

SG EZ-fill®

A fully integrated
ready-to-use solution for
your aseptic manufacturing





Company Profile

For more than 70 years, Stevanato Group through its historical brand Ompi, worked to make a difference in the pharmaceutical and healthcare industries.

Today, Stevanato Group is the market leader in manufacturing cartridges for insulin pen injectors and is the world's second-largest manufacturer of glass vials and prefillable syringes.

Stevanato Group boasts a range of commercially available products geared towards specific biopharmaceutical requirements.

The SG EZ-fill® platform includes vials, cartridges, and syringes that are sterilized and ready-to-fill and are available in both nested and tray configurations.

Three product lines target different manufacturing needs ensuring outstanding performance.

The SG Fina® product line is a highly customizable solution for injectables. SG Nexa® guarantees high-performance containers for sensitive drugs, and SG Alba® is the breakthrough solution for biologics and biosimilars. In order to maintain consistent, high-quality standards, all our products and manufacturing facilities are compliant with the latest international requirements.

SG EZ-fill® eases your business

Many pharmaceutical companies are looking for ways to lower their footprint and reduce total costs by relying on experienced external partners for non-core activities. When it comes to glass primary packaging, no solution matches SG EZ-fill®, whose proven advantages have turned its processing technology into an industry standard.

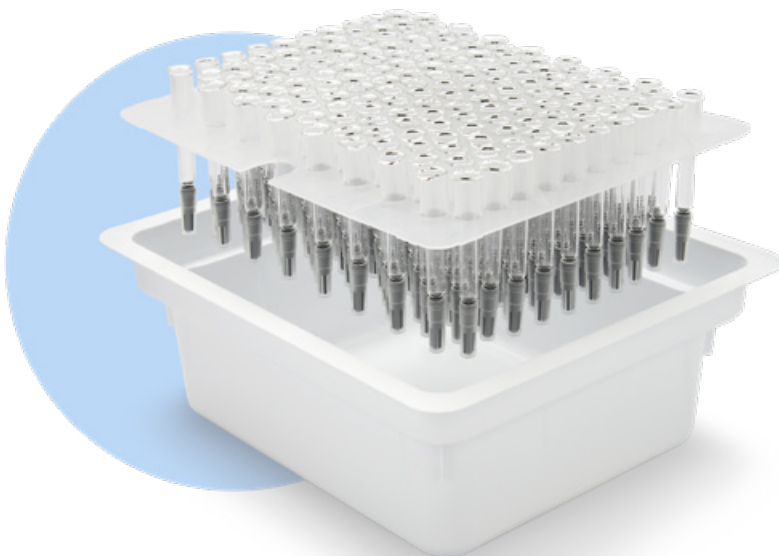
SG EZ-fill® World

Stevanato Group extends its expertise to the pharmaceutical industry by offering consultancy that it is needed throughout the entire project development process: from the feasibility study and engineering stage through the launch of the commercial product to the market.

A unique expertise in consultancy and services. Through an integrated approach SG EZ-fill® is not only offering sterilized glass primary packaging but it is also able to support the customer in the different phases

of the development process, offering consultancy, support and services related to the development or the partner selection for:

- Engineering services
- Fill & Finish
- Add-on components
- Analytical and clinical tests
- Regulatory





Customizable solutions for parenteral drugs

High-value sensitive injectables

Best-in-class for biologics



Glass primary packaging



Add-on components



Analytical and clinical tests



EZ-fill[®]
world



Regulatory support



Engineering solutions



EZ-guide



CMO / CRO



Isolators



Fill & Finish



Facility solutions

SG EZ-fill®
eases your
business

SG EZ-fill®: the market reference for your aseptic manufacturing

Over the years, SG EZ-fill® has become the market reference platform in terms of sterilized process technology able to minimize pharmaceutical and biotech companies' total cost of ownership.

Customers can benefit from an easy, flexible and streamlined process that cuts their non-core activities

increasing efficiency and cost effectiveness.

