



ADDRESSING THE EVOLVING NEEDS OF VARIABLE DRUG DELIVERY REGIMENS

In this article, Temitope Sodunke, PhD, Strategic Innovation Leader, BD Medical – Pharmaceutical Systems, introduces the BD Evolve™ On-body Injector and describes how the device is designed specifically to address the rapidly evolving needs of the pharma industry and meet patient requirements.

The pharmaceutical industry is rapidly evolving and experiencing a diverse set of competing challenges. These challenges include a changing healthcare landscape and transition of care out of the traditional clinical settings to alternative sites, including patients' homes.¹ Several biologic blockbusters have expiring patents,² increasing pressure on pharmaceutical companies to maximise revenue and stay ahead of competition. There is also an emergence of biosimilars fuelling the need for effective drug product differentiation. Lastly, patient demands and expectations are changing as they seek a greater role in their own care.³

To address these challenges, innovative pharmaceutical companies continue to advance their clinical development pipelines to develop new and more sophisticated biologics. Other companies are revisiting their lifecycle management strategies and general market entry approaches to compete more successfully (identifying new use cases, alternative delivery formats, and promoting value-added services that boost patient engagement). Some companies are riding new technology trends towards a more cost-effective and patient-centric healthcare delivery model.⁴

Figure 1: The BD Evolve™ On-body Injector with Bluetooth connectivity for remote and secure one-way communication.

“With the introduction of the BD Evolve™ On-body Injector, we now give pharma companies a wearable solution that is designed to enable new delivery formats in alternate settings.”



Dr Temitope Sodunke
Strategic Innovation Leader
T: +1 201 847 5735
E: temitope_sodunke@bd.com

BD Medical – Pharmaceutical Systems
1 Becton Drive
Franklin Lakes
NJ 07417
United States

www.bd.com

Pharma Strategy	Key Supporting Strategy	BD Evolve™ Features
<i>Deliver novel biologic</i>	<p>Innovate new products with delivery characteristics that improve patient experience and acceptance</p> <p>Leverage key clinical data to benchmark versus standard regimens</p>	<p>Customisable to support different treatment regimens (pulsatile, continuous, episodic, or single bolus delivery)</p> <p>Programmable for delayed or timed administration up to 3 days</p>
<i>Maximise value via lifecycle management</i>	<p>Maximise clinical differentiation against intensifying competition</p> <p>Improve line of sight to patient compliance with unobtrusive measurement and monitoring</p>	<p>Designed to enable new delivery formats in alternate settings and to support treatment conversions (IV to SC, IM to SC, bolus to basal)</p> <p>Equipped with connected capabilities – Bluetooth for remote and secure one-way communication with additional options to enhance injection data capture.</p>
<i>Differentiate a biosimilar</i>	<p>Differentiate biosimilar combination products</p> <p>Provide access to viable treatment regimens</p>	<p>Designed for effective SC delivery of up to 3 mL of medications</p> <p>Flexible to support adjustments to existing formulations and variations in treatment regimens</p>
<i>Optimise the standard of care</i>	<p>Augment value proposition of an asset around convenience and clinical efficacy</p> <p>Reduce healthcare costs while improving the patient experience</p> <p>Give providers an option that may improve outcomes and patient experience</p>	<p>Convenient for at-home medication delivery which may improve adherence</p> <p>Adaptable to enable reduced cost of patient care (reduced hospital visits and transportation)</p> <p>Flexible to support adjustments to existing formulations and variations in treatment regimens</p>

Table 1: Benefits associated with the BD Evolve™ On-body Injector.

To be successful with the above strategies, pharmaceutical companies will need to rely on drug delivery systems that:

1. Address the complexity and variability around novel drug delivery characteristics
2. Enable drug product differentiation through solutions centered on the patient experience
3. Are designed to optimise the standard of care.

