

# EZ-fill®

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



## Company Profile

Ompi is part of the Pharmaceutical Systems division of Stevanato Group. It offers a unique expertise in providing superior pharmaceutical containers from glass tubing. Our comprehensive portfolio covers every customer need: syringes, pen and dental cartridges, vials for liquid and lyophilized drugs and ampoules.

Syringes, cartridges and vials are produced both in bulk and sterile formats (Ompi EZ-fill®).

**As part of the Stevanato Group, Ompi also contributes to the wider mission of creating systems and processes that guarantee the integrity of parenteral medicines.**

Through continual innovation and the pioneering of new trends, we are committed to making a vital contribution to the pharmaceutical industry and ultimately offering superior

solutions to our customers, for their patient's safety.

To that end, we are dedicated to offering "synchronized solutions", in close collaboration with our Engineering Systems division, so that together we can significantly enhance the product integrity that can be guaranteed to patients, thereby exceeding customer expectations year after year.

# Ompi EZ-fill® eases your business



In a scenario where pharmaceutical industry looks for new manufacturing solutions to lower cost pressure, increase flexibility and quality, reduce time to market and outsource non-core activities, Ompi EZ-fill® is the perfect solution to address your specific needs, being you a CMO, a biotech company, a research laboratory or a pharmaceutical company.