Our Partners

 bormioli pharma

GERRESHEIMER

MOMENTIVE®
TECHNOLOGIES 



Highlights

~250

Fill & Finish
machines

80

Machine models
compatibility

30

Machine producers
chose SG EZ-fill®



Rubber Components



Machine Manufacturers



SG EZ-fill® Unique Benefits

SG EZ-fill® is designed to provide you the best solution for your parenterals, and in so doing create more opportunities for your business and contribute in helping more people to live healthier life.



Less time to market

It is the perfect solution to be managed both during clinical trials and during the industrialization phase.

More Flexibility

Thanks to its ready-to-fill format, it leverages the commonalities between the different container fill-finish processes by using a common multi-product line.

Increased quality and safety

Thanks to a specific design of the no glass-to-glass packaging material, it allows to preserve both particulate and cosmetic aspects, reducing breakages.

Reduced TCO

It allows pharmaceutical companies to outsource their non-core activities, to lower footprint, to reduce costs related to personnel and utilities.

From lab-scale to industrial production

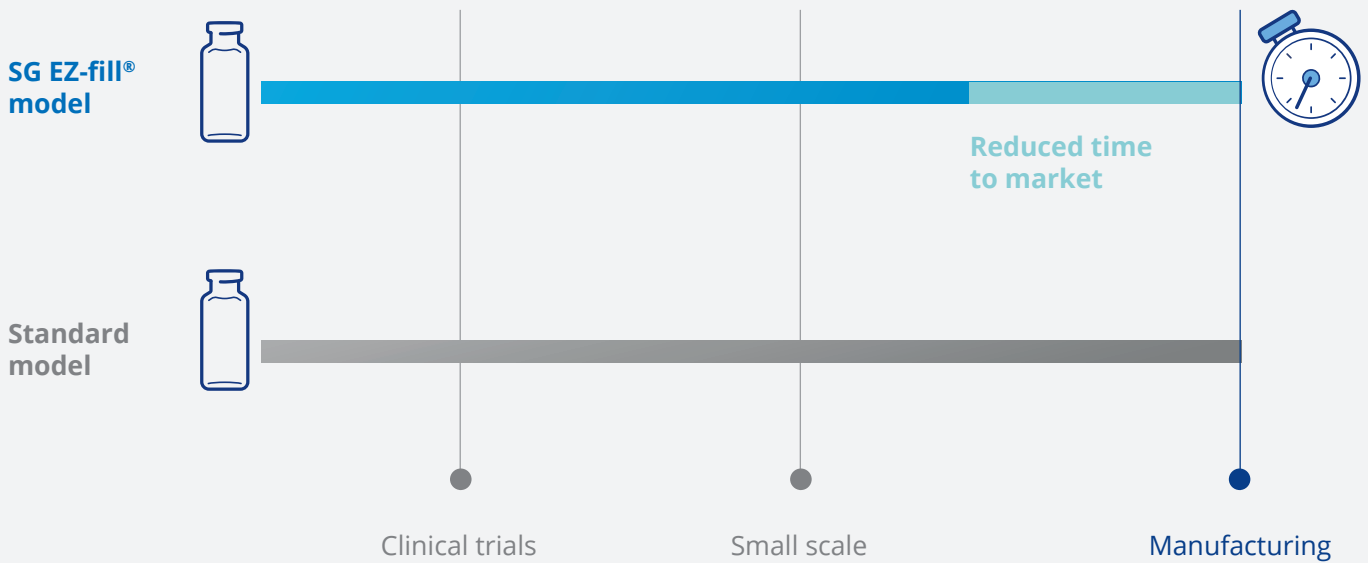
- The market reference for your aseptic manufacturing: a platform that includes syringes, cartridges and vials in a nest & tub format.
- Double configuration for vials and cartridges: both Nest & Tub and Trays.
- The perfect packaging both for small batches and industrial production.

