Stevanato Group

For more than 75 years, we have been committed to providing integrated solutions for pharma and healthcare, leveraging on constant investment and the acquisition of skills in new technologies. A rich, international heritage has brought us to become a global player in the pharma industry.

THE CONSTRAINTS AND INNOVATIONS IN THE PACKAGING OF BIOLOGIC DRUGS

Biologic drugs are transforming the treatment of chronic and complex diseases.

Yet due to the nature of these complex, protein-based therapies, their potential for interaction with packaging materials poses significant challenges for containment and delivery across the supply chain. At the same time, the growing preference for at-home treatment and self-administration is reshaping how patients use and interact with these new therapies.

To keep pace with shifting patient expectations and the complexity of biologic therapies, drug developers are embracing advanced delivery solutions, which are enabling safer, more convenient self-administration with improved drug stability and regulatory compliance.

We look at how modern packaging strategies are evolving to address the twin pressures of technical performance and patient-centric design - and why integrated systems like Alba® syringes, Nexa® syringes, and the Aidaptus® auto-injector are at the forefront of this transformation.

Market Dynamics and Patient-Centric Trends

Biologics are becoming increasingly favored for their targeted action and lower side effect profiles in treating complex and chronic diseases - including cancer, autoimmune disorders, and rare conditions - and are supported by advances in biotechnology, and an aging global population. Additionally, the emergence of biosimilars and evolving regulatory frameworks are driving further market expansion and influencing how biologics are developed, delivered, and administered.

A critical challenge in biologic drug development is managing interactions between the product and its

primary container. Leachables from materials like glass or silicone, or extractables from adhesives, can trigger protein aggregation or reduce efficacy. In addition, the large and structurally complex nature of biologic molecules makes them highly sensitive to environmental factors - requiring packaging strategies that maintain stability and prevent degradation.

In addition, patient preferences are increasingly shifting toward self-administration at home, driven by the desire for greater convenience and autonomy. As a result, drug developers face growing pressure to design packaging and delivery systems that support frequent, long-term use. To reduce the treatment burden, many biologics are being reformulated for less frequent dosing, often by increasing drug concentration. However, this creates additional challenges related to viscosity, stability, and administration time that must be addressed through innovative delivery solutions.

With growing demand and evolving treatment models, expectations are expanding beyond efficacy to include how biologics are stored, delivered, and used by patients. These pressures are driving developers to rethink packaging strategies and ensure they not only protect product integrity but also support real-world administration and patient-centered care.

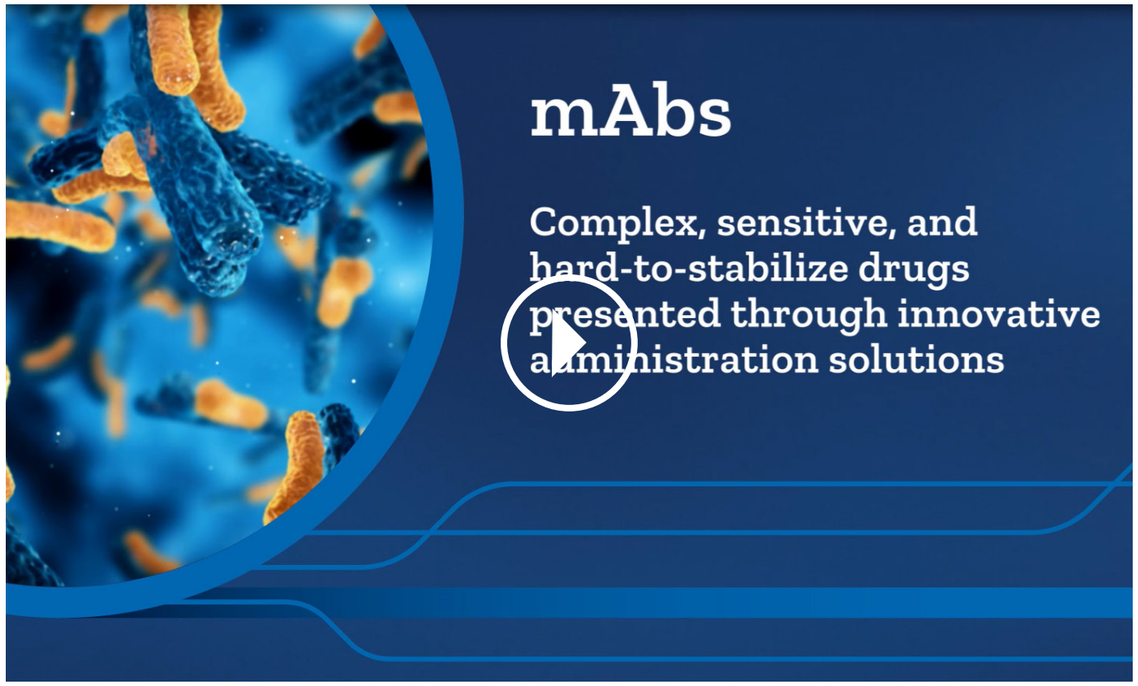
Regulatory Considerations and Lifecycle Alignment

Alongside scientific and market pressures, regulatory expectations have grown more stringent to demand a lifecycle-oriented approach to biologic packaging. Global frameworks and guidance on container-closure integrity place increased emphasis on the need for validated, contamination-resistant packaging systems that ensure product quality and safety from manufacturing through to patient use.

