SIMPLIFYING GLP-1 DELIVERY THROUGH A FULLY INTEGRATED APPROACH

THE IMPLICATIONS OF SOARING GLP-1 DEMAND

Incretins – commonly referred to as GLP-1 receptor agonists, as the first agents in this class (exenatide and liraglutide) as well as the first widely used therapy (semaglutide), mimic the gut hormone GLP-1 – represent one of the fastest-growing therapeutic classes globally. Initially developed for the management of Type 2 diabetes, these agents are now widely recognized for their ability to address the metabolic triad of

Stevanato Group

Stevanato Group is a leading global provider of drug containment, drug delivery, and diagnostic solutions to the pharmaceutical, biotechnology, and life sciences industries. The Group delivers an integrated, end-to-end portfolio of products, processes, and services that address customer needs across the entire drug life cycle at each of the development, clinical, and commercial stages.

glycemic control, weight reduction, and cardiovascular risk mitigation. As of today, the incretin class extends beyond single-receptor agonism (e.g., semaglutide, GLP-1) to include dual agonists (e.g., tirzepatide, GLP-1+GIP). Furthermore, ongoing clinical trials are evaluating multi-agonist approaches that combine incretin receptor activity with additional pancreatic hormones, such as amylin and glucagon. (e.g., cagrisema, GLP-1+Amylin and retatrutide, GLP-1+GIP+Glucagon[1]). Thanks to their demonstrated benefits across multiple indications and ongoing clinical investigations in additional areas such as Alzheimer's disease, incretin-based therapies have become the fastest growing class within the injectable therapeutics market.

With semaglutide expected to lose market exclusivity in several major markets in 2026 (including China, India, Canada, and Brazil), the

anticipated entry of new originator companies alongside the resolution of supply constraints affecting the big market players, has significantly expanded patient access. As a result, the treated patient population has more than doubled in recent years and is projected to continue growing at a double-digit rate in the medium term [2-3].

As access expands and patient demand increases – particularly in currently underpenetrated markets – the pharmaceutical industry faces several critical challenges. These include the need for optimal device and primary container selection, accelerated time-to-market strategies for biosimilar developers and new originator entrants, and the establishment of resilient supply chains to prevent shortages in the event of demand surges.

DEVICE SELECTION CONSIDERATIONS

While some GLP-1 treatments are being developed as oral formulations[4], injectable delivery is expected to remain a primary modality for the foreseeable future. In this context, device selection plays a critical role, as it can directly influence patient experience and therapy adherence, while also affecting treatment flexibility and the ability to support dose evolution over time. Beyond the patient interface, device choice has important implications for pharmaceutical partners, including development timelines, regulatory strategies, manufacturing scalability, and regional market access.

As a result, Stevanato Group has developed a portfolio of complementary injection device platforms – spanning pen injectors and autoinjectors – designed to address diverse therapeutic needs, patient preferences, and supply chain strategies across the GLP-1 landscape.

A COMPLEMENTARY PORTFOLIO OF DRUG DELIVERY SYSTEMS

As of 2026, Stevanato Group's GLP-1 offering includes three hand-held drug delivery device platforms: Alina®, a variable-dose pen injector; Deora™, a fixed-dose pen injector; and Aidaptus®, a two-step, single-use autoinjector.

Alina® is a variable-dose, disposable pen injector platform designed to support established and innovative therapies, with a user interface

focused on clarity and control. Its dose window displays only the selected dose, helping reduce the risk of confusion during dose selection, while a linear motion supports more intuitive handling during injection.

Based on a 3 mL cartridge, Alina® offers preconfigured off-the-shelf variants that support both variable-dose and fixed-dose GLP-1 applications. The platform also enables defined customization of key parameters – such as maximum selectable dose, markings, and colors – while maintaining a consistent user experience. The device is manufactured at Stevanato Group's facility in Germany, allowing pharmaceutical partners to leverage existing tooling and subassembly lines without the need for bespoke equipment development.