A UNIQUE STANDARD PACKAGING FOR INJECTABLES

SG EZ-fill® boasts a wide range of sterilized glass pharmaceutical primary packaging:

- from 0,5 ml to 5 ml syringes, staked needle or Luer, with NS, RNS, TC, OVS.
- from 2R to 30R vials in nest & tub format.
- from 2R to 50R vials in tray format, standard or upside-down configuration.
- 1,5 ml, 2 ml, 3 ml, 5ml and 20 ml cartridges, pre-capped or not.





Less Time to Market

From the clinical stage to industrialization

During the developing and manufacturing process for new and existing drugs, delays and temporary suspensions can occur, especially for the emerging biologics and orphan drugs. The causes can be different, including the limited availability of primary containers for such small batches.

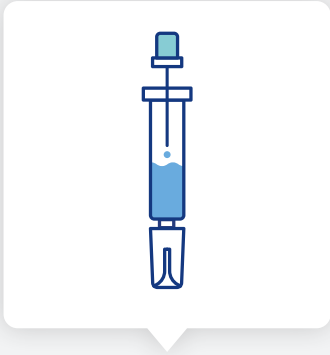
SG EZ-fill® represents the perfect solution from the clinical stage to industrialization. It provides glass

containers for direct filling, enabling a consistent reduction of the time-to-market and cutting costs related to the manufacturing process.

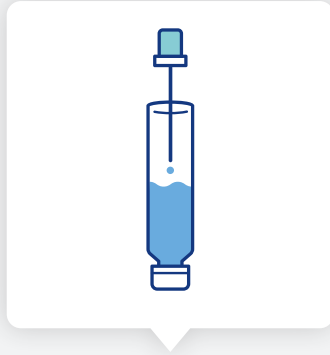
Same filling process during all the Development Process

- Faster Revenue gain
- Reduced risk of entry of new competitors
- Reduced risk of failures during tests/ clinical phases

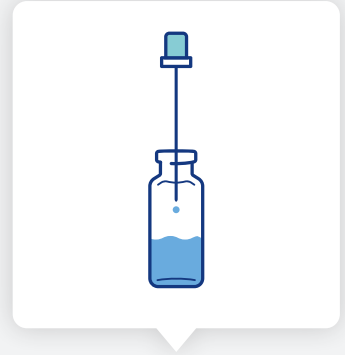
Syringes



Cartridges



Vials

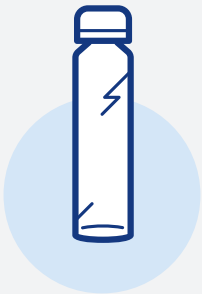


More Flexibility

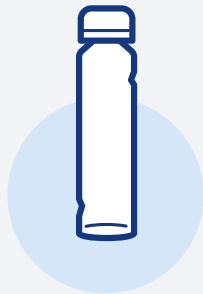
A flexible aseptic process with a common multi-product line

Providing the nest & tub format for all sterilized containers (vials, cartridges and syringes), SG EZ-fill® allows pharmaceutical companies to maximize flexibility in aseptic filling using a common filling platform (combi-line), as it has been developed together with the main Fill & Finish equipment manufacturers and it can therefore be integrated into the already existing

pharmaceutical manufacturing filling lines. Machine manufacturers have also been involved in the development of the packaging design and concept for the proper handling and machineability with a wide range of Fill & Finish units.



