



EZ-fill®

A fully integrated pre-sterilized containment solution for your aseptic manufacturing



MANAGING COMPLEXITY, DELIVERING VALUE



Company Profile

Founded in 1949, Stevanato Group is a leading global provider of drug containment, drug delivery and diagnostic solutions to the pharmaceutical, biotechnology and life sciences 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 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 Fina® product line is a highly customizable solution for injectables. Nexa® guarantees high-performance containers for sensitive drugs, and Alba® is the breakthrough solution for biologics. In order to maintain consistent, high-quality standards, all our products and manufacturing facilities are compliant with the latest international requirements.

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 containment solutions, no solution matches EZ-fill®, whose proven advantages have turned its processing technology into an industry standard.

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 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:

- Manufacturing technology
- Fill & Finish
- Add-on components
- Analytical and clinical tests
- Regulatory





Customizable solutions
for parenteral drugs



High-value
sensitive injectables



Best-in-class
for biologics

**Drug containment
solutions**



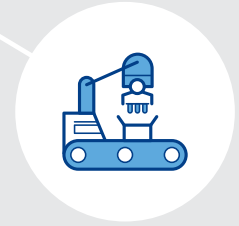
**Add-on
components**



**Analytical and
clinical tests**



**Regulatory
support**



**Manufacturing
technology**



EZ-guide



CMO / CRO



Fill & Finish



**Facility
solutions**



Isolators

EZ-fill® **Unique** **Benefits**

EZ-fill® is designed to provide you the best solution for your parenterals, and in doing so 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

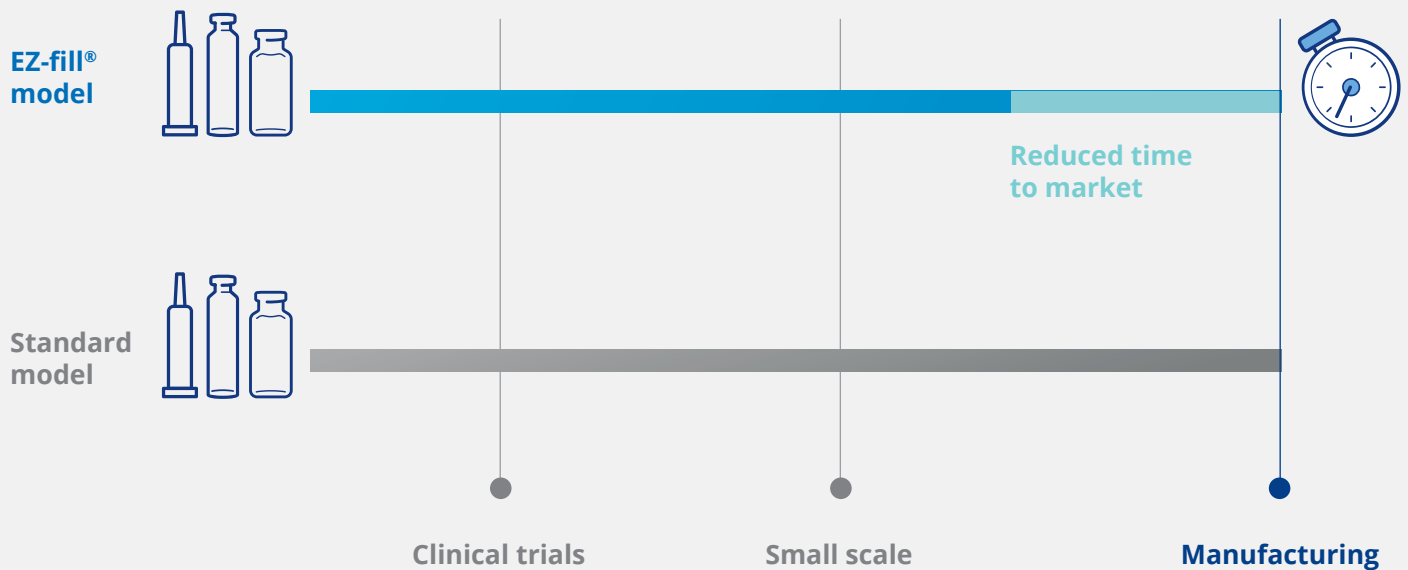
- The market reference for your aseptic manufacturing: a platform that includes syringes, cartridges and vials in a nest & tub format.
- Double configuration for vials and cartridges: both Nest & Tub and Trays.
- The perfect packaging both for small batches and industrial production.

A unique standard packaging for injectables

EZ-fill® boasts a wide range of pre-sterilized containment solutions:

- from 0,5 ml to 5 ml syringes, staked needle or Luer, with NS, RNS, TC, OVS.
- from 2R to 50R 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.