The **Deora™** fixed-dose pen injector is designed for the delivery of multiple "true" fixed doses up to 0.75 mL. Unlike variable-dose devices, the user does not need to manually measure each dose. Instead, Deora™ operates with a simple, two-step, pull-push mechanism for dose setting and delivery. The user pulls to set the dose then pushes to inject, receiving tactile and audible confirmation after each step.

Deora™ has been developed as a platform product, supporting multiple configurations. Compatible with both 3 mL and 1.5 mL cartridges, the device's delivered dose volume can be customized, so that changes during a treatment period – such as monthly dose modifications – can be accommodated without affecting the patient's experience. The device is engineered to align with standard manufacturing processes, with a low component count to simplify both production and assembly.

Aidaptus® is a two-step, single-use autoinjector designed to support subcutaneous drug delivery with an intuitive and familiar user experience. The platform accommodates both 1 mL and 2.25 mL prefilled syringes within a common form factor and

supports fill volumes ranging from 0.3 mL to 2.25 mL. This flexibility is enabled by a self-adjusting plunger rod technology that supports multiple dose and fill configurations without part changes, helping reduce SKUs and simplify final assembly. Compatibility with special thin wall (sTW) needles can help reduce injection time and force, while different drive spring configurations support consistent dose delivery across a wide range of viscosities. As a result, the platform is well-suited for use across multiple injectable assets and can support dose exploration during clinical development as well as commercial lifecycle management strategies.

Aidaptus® is delivered through a strategic collaboration with Owen Mumford Pharmaceutical Services, combining complementary expertise in devices, syringes, manufacturing, and industrialization. A multi-site manufacturing footprint and an integrated supply model support scalable and reliable global supply.

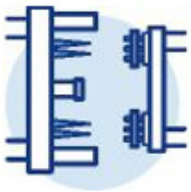
AN INTEGRATED OFFERING

Stevanato Group can serve GLP-1 production processes with comprehensive solutions that cover the full pharmaceutical value chain. The company's unique position in the market allows end-to-end provision of primary packaging, devices, machinery, and analytical services.

Stevanato Group supports the whole development journey.

OPTIMIZED PRIMARY PACKAGING

DEVICE TESTING



INJECTION MOLDING

ASSEMBLY EQUIPMENT

RELIABLE DRUG CONTAINMENT SOLUTIONS

Glass plays a crucial role in protecting drug integrity and the performance of any parenteral injection device. Leveraging our scientists know-how and accurate knowledge

of the forming process, we offer primary packaging optimized for the integration with drug delivery systems. Nexa® is our solution designed to address all of the challenges related to GLP-1 production and offering our customers a high-quality system enabling them to produce high volumes efficiently.

NEXA® EZ-FILL® READY-TO-USE CARTRIDGES FOR OPTIMAL PROCESSABILITY

The Nexa® EZ-fill® cartridges are ideal for complex and sensitive drugs, featuring an innovative baked-on siliconization technology that minimizes the release of subvisible particles and reduces the content of inorganic extracts from glass without compromising break-loose and gliding forces. The result is improved stability and minimized interactions between the drug (i.e. GLP-1) and the container. The manufacturing strategy for Nexa® EZ-fill® cartridges reduces the risk of rejections, complaints, and recalls through multiple measures. Firstly, manufacturing the cartridges does not involve glass-to-glass processes or packaging, leading to superior cosmetic quality and high mechanical performance.

These two factors are critical to ensure efficiency and reduce risk during the filling and final assembly phases for injection devices. Secondly, Stevanato Group integrates technologically advanced in-line systems in its manufacturing lines to inspect and control the tight parameters requested by pharmaceutical companies.

To test the stability of the cartridge's performance, Stevanato Group's Technology Excellence Centers performed a characterization study using 3 mL Nexa® EZ-fill® ready-to-use cartridges filled with a mimic solution representative of a GLP-1 agonist formulation (Semaglutide). Stability was assessed over a period of 6 months at 5°C ± 3°C.

The following graphs present the key results of the study and each caption notes the positive results in each case.