At BD, we understand these challenges and are developing solutions that will enable the delivery and successful commercialisation of complex biologics. With the introduction of the BD Evolve™ On-body Injector (Figure 1), we now give pharmaceutical companies a wearable solution that is designed to enable new delivery formats in alternate settings and is designed for customisation to support adjustments to existing formulations and variations in treatment regimens. Table 1

aligns key pharma strategies with supporting strategies BD can provide its pharma partner, together with specific beneficial features of the BD Evolve™ On-body Injector relevant to each strategy.

1. Addressing the Complexity & Variability Around Drug Delivery Characteristics

The number of biological drugs continues to increase rapidly (>900 biologics currently in development)⁵ as pharma companies seek novel formulation strategies as a way to treat challenging conditions more effectively and to retain their market position in the face of competition. Therapeutic formulations are progressing through development and becoming more complex as research continues to yield new types of drug products. Biologic attributes can range in dimension for volume, viscosity, dosing frequency and type of administration. In addition, some medications now require a more tailored delivery approach depending on the therapeutic area and

unique requirements of individual patient populations.⁶ The drug may need to be delivered in a single bolus format, turned on, off, or even modulated over time to enable more complex delivery profiles – continuous, episodic, timed, delayed, or delivery over multiple time frames.

For innovative pharmaceutical companies looking to commercialise a challenging biologic successfully, an advanced drug delivery device that is customisable and programmable to support different treatment regimens (across a range of delivery volumes for extended wear durations) can be beneficial. The BD Evolve™ On-body Injector is designed to be customisable to support different drug and delivery attributes and is designed to be programmable for delayed or timed administration of medications.

2. Enabling Differentiation Through Solutions Centred on the Patient Experience

A shared goal of both pharmaceutical companies and healthcare providers is to improve patient experience and outcomes. Today's patients are at the centre of the healthcare ecosystem, inspiring new research and delivery approaches, while becoming savvy consumers of health information. With the shift of care from hospitals to the home, patients are required to take a more active role in their care and demand more user-friendly, more convenient interventions. To address this trend, pharmaceutical companies are shifting formulations typically meant for intravenous (IV) delivery or intramuscular (IM) delivery to subcutaneous (SC) delivery formats.⁷

SC delivery offers patients greater convenience, flexibility for at home treatment, and greater control over their own treatment administration versus IV delivery. In addition, clinical researchers are looking at alternatives to intermittent bolus injections as a way to improve patient tolerability and elicit a more physiologically relevant response. For example, a recent NIH study in children with severe congenital hypoparathyroidism showed clinical advantage with medication delivered using a slow basal rate versus twice-daily injections.⁸

“BD Evolve™ enables effective SC administration of up to 3 mL of medication.”

Pharmaceutical companies seeking to differentiate their combination drug product can benefit from a device that enables effective SC administration of medications across a range of delivery volumes for extended wear in alternate sites. Such an advanced delivery device could also support value-added adjustments to existing formulations and improve the overall patient experience. The BD Evolve™ On-Body Injector is designed to enable new delivery formats in alternate settings and support various treatment conversions, such as IV to SC, IM to SC, and bolus to basal. BD Evolve™ also enables differentiation with smart capabilities to support remote and secure one-way communication of dosing information via Bluetooth.

3. Providing Solutions that Optimise the Standard of Care:

Healthcare systems are seeking solutions that enable providers to flex how treatment is delivered to the patient.⁹ With the shift to home-based care, providers are changing their perspectives to consider patients as partners in their care, whereby a patient is empowered to self-administer their medication and more empowered as part of the overall treatment decision making process. For many patients, the care journey can be cumbersome. From frequent hospital or care centre visits to managing multiple medications, patients are often loaded with all the extra steps involved in taking care of their health.

As an example, patients undergoing fertility treatments are often burdened with more than just the physiological and emotional stress of their treatment.¹⁰ These patients have to manage the organisational and logistical aspects of continuing their treatment including the need to make multiple trips to the clinic, sometimes over the weekend and in distant clinic locations.