EZ-fill® Unique Benefits

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.

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



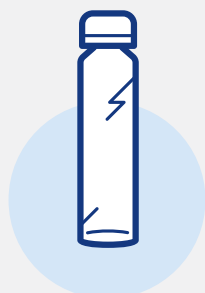
More Flexibility: A flexible aseptic process with a common multi-product line

Providing the nest & tub format for all sterilized containers (vials, cartridges, syringes), EZ-fill® allows pharmaceutical companies to maximize flexibility in aseptic filling using a common filling platform (combi-line).

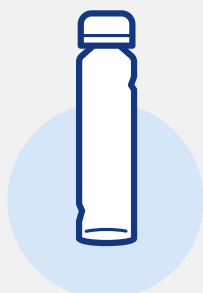
As it has been developed together with the main Fill & Finish equipment manufacturers, it can therefore be

integrated into the already existing pharmaceutical manufacturing filling lines.

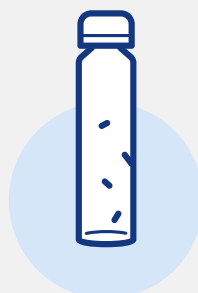
Machine manufacturers have also been involved in the development of the packaging design and concept for the proper handling and machineability with a wide range of Fill & Finish units.



Less breakages



Less cosmetic issues



Less particles



Less rejections

EZ-fill® Unique Benefits

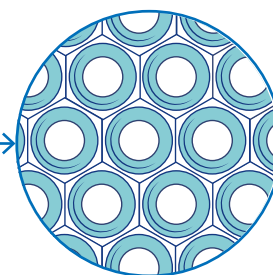
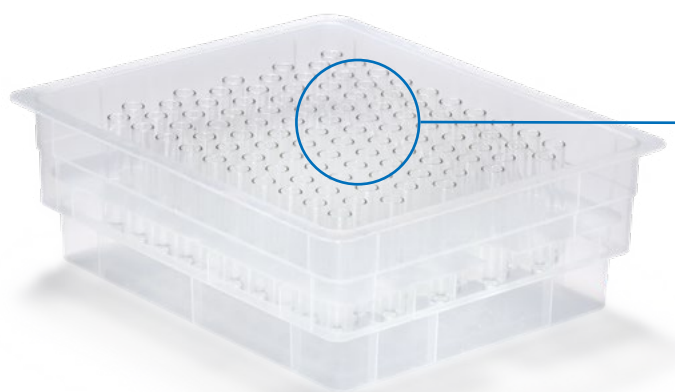
Increased quality and patient safety: No glass-to-glass contact increases the performance of the container

EZ-fill® provides the maximum safety during the transportation phase and in the buffering/in-feeding operations.

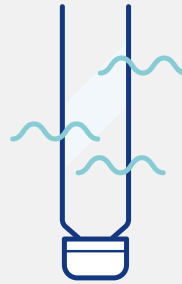
No glass-to-glass contact is assured through the separation of all containers in the secondary packaging.

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.



No-glass-to-glass contact

Packaging**Washing****Sterilization****Filling****EZ-fill®****Pharma Company**

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 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

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

Over the years, 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

gerresheimer



Highlights

~250

Fill & Finish
machines

80

Machine models
compatibility

30

Machine producers
choose EZ-fill®



Rubber Components



Machine Manufacturers



A proven process: Validated and constantly monitored operations

EZ-fill® process is a proven concept, GMP compliant and already approved by numerous top pharmaceutical companies. Each phase of 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

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

Stevanato Group develops in-house steam sterilization for cartridges in order

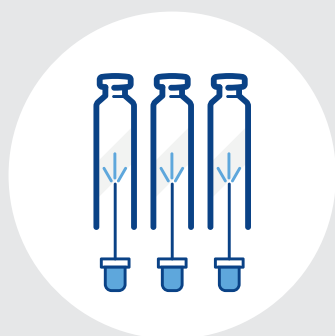
to be even more and more close to authorities and customers' needs, giving an important alternative for this crucial phase of the production without changing final packaging configuration.

The EZ-fill® process



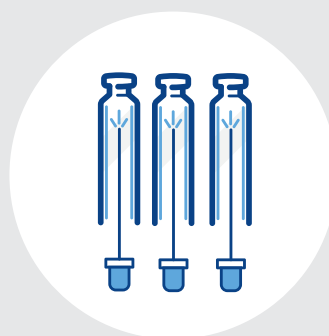
Incoming material

All the raw materials for 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 EZ-fill® area (ISO 8).



