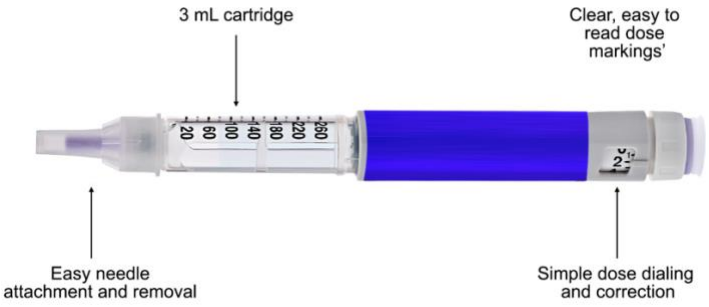
Self-Injection of Biologics Made Easy

By: Bryan K. Braxton, Ph.D, Director Aseptic R&D

The combination of an aging population and more people suffering from chronic diseases is making it difficult for healthcare professionals to effectively treat patients over the long-term, subsequently impacting patient compliance. Additionally, increasing patient volume and rising prevalence of chronic diseases are necessitating a need for self-injection devices. This has led to increased demand for patient-friendly self-administration systems, such as single-and dual-chamber cartridges in combination with a pen device. In fact, industry gurus estimate the global autoinjectors market, which includes cartridge-based systems, to be valued at more than $6.2 billion by 2027.[1]



Surpassing Injection Volume Limitations

Cartridge-based pen devices have found a place in managing Type 1 diabetes, pain management, cancer, hormone disorders, and Parkinson's disease. These devices contain a cartridge, a dial to measure dosage, and a disposable needle. Ready-to-Use (RTU) 3mL cartridge-based, single-use Pen Devices are specifically designed to ensure consistency of delivery for high-volume, high-viscosity injectable drug delivery systems. They are more simple, accurate, less intrusive, and convenient delivery than using a vial and syringe.

New biologic treatments that require greater dose volumes demand that devices be able to deliver larger and larger volumes. According to the National Center for Biotechnology Information, subcutaneous (SC) delivery of biologics has traditionally been limited to fluid volumes of 1–2 mL, with recent increases to volumes of about 3mL. This injection volume limitation poses challenges for high-dose biologics, as these formulations may also require increased solution concentration in many cases, resulting in high viscosities which can affect the stability, manufacturability, and delivery/administration of therapeutic drugs. Currently, there are technologies that can help to overcome these challenges and facilitate the delivery of larger amounts of drug through the SC route. This can be achieved either by enabling biologic molecules to be formulated or delivered as high-concentration injectables (>100 mg/mL for antibodies) or through facilitating the delivery of larger volumes of fluid (>3 mL).[2]

Aseptic Robotic Fill/Finish

Until recently, manufacturers did not have many options for rapidly producing products that command accurate cartridge filling in accordance with strict cGMP requirements. The aseptic robotic fill/finish possible with the GENiSYS® R offers adaptive and flexible process automation for ready-to-fill vials, syringes, and cartridges – all on the same machine. Both peristaltic and rotary piston dispensing systems are available to accurately fill each container directly on an electronic balance to provide up to 100% in-process fill weight inspection. The integrated Electronic Batch Report (EBR) System records critical process information that can be used to create 21 CFR Part 11 compliant batch reports. The state-of-the-art GENiSYS® R supports small batch sizes to aseptically and accurately fill 3mL glass cartridges. The innovative GENiSYS® R facilitates delivery of sterile clinical and small-scale commercial supplies with very aggressive timelines.

Glass Cartridges Protect Your Drug

Higher injection volumes and viscosities present a unique challenge to companies as they assess primary packaging component technologies. Primary packaging is of critical importance in biologics as this is the main point of contact between the drug and the device. Additionally, glass is easy to sterilize with heat and can protect medicines from ultraviolet rays. Finally, glass is easily recycled. These are all reasons why the global glass packaging market could reach $7.5 billion by 2028.[3]

Partnering with a CDMO like Pii can progress your drug's parenteral delivery from early-stage development concept to clinic. Pii can fill cartridges for use with a customer's pen device, for a variety of products, including biologics. Supporting a range of therapies that require frequent injections and variable dosing, the 3mL cartridge in combination with a pen device can improve patient compliance.

References

1. Sterile Injectables Device and Packaging Trends, by James Grote, Pharma's Almanac, Nice Insight, March 14, 2022.
2. Subcutaneous Delivery of High-Dose/Volume Biologics: Current Status and Prospect for Future Advancements, Advait V. Badkar, et. al., Jan. 13, 2021.
3. Global $7.46 Bn Pharmaceutical Glass Packaging (Vials, Bottles, Cartridges & Syringes, Ampoules) Markets to 2028, ResearchandMarkets.com, Sept. 24, 2021.

About Pii

Pharmaceutics International, Inc. (Pii) is a contract development and manufacturing organization (CDMO) with a passion for solving problems efficiently with the highest quality standards. Pii's Hunt Valley, Maryland campus includes 70 manufacturing suites with 4 integrated aseptic filling lines delivering quality, safety, and efficiency. Our professionals have extensive experience with small and large molecule compounds, developing and manufacturing complex parenteral drugs, extended-release formulations, non-aqueous injectable drug products, and lyophilization. Learn more at https://www.pharm-int.com/

About the Author

Devan Patel, Senior Director, Project Management

Devan Patel joined Pii in 2012 as a member of the Project Management team.

Devan has held roles of increasing responsibility in Project Management leading key development and commercial programs for Pii for both the orals and injectables. With his leadership, Pii has built a world-class Project Management Organization (PMO) consistently characterized by superb customer experience. Over the years, Devan has used his knowledge and technical skills to play a vital role for the Operations team, managing key initiatives for the Parenteral/Sterile business unit, including managing the overall scheduling and planning of all Aseptic Operations. His collaborative style when working with cross-functional teams across Pii's business units and ability to anticipate problems before they occur as raised the role of project management to an artform. Devan delivers a positive, outcomes-focused experience for our client-partners, from initial contact through successful completion of each project.

Devan earned his Bachelors in Cell Biology and Molecular Genetics from the University of Maryland and a M.B.A. from Johns Hopkins University.

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