“BD Evolve™ is filled at the time of use, designed to provide flexibility to support adjustments to existing formulations and variations in treatment regimen and can be worn for up to three days.”

“Providers are changing their perspectives to consider patients as partners in their care, whereby a patient is empowered to self-administer their medication and more empowered as part of the overall treatment decision making process.”

An advanced delivery device that can be pre-programmed to deliver the hormone treatment within the specified delivery window in the comfort of the patient's home could mean that the patient no longer needs to go into the clinic over the weekend. These patients can be empowered to self-administer their medication at home and providers can have the assurance that the right amount of medication will be delivered within the required therapeutic window.

Aside from patient convenience, these benefits can potentially lower the overall cost of patient care – reducing follow-up visits to the physician, clinics no longer have to open at the weekend or after hours to accommodate the specific timing of injection – thus reducing the total overhead costs for the providers. Patients can also save on the cost of transportation (to and from the clinic) and minimise lost wages, in cases where work is missed and wages are unpaid.

BD Evolve™ is filled at the time of use, designed to provide flexibility to support adjustments to existing formulations and variations in treatment regimen and can be worn for up to three days; allowing for convenient at-home medication delivery which may improve adherence as well as reduce the cost of care.

BEYOND TRADITIONAL DELIVERY BOUNDARIES

As an industry leader in parenteral delivery devices that help treat chronic disease, BD continually explores new ways to advance the standard of care for various conditions and healthcare challenges. An area of focus has been the delivery and successful commercialisation of complex biologics, a priority underserved by current delivery formats.

Our solution is designed to incorporate preferential attributes for our pharmaceutical partners, providers, and patients with the goal to improve the patient experience and lower the overall cost of care. With

the introduction of BD Evolve™ On-body Injector, we now give pharmaceutical customers an innovative solution for customisable and programmable SC administration of biologics. It is a system that is flexible, allowing for continuous, episodic, or delayed delivery across a range of volumes for extended wear and durations in alternate sites.

The BD Evolve™ On-body Injector goes beyond traditional delivery boundaries to address the changing needs of combination drug products:

- BD Evolve™ is designed to enable the delivery of novel biologics, support different drug and delivery attributes, and is programmable for delayed or timed administration of medications
- BD Evolve™ is designed to enable differentiation with connected capabilities to support remote and secure one-way communication of dosing information via Bluetooth
- BD Evolve™ enables effective SC administration of up to 3 mL of medication and provides greater flexibility for adjustments to existing formulations and variations in treatment regimens with up to three-day wear allowing for convenient at-home medication delivery which may improve adherence, reduce the cost of delivery, and optimise the standard of care.

In summary, the BD On-Body Injector System is a new solution that pushes traditional boundaries of drug delivery formats to serve the delivery demands of combination drug products.

BD Evolve™ On-body Injector is a product in development; some statements are forward-looking and subject to a variety of risks and uncertainties.

REFERENCES

1. Dilwali P, “From Acute Care to Home Care: The Evolution of

- Hospital Responsibility and Rationale for Increased Vertical Integration*". *J Healthcare Management*, 2013, Vol 58(4), pp 267-276.
2. Lybecker K, "The Biologics Revolution in the Production of Drugs". *Research Report*, Fraser Institute, July 12, 2016.
 3. Santilli J, Vogenberg F, "Key Strategic Trends that Impact Healthcare Decision-Making and Stakeholder Roles in the New Marketplace". *Am Health Drug Benefits*, 2015, Vol 8(1), pp 15-20.
 4. Taylor K, Ronte H, Haughey J, "Pharma and The Connected Patient – How digital technology is enabling patient centricity". *Research Report*, Deloitte, 2017.
 5. Beddoes C, "Understanding the Market for Wearable Large Volume Injectors". *ONdrugDelivery*, Issue 70 (Sep 2016), pp 4-7.
 6. Wen H, Jung H, Li X", *Drug Delivery Approaches in Addressing Clinical Pharmacology – Related Issues: Opportunities and Challenges*". *J AAPS*, 2015, Vol 17(6), pp 1327-1340.
 7. Haller M, "Converting Intravenous Dosing to Subcutaneous Dosing with Recombinant Human Hyaluronidase". *Pharm Tech*, 2007, Vol 31(10).
 8. Winer K et al, "Effects of Pump versus Twice-daily Injection Delivery of Synthetic Parathyroid Hormone 1-34 in Children with Severe Congenital Hypoparathyroidism". *J Pediatrics*, 2014, Vol165(3), pp 556-563.
 9. Pomey M et al, "Patients as Partners: A Qualitative Study of Patients' Engagement in Their Health Care" *PLoS One*, 2015, Vol 10(4), e0122499.
 10. Wu A, Elliott P, Katz P, Smith JF, "Time Costs of Fertility Care: The Hidden Hardships of Building a Family". *Fertility Sterility*, 2013, Vol 99(7), pp 2025-2030.

