



Products & Capabilities

Contract Manufacturing Solutions for Drug Delivery Systems



Stevanato Group

MANAGING COMPLEXITY, DELIVERING VALUE

Process Harmonization Through an Integrated Development

Stevanato Group provides a comprehensive suite of products, technologies and services for companies seeking to launch advanced drug delivery systems.

Thanks to our integrated approach to product development, we can harmonize each of the different production phases – from the definition phase to the production phase, including global supply of your device.

We have decades of experience in production technologies, quality control and knowledge of the regulatory environment resulting in high-quality drug delivery devices that are fully optimized to perform as a system.



AUTO-INJECTORS



WEARABLES



PEN INJECTORS





Definition Phase

Bringing your ideas to life, resulting in a product requirement document that anchors the project moving forward



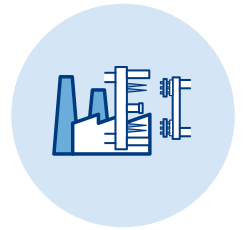
Concept Phase

Defining a suitable container closure system, elaborating device concepts & constructing mock-ups



Development Phase

Optimizing development & documentation; testing, studies, risk management, regulatory verification & DfM



Production Phase

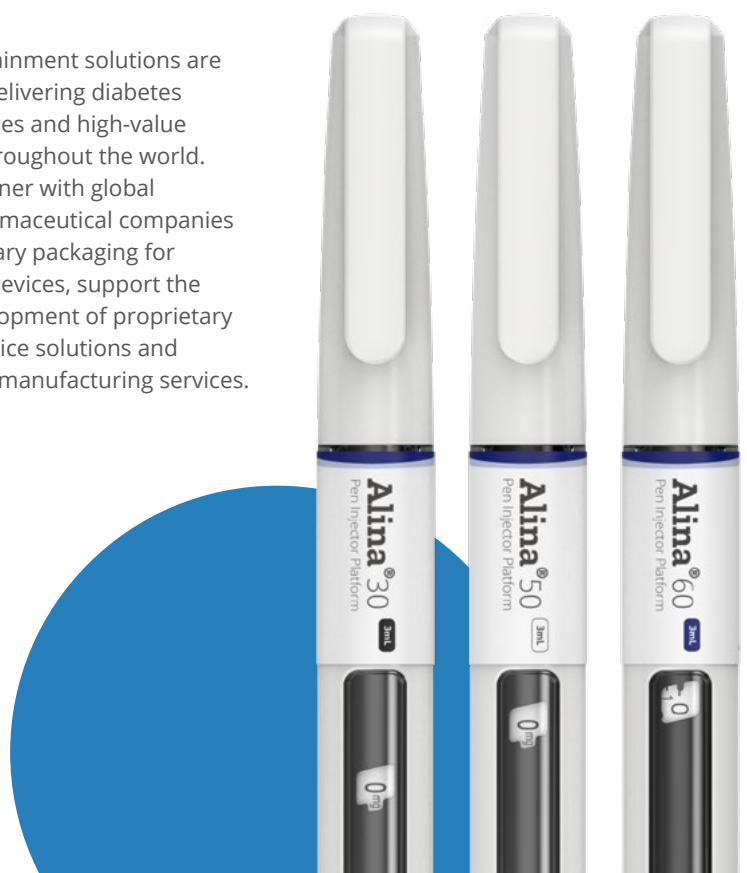
Synergizing our extensive production & assembly capabilities to maximize efficiency & product quality

Experienced Partner Trusted for Generations

Stevanato Group is a trusted partner in the pharmaceutical industry, with over 70 years of experience in glass processing technologies.

Our drug containment solutions are relied upon for delivering diabetes treatment, vaccines and high-value biologic drugs throughout the world.

Today, we partner with global biotech and pharmaceutical companies to optimize primary packaging for integration into devices, support the design and development of proprietary drug delivery device solutions and provide contract manufacturing services.





Analytical Services

Our Technology Excellence Centers Supporting Container & Device Selection

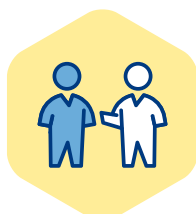
Over the years, we have amassed an exceptional amount of experience testing and comparing glass containers and drug delivery solutions. Customers can access this resource through our Technology Excellence Centers (TEC) in Italy and the

USA, where we offer an array of analytical and testing services.

The results of these studies help our customers choose and de-risk both custom and platform containers and devices to develop best-in-class drug products.

Key Benefits of our Analytical & Testing Services

HIGHLIGHTS



A key partner throughout the drug development journey, from molecule to market.