Both EU Annex 1 and FDA regulations require validating the compatibility, integrity, and safety of packaging and delivery systems. Annex 1 (Section 8) mandates container closure integrity testing (CCIT) to ensure sterility is maintained, explicitly stating that visual inspection alone is insufficient. In the U.S., 21 CFR 211.94 and the FDA's container closure guidance call for rigorous testing of container systems to ensure adequate protection, chemical compatibility, and functional performance - especially for high-risk formats like injectables and inhalation products.

In parallel, extractables and leachables (E&L) testing is now considered essential to assess the potential for harmful chemical migration. USP <1663> evaluates extractables - compounds that could leach under worst-case conditions - while USP <1664> focuses on leachables that actually migrate into the drug under normal use. These studies are supported by ICH Q3C and Q3D, which set safety thresholds for residual solvents and elemental impurities respectively, both of which may originate from packaging or processing equipment.

Taken together, these evolving regulatory standards reinforce the need for manufacturers to not only understand but proactively address container-closure risks. This makes it essential in choosing a partner with the capabilities to navigate complex regulatory demands and deliver validated packaging solutions.



Innovation in Syringe Design – Alba® and Nexa® Platforms

The need to accommodate the specific demands of biologic drug delivery is accelerating innovation in syringe technology.

Stevanato Group's Alba® and Nexa® platforms represent next-generation solutions designed to overcome key challenges related to drug stability, device compatibility, and user-friendly administration that supports both regulatory compliance and patient-centric care.

Alba® Syringes: A Breakthrough Platform for Sensitive Biologics

Alba® platform is specifically designed for sensitive, high-value biologic drugs. Its proprietary plasma-treated, cross-linked silicone coating creates a stable barrier between the drug and container, minimizing interaction between the drug and its container to maintain long-term drug stability.

Featuring an ultra-low extractables profile - reducing sub-visible particles, tungsten, and glue-related impurities - makes it ideal for formulations prone to degradation or requiring high purity. Functionally, Alba® provides consistent gliding force over its shelf life, to ensure reliable performance in auto-injectors and enhanced patient comfort.

With a strong focus on drug integrity, device performance, and patient safety, Alba® is the next-generation syringe platform that helps pharmaceutical companies meet the stringent demands of biologic delivery while streamlining product development and lifecycle management.

Nexa® Syringes: Superior Quality and Performance for High-Value Sensitive Injectabless

The rise of GLP-1 receptor agonists for diabetes and obesity is reshaping injectable drug delivery and creating demand for systems that ensure safety, reliability, and seamless integration with auto-injector devices. Stevanato Group's Nexa® platform meets these demands with a syringe system engineered for consistency, precision, and compatibility.
Nexa® syringes are optimized for use in self-injection devices to deliver a smooth and predictable gliding and injection force - a critical factor in patient adherence and comfort. Featuring ultra-low levels of tungsten and glue residuals, it reduces the risk of interaction with sensitive biologics and supports higher drug stability and safety standards.

Manufactured to the highest cosmetic and dimensional specifications, Nexa® syringes offer mechanical resistance reducing the risk of breakage during processing, transport, and use. With each unit undergoing 100% camera inspection, you can be sure of superior cosmetic quality and compliance with the most stringent regulatory and manufacturing requirements.

Designed for pharmaceutical companies launching high-value, self-administered therapies, Nexa® enables smooth integration into automated assembly lines and device systems, providing a robust container platform that enhances performance, simplifies quality assurance, to support the successful delivery of next-generation injectable treatments.
Together, Alba® and Nexa® represent the forefront of syringe innovation - combining pharmaceutical performance with patient-centric design. By integrating a Special Thin-Wall Needle, they reduce extrusion force and injection time by nearly 50%, thereby enhancing usability and patient experience.

Enabling Innovation Through Auto-Injector Integration: The Aidaptus® Platform

As the demand for self-administered therapies grows, so must the auto-injector technologies responsible for accommodating these complex formulations - without compromising reliability or patient experience. Stevanato Group's answer comes in the form of its collaborative partnership with Owen Mumford Pharmaceutical Services (OMPS), a pioneer in the auto-injector space whose portfolio includes the Aidaptus® auto-injector platform.

At its core, Aidaptus® is a 2-step, single-use auto-injector with a versatile design that accommodates both 1mL and 2.25 mL prefilled glass syringes in the same base device. Stevanato Group is the exclusive ma-

nufacturing and commercial partner for Aidaptus®.

One key feature of this device is its self-adjusting plunger, which compensates for variations in stopper positions. This eliminates the need for device reconfiguration when switching drug batches or formulations, enhancing patient usability and simplifying production logistics. Precision engineering is another defining attribute of Aidaptus®, with tight dimensional tolerances that maintain consistent injection depth and support safe subcutaneous delivery, with a robust mechanical design that enhances durability for a wide range of drug characteristics and patient conditions.

Critically, Aidaptus® is compatible with both Alba® and Nexa® syringe platforms. This flexibility enables pharmaceutical companies to optimize for specific drug and formulation requirements without compromising device performance or patient experience. By aligning drug containment and delivery systems in a single integrated platform, Aidaptus® empowers both innovation and operational efficiency with commercial scalability.

Meeting the Dual Demands of Innovation and Usability

Together, these platforms form a connected ecosystem that supports both technical and commercial objectives that enable pharmaceutical companies to meet increasing regulatory expectations while delivering therapies that are not only safe and effective but also accessible and user-friendly.

As the biologics market grows and patient preferences continue to evolve, solutions like Alba®, Nexa®, and Aidaptus® will be instrumental in bridging the gap between complex formulations and patient-centric delivery to ensure the future of drug development is both innovative and inclusive.

Aidaptus® auto-injector