Less breakages



Less cosmetic issues



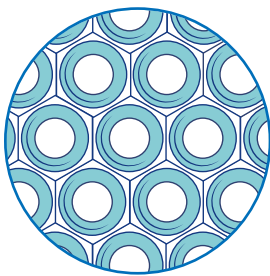
Less particles



Less rejections

Increased Quality

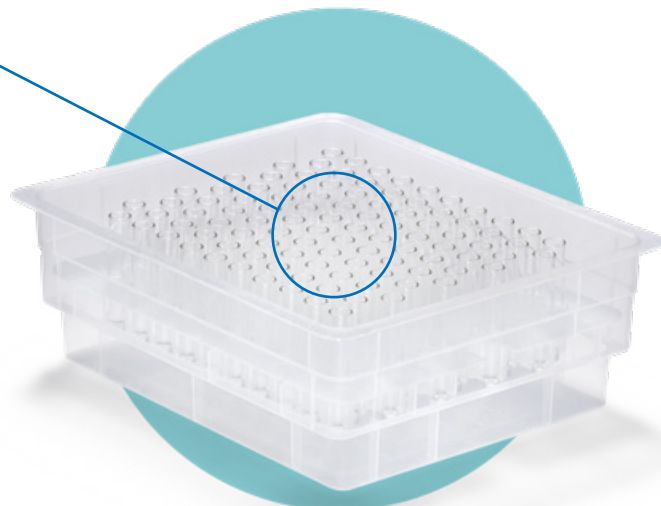
No glass-to-glass contact increases the performance of the container



No-glass-to-glass contact

SG EZ-fill® provides the maximum safety during the transportation phase and in the buffering/in-feeding operations. No glass-to-glass contact is assured through the separation of all containers in the secondary packaging. This allows an effective mitigation of the risk of breakages, cosmetic issues and particle generation.

This means a valuable advantage both on the mechanical point of view and on the performance point of view because it dramatically reduces production stops and rejects in the final inspection due to container breakages.



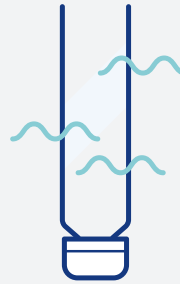
Packaging



Washing



Sterilization



Filling



SG EZ-fill®

PharmaCo

Reduced total cost of ownership

Outsource your non-core activities

With even more longer and expensive product developing times and an aggressive competition, realizing a lean production process and the specialization are pivotal for the success of the pharmaceutical companies.

As SG EZ-fill® outsources your

non-core activities, you can benefit from a complexity reduction allowing:

- Less implementation and operating costs
- Less validation costs
- Less utilities costs (e.g. energy, WFI)
- Less labor costs
- Lower footprint

A proven process

Validated and constantly monitored operations

SG EZ-fill® process is a proven concept, GMP compliant and already approved by numerous top pharmaceutical companies. Each phase of SG EZ-fill® production process is conducted in state-of-the-art facilities with the latest generation equipment within certified cleanrooms (ISO 8, ISO 7 and ISO 5) using validated process that are constantly monitored and controlled.

Steam and EtO sterilization

SG EZ-fill® adopts steam sterilization in addition to Ethylene Oxide (EtO) sterilization method.

Stevanato Group developed in-house steam sterilization for cartridges and vials in order to be even more and more

close to authorities and customers' needs, giving an important alternative for this crucial phase of the production without changing final packaging configuration.

The SG EZ-fill® process



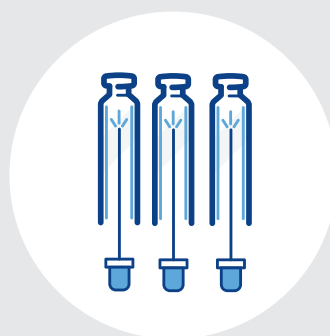
Incoming material

All the raw materials for SG EZ-fill® syringes, vials and cartridges undergo incoming inspections that are necessary to declare them suitable for ISO 7 / ISO 5 production. Syringes, vials and cartridges are supplied to the SG EZ-fill® area (ISO 8).



Washing

Containers are washed into the washing machine with WFI (Water for Injection).



Siliconization

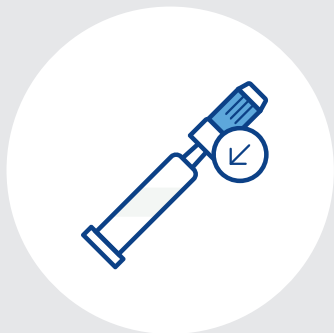
Syringes and cartridges are siliconized with high-performances layer distribution process (silicone oil for syringes, baked silicone for cartridges).



Depyrogenation

Vials and cartridges are dried and depyrogenated in a pharma tunnel.

Stevanato Group boasts an in-house steam sterilization technology for vials and cartridges developed to meet authorities and clients requirements.