Tailored testing solutions integrating laboratory expertise & engineering competences.



Established network of partners supporting E&L studies and other services beyond our existing offerings.



ISO 9001:2015, and ISO 13485:2016 certified. Drug handling, including **DEA Schedule III Controlled Substances**.

For Every Stage
of Your Product
Life-Cycle Drugs,
Devices & Combina-
tion Products

Our laboratory services can help at every stage of your drug, device or combination product life-cycle.

As members of UNI and ISO, we combine the latest technologies and methodologies with a problem-solving approach, to bring valuable insight for overcoming specific products or process challenges.

The results of these studies can be easily integrated with customer design controls, plant investigations or continuous improvement programs.

Our Expertise Covers

- Glass primary containers including coatings & treatments
- Product & process development through Design of Experiment
- Fill/finish studies to confirm the processability of drug products in their containers
- Container closure system & optimization and integration of glass containers in drug delivery systems
- Drug Delivery System characterization & functionality testing

Highlights

10+
years of experience

2
locations (Italy & USA)

40+
scientific experts

EXAMPLES OF SERVICE OFFERINGS

Chemical Analysis	Surface Characterization	Container Performance	Device Performance
Delamination propensity studies	Surface morphology investigation	Gliding and extrusion force testing	Custom test method development and execution
Extractables & Leachables via our Partner Network	Silicone layer distribution	Sub-visible particle release	Mathematical modeling
Contamination identification	Surface defects evaluation	Mechanical properties	Mechanical simulation
Material characterization		Failure analysis	Fluid dynamics simulation
		CCI/leakage testing	Sub assembled components and core technologies analysis



Assembly Solutions

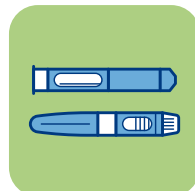
State-of-the-Art Assembly Equipment. Reliable & Low-Maintenance

Stevanato Group designs, develops, and manufactures state-of-the-art sub-assembly and final assembly equipment for a wide variety of drug delivery devices through our in-house industrialization capabilities.

These tailor-made solutions are tuned to streamline the assembly processes of auto-injectors, pen injectors, wearables and inhalers, while maintaining the highest levels of efficiency, quality and consistency.

Key Benefits of Selecting Our Assembly Solutions

HIGHLIGHTS



Designed for medical devices including auto-injectors, pen injectors, wearables and inhalers.



High overall equipment effectiveness that ensures production reliability, efficiency and consistent output quality.



In-process controls for critical quality and device attributes.



Fully servo driven for dynamic speed, accurate positioning & minimal maintenance.

Flexible & Modular Assembly Solutions From Small Scale to Mass Production

We recognize that forecasting production demands can be challenging. Pharmaceutical companies desire equipment solutions that can easily adapt to market feedback.

Our modular approach to new equipment builds enables easy scaling of product assembly from lab development through to mass production.

Additionally, our platforms and modules can be adapted to assemble multiple products on the same line to bring flexibility and long-term value from your investment.

Our Offer Includes

- Manual, semi-automatic & fully-automatic solutions
- Fully scalable designs; from lab to mass production adopting the same control software
- Flexibility that enables processing of multiple products on the same line to optimize investments

Output Speed By Platform Type

Measured in Parts Per Minute

> Commercial Line

up to
160ppm

> Pilot Line

6-40ppm

> Benchtop or Lab Unit

1-4ppm

Technology transfer from benchtop to high volume PLATFORM OVERVIEW



Design development FDA



Pilot & clinical production



Medium to high volume production

Type	Benchtop	Pilot Line	Commercial Line
Description	Manual or semi-automatic assembly of medical devices. Ideal for development purposes.	Compact footprint for assembly processes with a low or medium volume. Ideal for clinical and pilot productions.	Flexible platforms based on linear transport system for complex assembly tasks. Best-in-class for high volume.



Contract Manufacturing

Precision Contract Manufacturing Services. Where Accuracy & Capacity Count

Stevanato Group offers high-quality, high-volume contract manufacturing services for drug delivery systems and have invested significantly in production capabilities such as tool design, injection molding, metrology and complex

assembly.

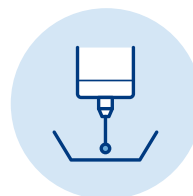
These services work collectively to ensure each component is produced with accuracy and precision - essential for complex products with narrow tolerances.

Key Benefits of Our Approach to Production

HIGHLIGHTS



ISO 15378 & ISO 13485 certified Quality Management System compliant with 21 CFR Part 820.



Six sigma approach throughout the entire industrial production lifecycle.



