THE GREAT SHIFT

HOW SUBCUTANEOUS INJECTABLES ARE REDEFINING DRUG DELIVERY

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Singota® Solutions is a CDMO located in Bloomington, Indiana (with 3 strategic locations outside the U.S.) that specializes in Parenteral, Early Phase Drug Development and Aseptic Filling projects.

Imagine a world where your life-saving medication doesn't require a hospital visit, an IV drip, or hours of your time. Instead, it's as simple as a quick injection you can administer at home. Welcome to the era of subcutaneous (SC) injectables - a transformative shift in drug delivery that's turning heads and changing lives.

This isn't just a minor tweak in administration routes; it's a seismic shift in how we approach treatment, patient compliance, and healthcare efficiency. Let's delve into the science, the challenges, and the innovations propelling this change. In this article, we explore how subcutaneous injectables are reshaping the pharmaceutical landscape.

The Rise of Subcutaneous Injectables

Traditionally, many biologic therapies, such as monoclonal antibodies used in cancer treatments, have been administered intravenously (IV). While effective, IV administration of medicines require clinical settings, trained personnel, and significant time commitments from patients.

Recent advancements, however, are challenging this norm. Pharmaceutical companies are developing SC formulations of existing IV therapies, offering comparable efficacy with added convenience. For instance, Merck's development of a SC version of Keytruda demonstrated non-inferiority to its IV counterpart in lung cancer patients, with the added benefit of a 2-3 minute administration time compared to a 30-minute IV infusion.

Similarly, Bristol Myers Squibb's SC formulation of Opdivo, branded as Opdivo Qvantig, received FDA approval, providing a more accessible option for patients with solid tumors.

Advantages of SC Administration:

- **Patient Convenience**: SC injections can often be self-administered, reducing the need for frequent hospital visits and allowing patients to maintain their daily routines with minimal disruption. Patients gain quality of life benefits by having more control over the time of day they prefer for drug administration. They also avoid the cost and time burdens of arranging transportation from home to site of care. For any patients who may be immuno-compromised, there is a benefit to avoiding the infectious disease risk of entering the healthcare site’s more crowded space to receive needed medicine.

- **Healthcare Efficiency**: By shifting administration from clinical settings to at-home environments, healthcare systems can allocate their physical space and onsite resources more effectively, focusing on patients requiring more intensive care.

- **Cost Reduction**: SC formulations can lower overall treatment costs by minimizing hospital stays, reducing the need for specialized equipment, and decreasing personnel requirements and associated labor costs. Potentially offsetting this, SC formulations are often higher concentration doses and may command premium prices for the manufacturer. Such higher concentration dosing may ultimately serve the patient’s best interest though, by enabling a longer duration of patient response and fewer overall drug administrations.

- **Improved Compliance**: The simplicity and convenience of SC injections can lead to better patient adherence to treatment regimens, potentially improving outcomes.

Challenges in Developing SC Formulations

While the benefits are clear, developing SC formulations isn't without hurdles:
Formulation Challenges: Since subcutaneous injections typically must be delivered at a higher concentration, stability and immunogenicity risk have to be understood and properly managed to enhance patient outcomes.

Volume and Viscosity: A subcutaneous injection must be designed with a limited volume size given the target tissue's capacity to absorb the injection. High-viscosity formulations can cause injection site discomfort or require specialized delivery devices.
Immunogenicity: Altering the administration route can affect the immune response, necessitating thorough evaluation during development to confirm equivalent safety.

Device Integration: Developing user-friendly delivery devices, such as autoinjectors or wearable pumps, can dramatically improve patient compliance and willingness to take medicine via SC administration.

Innovations Driving the Transition

Advancements in formulation science and delivery technologies are addressing these challenges:

- Enzyme-Based Enhancers: Co-formulating drugs with enzymes like hyaluronidase can increase tissue permeability, allowing for larger volume injections.
- Wearable Injectors: Devices capable of delivering high-volume, high-viscosity drugs over extended periods are expanding the possibilities for SC administration.
- Prefilled Syringes and Autoinjectors: These devices simplify administration, improve dosing accuracy, and enhance patient confidence.

Embracing the Future with Singota Solutions

The shift towards subcutaneous injectables represents a significant advancement in patient-centric care, offering convenience, efficiency, and improved patient medication use compliance. However, developing these formulations requires expertise in overcoming the associated scientific and technical challenges.
At Singota Solutions, we specialize in early-phase injectable drug development, providing tailored solutions that address the complexities of SC formulation. Our integrated approach combines formulation development, analytical testing, and aseptic fill/finish services, ensuring your product is ready for the next stage of development.

In the world of drug delivery, it turns out the biggest breakthroughs don't always come with a splash - sometimes, they come with just a tiny poke under the skin.