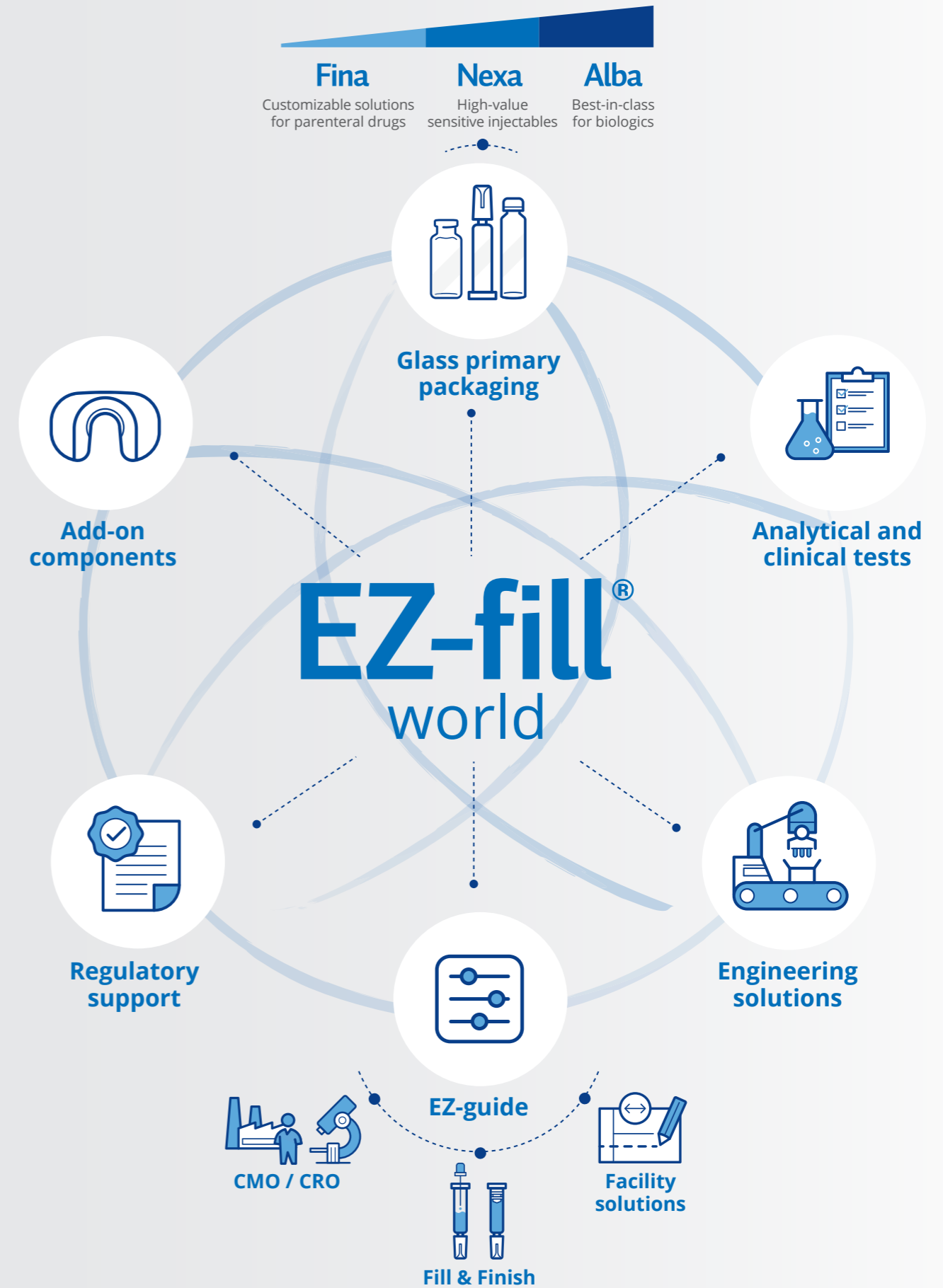
## Ompi EZ-fill® World

Ompi 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 Ompi EZ-fill® is not only offering sterile 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





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

Over the years, Ompi EZ-fill® has become the market reference platform in terms of sterile 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.

# EZ-fill® Unique Benefits

Ompi 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.

