



A FLEXIBLE PLATFORM DEVICE TO STREAMLINE MARKET LAUNCHES

Chronic diseases are one of the world's major challenges, causing staggering human and economic costs. As well as affecting quality of life for patients and their families, they place a huge burden on overstretched healthcare systems and global economies, while also presenting an important challenge to pharma companies.

One such example is diabetes. Worldwide, around

537 million adults are living with diabetes, and that figure is expected to rise to 643 million by 2030 and 783 million by 2045 [1]. It is a disease that accounted for more than \$966 billion of health expenditure in 2021 – 9% of total spending on adults – although it is understood that half of people with diabetes do not meet treatment goals for glucose lowering, which is key to managing their condition.

One of the major drivers behind the growing number of diabetic patients is rising rates of obesity, a factor that is known to put patients at greater risk of developing diabetes. Currently, more than 650 million people around the world are living with obesity and this figure is expected to reach more than one billion people by 2030 [2]. The condition accounts for 8% of global healthcare budgets and in the US alone the economic impact

associated with obesity is more than \$1 trillion. Despite these startling statistics, however, fewer than 3% of people with obesity are pharmacologically treated for it.

Pharma innovation continues to play a key role in addressing the human and financial burden of managing chronic conditions such as diabetes and obesity. The growing emphasis on self-administration of medication,

for example, provides the means to ease the pressure on health services, improve compliance and make everyday life more convenient for patients. And with the Covid-19 pandemic accelerating this trend as routine patient visits to healthcare facilities plummeted, pharma companies have intensified their focus on drug delivery devices that patients can use in their own homes.

Key to the success of any drug delivery device are factors such as proven technology, low development costs, fast time-to-market and a strong intellectual property (IP) position for the pharma company. Against this background, platform drug delivery devices have become more important than ever, providing an 'off-the-shelf' choice that minimises project risk and avoids the requirement for an up-front investment of millions of dollars to fund the development of new bespoke devices. Instead, the availability of customisation options to suit a variety of different drugs and primary packaging with minimal change in components keeps costs down and offers faster time-to-market, enabling patients to benefit from new therapies sooner rather than later.

Stevanato Group's Alina pen-injector is an example of a platform device for variable and multi-dose treatments for conditions such as diabetes and obesity. The device has a user-friendly

design to improve the patient experience. It is intuitive for patients, with minimal user steps, and is designed to give confidence and reassurance.

To help patients select the right dose, Alina has only one number visible in the dosing window at any given time and the dose can be corrected with a simple dial back. Patients receive visual, audible and tactile feedback for dose setting, correction and injection, and the injection force is optimised for patient comfort.

For pharma companies choosing Alina, there are many advantages. The device can be used for different applications as it can deliver a range of different maximum doses – 0.30mL, 0.50mL and 0.6mL – in one shot. In addition, the availability of a range of branding and customisation options means that individual colours can be selected for each market segment.

Design for manufacturing and ease of final assembly have also been taken into account to optimise the production process. The device is manufactured at Stevanato Group's FDA-inspected facility in Germany, where access to tooling and sub-assembly equipment is available to clients aiming to maximise the return on investment in their device programmes and reduce time to market. Dedicated production tooling and lines are available on request for customisation or to support

overall risk mitigation strategies.

Alina is fully compatible with Stevanato Group's range of glass cartridges – such as bulk and ready-to-use EZ-fill cartridges – as well as the company's final assembly equipment. Moreover, Alina is compatible with a variety of fill-and-finish systems.

Alina can be provided as a flexible device platform because, as a full solution provider, Stevanato Group has a deep understanding of how pharmaceutical products, containers, closures and drug delivery devices interact with each other and work together to form a cohesive system. This holistic approach means pharma companies looking for customised drug delivery and containment solutions can benefit from tailored solutions that combine products and technologies into a coherent, integrated offering.

Stevanato Group's scalable approach allows for straightforward technology transfer from low volumes – typical in the clinical phase – to mass production on

high-volume equipment, enabling pharma companies to anticipate challenges, mitigate risk and reduce investment costs.

By working closely with a supplier who can provide a holistic strategy – offering optimised glass containment and device services as well as the appropriate equipment and analytical testing – companies can simplify their commercial journey.

Indeed, Alina was developed to address the need to reduce the complexity of the supply chain, and this philosophy of efficiency is applied to all processes relevant to the development of a combination product, from initial concept through to its launch on the market.

Through the combined support of a platform such as Alina and the complementary Stevanato Group's expertise as full-solution provider, therefore, pharma companies have the flexibility and capability to streamline the market launch of new drug delivery devices, and patients are ultimately given greater flexibility in managing their chronic conditions.

1. "Diabetes facts & figures". International Diabetes Federation, Dec 2021.
2. "World Obesity Atlas 2022". World Obesity, Mar 2022.