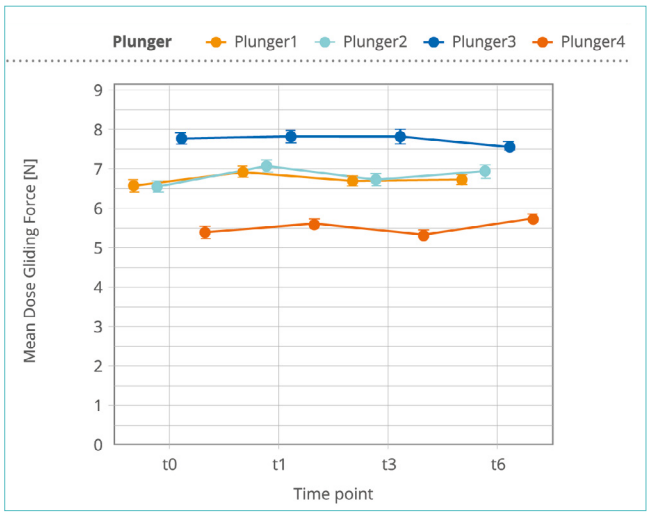


Figure 1

Results of Mean Dose Gliding Force at 5±3°C over six months. The homogeneous silicone layer in the Nexa® EZ-fill® 3 mL cartridges creates a consistent gliding performance over time, with less variability between samples.

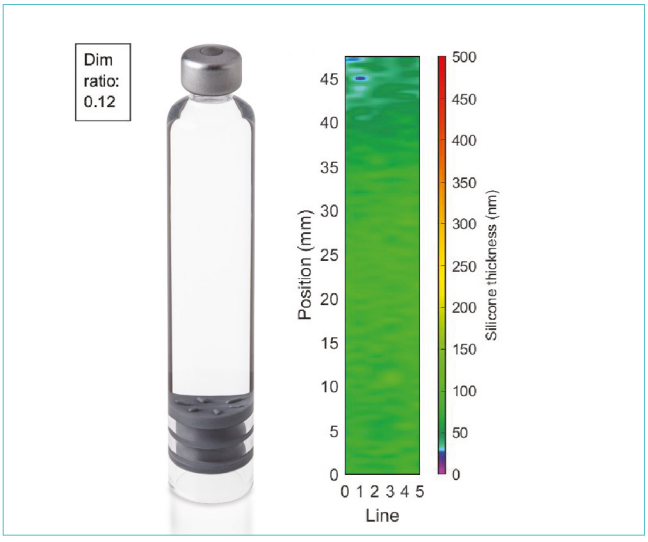


Figure 2

Results showing homogeneous silicone layer in terms of highly consistent thickness and even distribution.

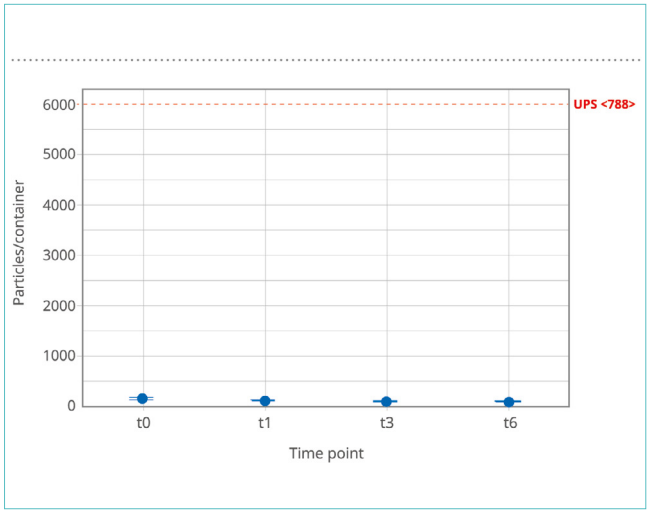


Figure 3

Results of sub-visible particle testing ≥ 10 µm at 5±3°C over six months. Nexa® EZ-fill® 3 mL cartridges, tested according to USP <788>, show a low sub-visible particles release, always below USP limits: 6000 particles/container ≥ 10 µm and 600 particles/container ≥ 25 µm.