Closure assembly

Closures (RNS, NS, OVS, TC) are assembled with the syringes and cartridges can optionally (upon customers' request) be pre-capped.



Nesting and tub insertion/tray loading

Containers are placed into two final packaging solutions:

- Tray: one piece box (for vials and cartridges)
- Nest & Tub: for all types of containers (syringes, vials, cartridges).



Tyvek sealing & steribag bagging

Both formats are sealed with a Tyvek® lid, packaged in steribags and case-pack allowing for sterilization. Key attention is given to the cleanliness of the packaging components as to the production of the glass container itself. Final configuration includes packaging in pallets.



Sterilization

SG EZ-fill® offers both types of sterilization present on the market: Steam and EtO.

Our best-in-class products for specific needs

SG LDP EZ-fill®: Ready-to-use low delamination propensity vials

After an extensive investigation on the chemical performance of the inner surface of vials and on the critical glass forming process parameters that influence the final delamination propensity of vials, Stevanato Group launched SG LDP EZ-fill® Vials as a result of an optimized forming process that minimizes the surface inhomogeneities formation.

SG LDP EZ-fill® Vials are ready-to-fill glass vials with low delamination propensity: they are produced with Type I Borosilicate glass and have no coating applied, so they ensure no need to re-file to official authorities: they can easily be applied to already registered products.



SG LDP EZ-fill® Vials Benefits

- Higher stability of the drug during its shelf life.
- No glass formulation changes
- No coatings
- No need to re-file your drug

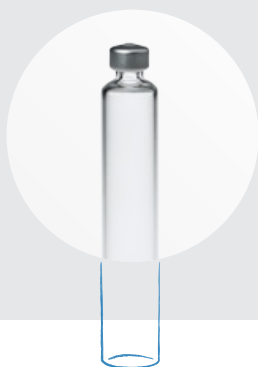


SG Nexa[®] 3x EZ-fill[®]: Quality & performances for your most demanding drugs

SG Nexa[®] 3x EZ-fill[®] platform represents Stevanato Group's state-of-the-art solution when high quality and outstanding performances are needed.

SG Nexa[®] 3x EZ-fill[®] containers are superior in terms of functionality and performances compared to standard market solutions.

SG Nexa[®] 3x EZ-fill[®] containers' performance are achieved thanks to a specific manufacturing process with no glass-to-glass contact and reduced glass-to-metal contact. In addition, their quality is certified by a 100% camera inspection of the most important parameters, such as silicone layer and crimping.



SG Nexa[®] 3x EZ-fill[®] Benefits

- Superior cosmetic performance, reducing false rejects rates
- Proprietary 100% camera inspection
- Quality improved process platform for forming, transporting and handling
- No modification of glass surface and geometry
- Reduced number and depth of initial glass flaws

Our best-in-class products for specific needs

SG Alba® EZ-fill®: Our breakthrough solution for biologic drugs

SG Alba® EZ-fill® is a turning point in the development of parenteral primary packaging, representing the best-in-class solution for biologics.

The reduced variability of materials in contact with the drug throughout its lifecycle makes our SG Alba® EZ-fill® platform the perfect solution for de-risking the development process, saving costs and securing a fast introduction to market.

The drastic reduction of silicone oil particles and the extremely low-propensity to delaminate addresses some of the key requirements of protein-based drugs.

The simple way to streamline your biologic drugs development path.

- SG Alba® EZ-fill® helps you to stay compliant with regulations on particle limits, e.g USP <788>, <787>.
- SG Alba® EZ-fill® de-risks the development process throughout its lifecycle
- SG Alba® EZ-fill® enables a shortened time to market

SG Alba® EZ-fill® Benefits

- featuring an internal layer crosslinked with the glass surface. This allows a silicone-oil particles reduction up to 95%.
- acting as a barrier between the drug and the glass reducing the amount of inorganic extractables
- ensuring an increased stability of the functional performances (gliding and break-loose forces) assuring an optimized drug administration
- creating a barrier effect preventing the occurrence of delamination.





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