guidance.

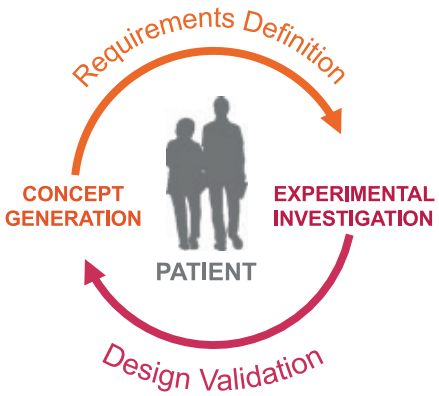

Figure 6: Patient-centered design approach.

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ABOUT BD

BD is a leading medical technology company that partners with customers and stakeholders to address many of the world's most pressing and evolving health needs. Our innovative solutions are focused on improving medication management and patient safety; supporting infection prevention practices; equipping surgical and interventional procedures; improving drug delivery; aiding anaesthesiology and respiratory care; advancing cellular research and applications; enhancing the diagnosis of infectious diseases and cancers; and supporting the management of diabetes. We are more than 45,000 associates in 50 countries who strive to fulfil our purpose of "Helping all people live healthy lives" by advancing the quality, accessibility, safety and affordability of healthcare. In 2015, BD welcomed CareFusion and its products into the BD family of solutions. For more information on BD, please visit www.bd.com.

Your Drug Is Your Innovation

BD

Helping all people live healthy lives

Self-Injection Systems

Prefillable Syringes | Patch Injectors | Pen Injectors

Autoinjectors | Safety and Shielding Systems | Pen Needles

Your drug is an innovation with significant potential to impact patients' lives.

Competition is intensifying. The regulatory process is getting more complex. Selecting the right device that has been optimized for the patient is fundamental. Integrating device design through industrialization with global freedom to operate is essential.

These are just several critical factors impacting your risk and time-to-market.

Selecting a self-injection partner is a big decision with a lot at stake – for your drug, your company, patients, healthcare professionals. And you.

You need a partner who delivers on what matters to maximize your potential.

Contact a BD expert today
at 1-800-255-3310 or BDPS_marketing@bd.com
Learn more at: www.bd.com/self-injection

Arthritis Foundation Ease of Use℠

Who do you trust with your innovation?

Products with the Arthritis Foundation's Ease of Use℠ Commendation are tested and proven to make daily tasks easier. BD products that have received the Commendation include BD Physioject™ Disposable Autoinjector, BD UltraSafe™ Passive Needle Guard and BD Nano™ Pen Needles. Learn more at arthritis.org/easeofuse.

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