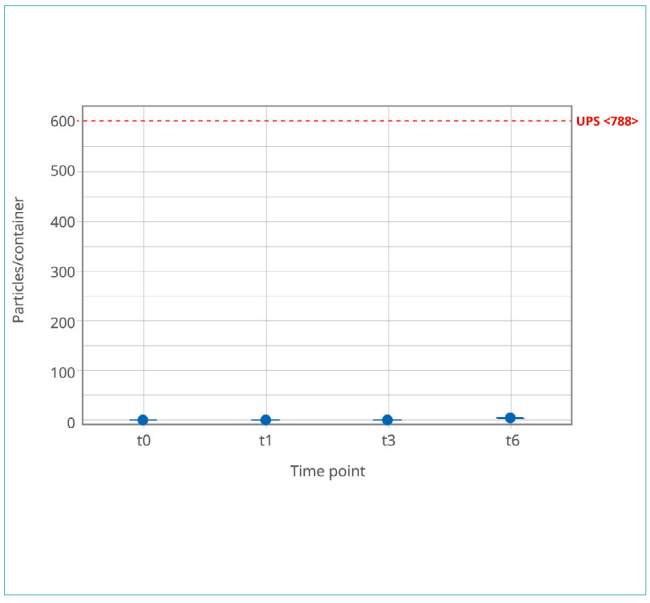


Figure 4

Results of sub-visible particle testing ≥ 25 µm at 5±3°C over six months, showing remarkably consistent performance over time.

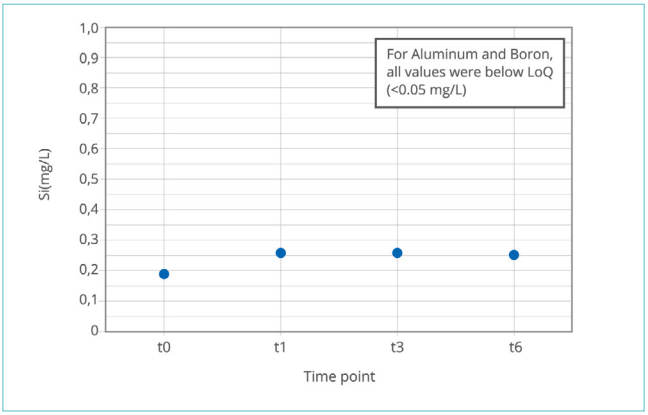


Figure 5

Results of Mean Silicon Value (mg/L) at 5±3°C over six months. The major glass extractable elements are: Aluminum (Al), Boron (B) and Silicon (Si). Nexa® EZ-fill® 3 mL cartridges showed comparable mean extractable values over time.

NEXA® SYRINGES FOR CONSISTENT PERFORMANCE

Nexa® high-performance syringes demonstrate proven integration with autoinjectors, supporting the growing demand for drug products that patients can self-administer from the comfort of their own homes. The lean manufacturing processes are designed to ensure no glass-to-glass and no metal-to-glass contact. These syringes offer a series of further benefits to pharma companies in their go-to-market strategies and processes, including:

- Ultra-low tungsten manufacturing, with particle reduction through barrel washing.
- Optimized silicone oil distribution to provide enhanced gliding performance and consistent injection times.
- Advanced in-line inspection technologies to minimize the risk of breakages in downstream process and potential wastages.

SCALABLE MANUFACTURING

Here too, Stevanato Group's in-house engineering capabilities limit the complexity and risks that can arise when engaging with multiple third parties. Where required, Stevanato Group offers in-house expertise in the design and delivery of highly efficient and flexible device assembly production lines. This option delivers time and cost savings for pharma partners in various scenarios, including where final assembly must be completed at the pharma company's site or at their contract development and manufacturing organization (CDMO). Additionally, the core and consistent assembly technology that spans from Stevanato Group's smaller benchtop assembly unit to its higher commercial assembly platform supports efficient industrialization and scale-up.

REFERENCES