Development, verification and optimization from risk management, prototyping and usability testing to stability study and clinical evaluation.



Worldwide product registration experience.

Experienced in Design for Manufacturing. Production Without Interruption

Our tool designers and engineers have extensive experience in Design for Manufacturing (DfM), ensuring that parts are producible at high volume.

When coupled with our state-of-the-art manufacturing equipment and technologies, we can ensure accurate, repeatable production. Our tool maintenance programs and availability of spare parts safeguard against long-term production interruptions and minimize downtime.

Additionally, we are accustomed to supporting specific customer requirements such as bio-compatibility, shipping validation or stability tests.

High Level Overview

- Expert tool designers & engineering teams experienced in DfM and DfA
- 200+ injection molding machines in U.S. & Germany
- GMP production areas, ISO 7 (Class 10'000) & ISO 8 (Class 100'000) clean rooms
- Experts in high-speed, automated equipment for sub-assembly, final assembly, inspection, packaging & serialization
- Advanced measuring technologies with computer tomography, optical and tactile methods

Your Contract Manufacturing Partner

Flexible

production capacity

Partnership

with reliable industry leaders

20+

dedicated project managers & engineers

OVERVIEW

	Capacity	Specifications
Production Areas	19,500 sqm	GMP production areas, ISO 7 (Class 10'000) & ISO 8 (Class 100'000) Clean Rooms
Injection Molding Machines	200+	Clamping force from 20-500T, up to 128 cavities
Assembly Installations	40+	From manual to fully-automated assembly, vacuum-fed material handling system
Warehousing	6,800+ pallets	Fully automatic, temperature controlled, humidity monitored



Drug Containment Solutions

High-Quality Pharmaceutical Glass Protecting Drug Integrity

Glass containers play a crucial role in ensuring drug integrity and optimal performance in drug delivery systems. Through continuous innovation in our forming process, we have become a leading producer of high quality, high value, ready-to-use, drug containment solutions.

EZ-fill® containers have become the

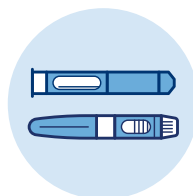
market standard and are integral to many advanced drug delivery platforms. In addition to our standard offerings, we specialize in customizing cartridges, syringes, barrels, vials, and micro-vials to meet the unique requirements of specialized applications, supporting both safety and reliability in drug administration.

Key Benefits of our Drug Containment Solutions

HIGHLIGHTS



Tight geometric tolerances due to accurate production techniques, dimensional and cosmetic controls.



Verified compatibility with safety systems, auto-injectors, pen injectors and wearables.



Reliable functional performance, accurate dosing and smooth gliding profiles.



Reduced total cost of ownership due to reduced drug waste in fill & finish processes and downstream operations.

Designed for Drug Delivery Systems. Specialty Solutions

NEXA® GLASS SYRINGES & CARTRIDGES

Ready-to-use syringes and cartridges designed with enhanced mechanical strength and superior cosmetic quality compared to standard glass containers. Optimized for self-injection settings, these containers ensure consistent and smooth gliding performance - even with highly viscous drugs - supporting a safe and a reliable drug delivery.

ALBA® BREAKTHROUGH SOLUTION FOR BIOLOGICS

Alba® pre-fillable syringes are featured by a cross-linked coating technology based on standard silicone, significantly reducing potential interaction between drug product and container surface, thereby providing a superior packaging solution for sensitive biologics.

Our Offer Includes

- EZ-fill® & bulk glass containers; including vials, cartridges & syringes
- Characterization of the primary container-closure system for integration with devices
- Nexa® platform; superior mechanical performance for auto-injectors and pen injectors
- Alba® platform; a breakthrough solution ensuring exceptional stability and performance over-time for sensitive biologics.

Outsource Non-core Activities With EZ-fill®

NEST & TUB
ideal for combi lines



TRAY
ideal for industrial filling lines



PRODUCT COMPARISON

Features / Platform	NEXA®	ALBA®
Stronger mechanical resistance than standard glass containers	●	●
Higher control on glass cosmetic defects using state-of-art inspection technology	●	●
Ultra-low levels of tungsten ¹	●	●
Higher silicone performance for excellent gliding ²	●	●
Cross-linked coating for extremely low particles - near to zero		●
Available Drug Containment Solutions	Syringe, cartridge, vial	Syringe ³

1- For syringes 2 - For syringes and cartridges 3 - Syringe (EZ-fill® only). Cartridge platform under development

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**Global presence with operating units
and commercial offices in 0 countries.**

Visit our website to contact us.



stevanatogroup.com

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