ABOUT THE AUTHOR

Temitope Sodunke is Strategic Innovation Leader for BD Medical – Pharmaceutical Systems, responsible for identifying and assessing new areas of opportunities (product, solution, and services) around delivery systems for injectable drug therapies. She has over 15 years of experience across multiple industries (pharma, defence, finance, and medtech). Her areas of expertise include innovation, strategy, and new product development. Dr Sodunke received her BSE in Biomedical Engineering from the University of Rochester (NY, US) and completed her graduate studies (MSE in Chemical Engineering and PhD in Mechanical Engineering) at the University of Pennsylvania (PA, US) and Drexel University (PA, US). She then completed a post-doctoral fellowship in Radiation Oncology at Harvard/MGH (MA, US).

Quote ONdrugDelivery and save \$100

PharmaED's

Extractables & Leachables Summit, 2020

Ensuring Quality, Safety, Suitability and Regulatory Compliance for Drugs, Biologics and Medical Devices

Wyndham Philadelphia Historic District

2nd-3rd
April
2020



PharmaED
RESOURCES, Inc.

Conference Highlights Include:

- CDRH Scientific Perspective on Chemical Analysis for Medical Devices
- Best Practices in Materials and Chemical Characterization of Med & Pharma Devices and Their Primary and Secondary Packaging
- Key Insights from Industry Working Groups—USP and BPOG
- Full Coverage of Relevant USP & ISO 10993 Chapters

Featured Speakers Include:

- Dennis Jenke, *Triad*
- Berk Oktem, *FDA*
- Ping Wang, *J&J*
- Carsten Worsøe, *Novo Nordisk*
- Sherry Parker, *WuXi AppTec*

Register online at: www.pharmaedresources.com

For further info, contact Kim: (217) 721-5774, or email us: khubbard@pharmaedresources.com



THE DIFFERENCE OF **ONE DRUG DELIVERED**

FOR BETTER TREATMENT OF CHRONIC DISEASES. Across the healthcare continuum, BD is the industry leader in parenteral delivery devices that help health systems treat chronic diseases. We not only continually advance clinically proven, prefillable drug delivery systems, we do so with a vision to help healthcare providers gain better understanding of how patients self-inject their chronic disease therapies outside the healthcare setting. This is why we partner with leading pharmaceutical and biotech companies worldwide to develop digitally connected self-injection devices—including wearable injectors and autoinjectors—to capture valuable data that can be shared with caregivers. Discover how BD brings new ideas and solutions to customers, and new ways to help patients be healthy and safe. **Discover the new BD.**



BD Libertas™ Wearable Injector



BD Libertas™ Wearable Injector
with Smart option

Learn more at bd.com/drugdeliversystems.bd.com/



BD Libertas™ Wearable Injector and BD Libertas™ Wearable Injector with Smart option are products in development; some statements made are subject to a variety of risks and uncertainty.

BD, the BD Logo and Libertas are trademarks of Becton, Dickinson and Company or its affiliates.
© 2019 BD. All rights reserved. BDPS27475