Washing

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



Siliconization

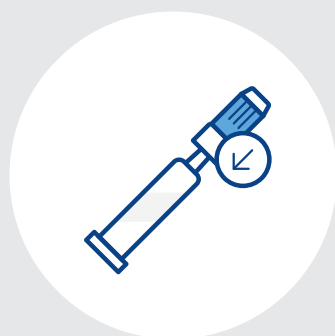
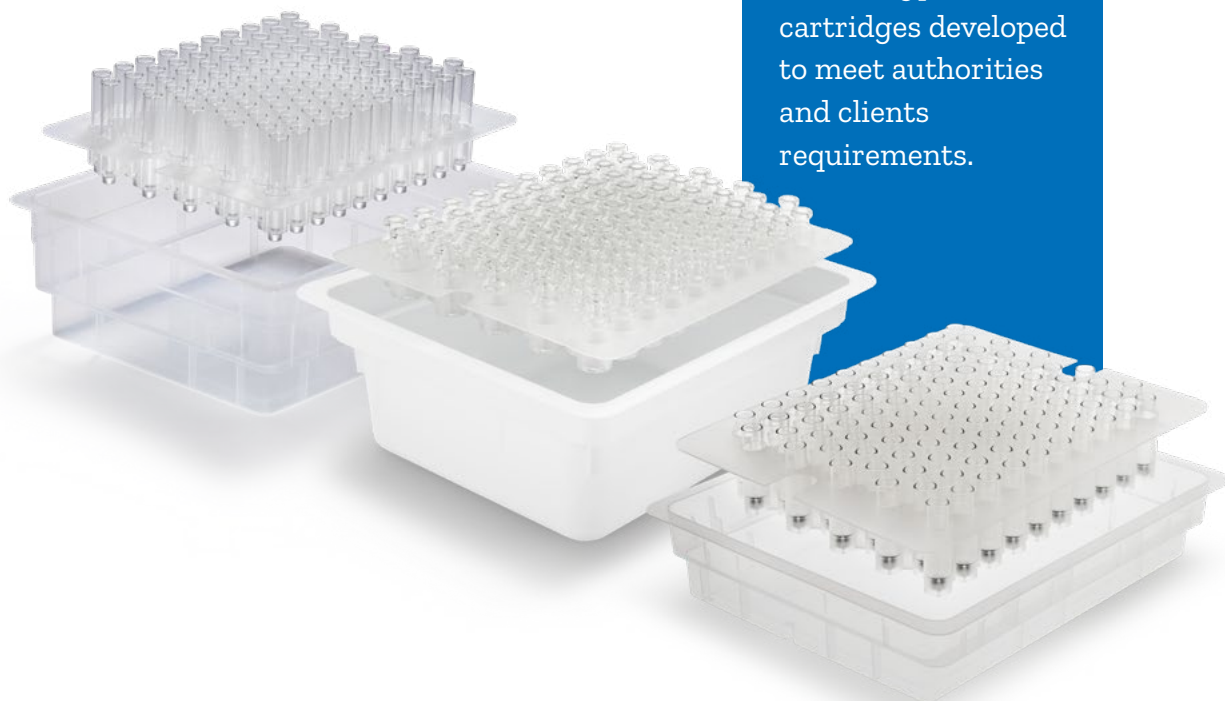
Syringes and cartridges are siliconized with high-performances layer distribution process (silicone oil for syringes, baked silicone for cartridges).



Depyrogenation

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

Stevanato Group
boasts an in-house
steam sterilization
technology for
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

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

Our best-in-class products for specific needs

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 LDP EZ-fill® Vials as a result of an optimized forming process that minimizes the surface inhomogeneities formation.

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.



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



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

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

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

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.



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

Alba® EZ-fill®: Our breakthrough solution for biologics

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 Alba® EZ-fill® platform the perfect solution for de-risking the development process.

The drastic reduction of silicone oil droplets and any potential product related substance (e.g. extractable compound) addresses some of the key requirements of protein-based drugs.

The simple way to streamline your biologic drugs development path.

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

Alba® EZ-fill® Benefits

- Minimizing sub-visible particles and mitigate potential drug silicon interaction
- Acting as a barrier between the drug and the glass, reducing the amount of inorganic extractable
- Ensuring highly predictable functional performances (gliding and break-loose forces) to maintain the proper drug delivery
- Leading to a faster and easier regulatory approval thanks to the glass and silicone experience.





Headquarters

Via Molinella, 17
35017 Piombino Dese
Padova, Italy

**Global presence with operating units
and commercial offices in 10 countries.**

Visit our website to contact us.



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