Drug Development & Delivery

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Issue: Exclusive Online Content, **Posted Date:** 8/11/2014

Selecting the Right Delivery System for Subcutaneous Injection Therapies

By: Alan Shortall, Chairman and CEO of Unilife

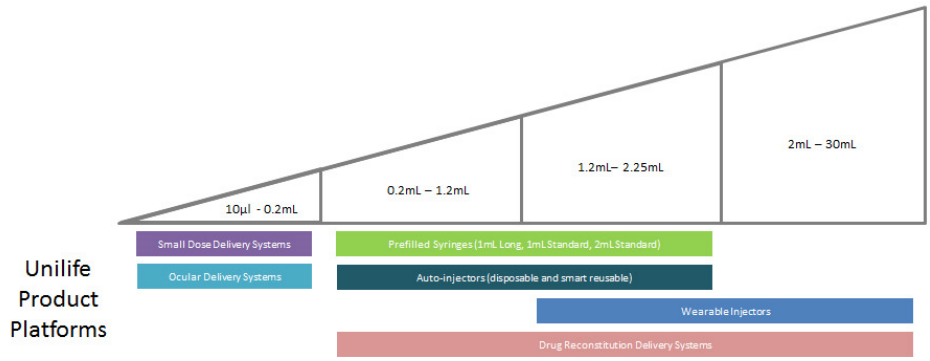
What is the peak dosing volume for a drug designed to be delivered via a bolus subcutaneous injection? At one time, the answer would have been a straightforward “up to 1 mL.” That answer however is fast on its way to redundancy. The rise of viscous biologic drugs, the shift toward patient self-injection, and the emergence of safer, simpler, and more convenient devices are all contributing to the expansion of what is possible for subcutaneous administration. The positive impact these converging market trends will have on healthcare productivity, therapy adherence, and brand differentiation is enormous.

Imagine the financial savings that can be attained by converting an approved oncology therapy from IV infusion in a specialty care center to a convenient subcutaneous self-injection in the home. Consider the potential for improving patient compliance with a therapy regime when a drug originally targeted for weekly self-injection can instead be administered monthly with reduced pain and discomfort. Additionally, what percentage of a patient population could a pharmaceutical company convert to their brand of therapy if it was supplied in a smart reusable auto-injector that reminded the user when to administer the medicine, enabled them to control the speed of automatic injection, and conveyed the pertinent information directly to their healthcare provider via Bluetooth?

To help pharmaceutical companies harness such opportunities to enable, enhance, and differentiate their injectable therapies targeted for subcutaneous injection, device companies, such as Unilife, have created a diverse range of product choices.

Prefilled syringes with an ergonomic design and automatic safety features can be supplied in a range of sizes including 1 mL Long, 1 mL Standard, and 2 mL Standard. Auto-injectors, particularly a new generation of smart reusable systems, can be leveraged for the controlled self-injection of doses of up to 2.25 mL or more. Wearable injectors, also known as bolus injectors or patch pumps, can be leveraged for the subcutaneous administration of dose volumes between 1 mL and 30 mL. And at the other end of the spectrum, highly accurate and precise devices allow for the subcutaneous injection of small doses measured in microliters.

Serving Customer Needs Across the Dose Volume Spectrum for Injectable Therapies



For any new product innovation to succeed in any market, it has to either save time or money. Safer, simpler, and more convenient delivery systems that are customized to the specific needs of a well-defined patient population have the potential to achieve both outcomes for a pharmaceutical company’s injectable therapy. Such delivery systems, which are differentiated and add value to the end-user, can be leveraged by a pharmaceutical company to build preference rates amongst patients, prescribers, and payors, with the potential to improve therapy adherence and build or protect market share.

But how do pharmaceutical companies select the right device to deliver the right drug with the right viscosity and the right dose volume over the right period of time to the right patient? The answer depends on a range of factors, including injection frequency, dose volume, drug viscosity, delivery rate and duration, as well as human factors, including pain, portability, or convenience that can drive therapy compliance and preference rates amongst the target patient population. Device-related factors that may also play a significant role include dose variability across a patient population, ease of use, the number of components, the need for dose adjustment, whether the drug must be refrigerated or kept at room temperature, and regulations regarding disposal of sharps or electronics.

The quest to find the right balance between dose volume, viscosity, and delivery duration in particular is becoming increasingly important to pharmaceutical and biotechnology companies for subcutaneous injection therapies. For example, would it be more desirable to subcutaneously administer a relatively viscous drug over a dozen seconds with a disposable auto-injector, or to utilize a disposable wearable injector pre-programmed to inject a larger, more diluted volume over a minute?

With devices becoming increasingly integral to the clinical development, regulatory approval, and lifecycle management of drug-device combination products, pharmaceutical companies are recognizing the strategic benefits of partnering with an industry expert that can help them optimize the clinical and commercial potential of their injectable therapies.

Until now, the selection of an experienced long-term partner with an agnostic view of the market for injectable drug delivery has been difficult. The market has traditionally been largely fragmented, with various device companies specializing in particular segments, such as disposable auto-injectors or ready-to-fill glass syringe barrels. Few companies until now have offered pharmaceutical companies a broad selection of device technologies that can accommodate most requirements for injectable biologics, drugs, and vaccines. As a consequence, pharmaceutical companies have been required to work with a wide variety of suppliers for particular devices as well as related sub-components, such as glass barrels and elastomers.

While pharmaceutical companies have established processes to coordinate the supply of products from multiple vendors, it can also create some challenges. These can include a reliance on the use of commodity products that limit opportunities for brand differentiation and customization, as well as the potential for quality variances between suppliers of the same component.

The responsibility for integrating parts of a particular device components, for example, the compatibility between a prefilled syringe glass barrel and an auto-injector, also falls largely on the shoulders of the pharmaceutical company. Furthermore, device manufacturers specializing in a particular market segment are likely to be naturally biased toward the selection of such a product by a prospective pharmaceutical company.

As a long-term partner to pharmaceutical and biotechnology companies for injectable drug delivery systems, Unilife has developed a broad, customer-centric portfolio of products that can be efficiently customized to meet the needs of a specific drug, patient, and commercial requirements. This platform-based portfolio includes prefilled syringes, auto-injectors, wearable injectors, drug reconstitution delivery systems, and small dose delivery systems. The breadth and depth of these platforms, together with an ability to create other innovative device solutions, enable Unilife to broadly accommodate its customers' needs across virtually all injectable drug categories outside of insulin, which is already a well-served space.

For drugs targeted for subcutaneous self-injection, Unilife is well positioned to meet customer requirements from the delivery of small doses measured in microliters to volumes as high as 30 mL or more. Within the 1 mL to 3 mL dose volume range that is becoming a focal point for many biologics, Unilife provides a multitude of product choices, including prefilled syringes with integrated, automatic needle retraction, smart reusable auto-injectors that can control the speed of injection and provide needle-free disposal, dual-chamber systems for the automatic reconstitution or mixing of combination therapies, and a broad platform of wearable injectors.

With such an extensive portfolio, Unilife is able to remain impartial during the decision-making process for a particular device technology. Instead, it focuses on supporting the pharmaceutical customer to ensure they receive the product that best matches their specific requirements. Unilife can also work with customers to select preferred materials or component suppliers.

These competitive advantages make Unilife an attractive choice for pharmaceutical and biotechnology companies seeking a long-term partner that can enable them to enhance and differentiate their drug portfolios. To find out more about Unilife's range of products and services, please contact a member of our commercial development team via **www.unilife.com** or +1 717 384 3400.

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