### Not only syringes, not only vials. Syringes, Vials and Cartridges

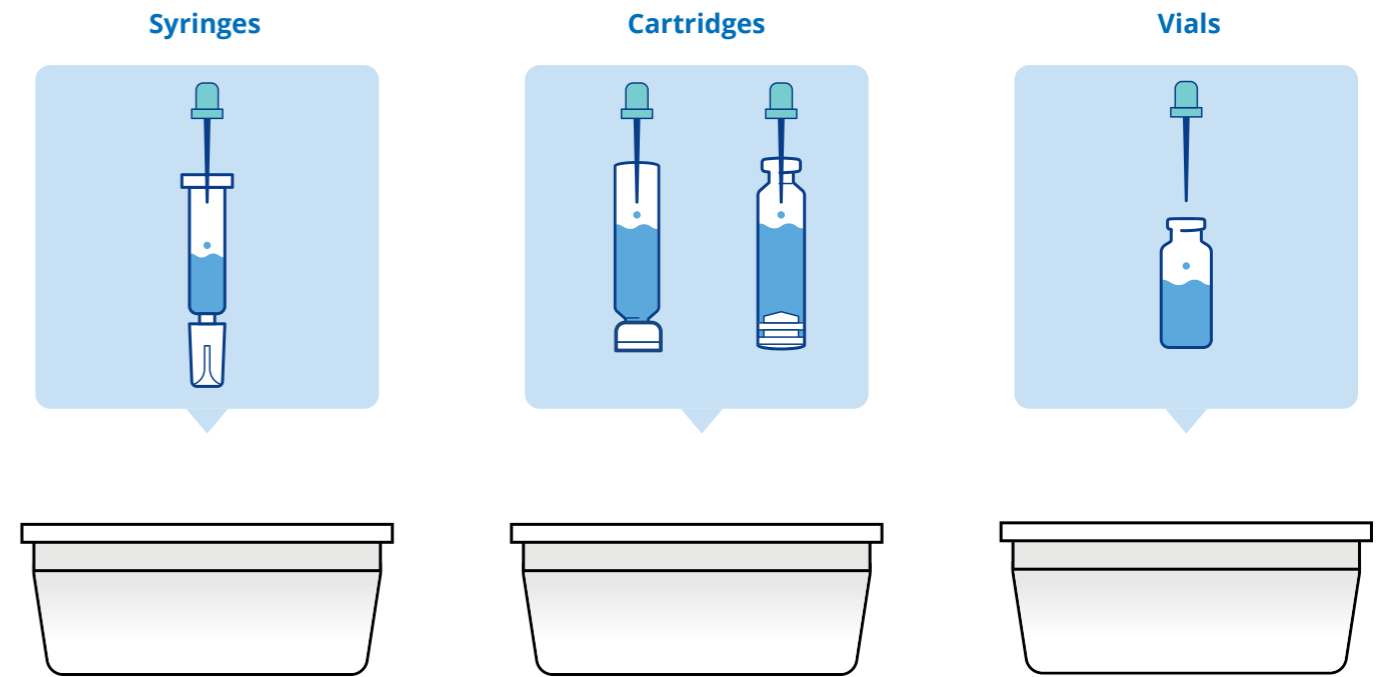
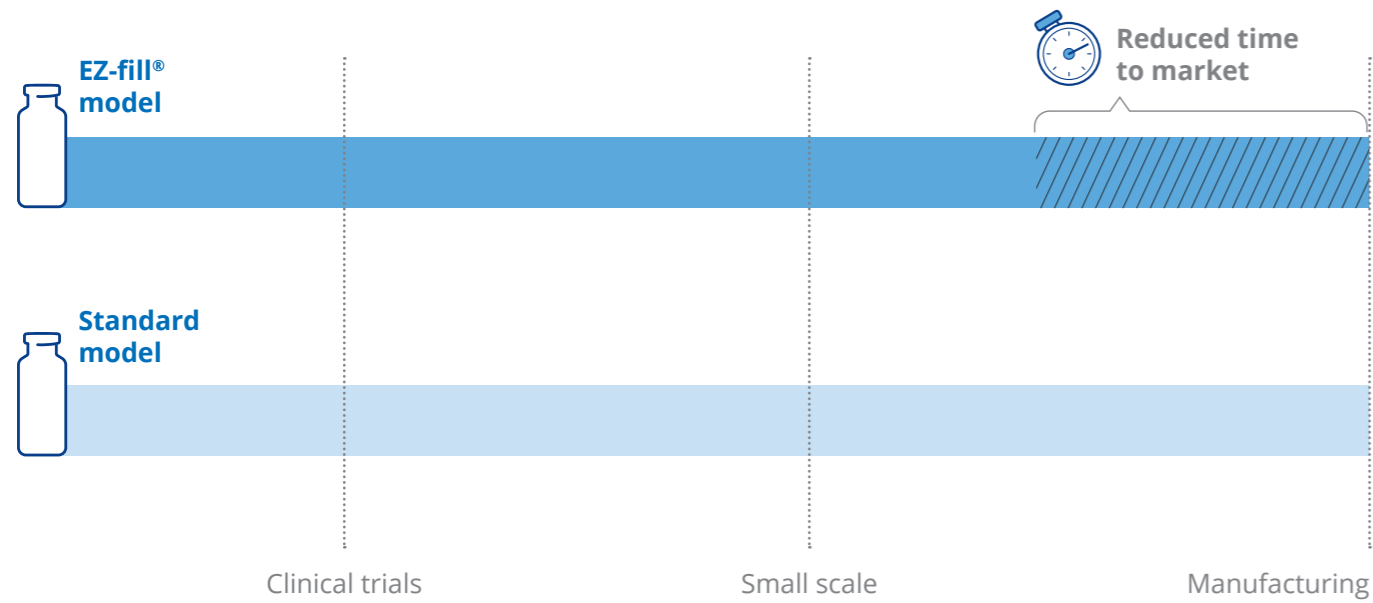
- The widest range of clean, sterile, depyrogenated and ready-to-fill glass containers for pharmaceutical use.
- The market reference for your aseptic manufacturing: a platform that includes syringes, cartridges and vials in a nest & tub format.
- Double configuration available: both in nest & tub and tray.
- The perfect packaging both for small batches and industrial production.

#### A UNIQUE STANDARD PACKAGING FOR PARENTERALS

Ompi EZ-fill® boasts a wide range of sterile glass pharmaceutical primary packaging:

- from 0,5 ml to 5 ml syringes, staked needle or Luer, with NS, RNS, TC, OVS.
- from 2R to 20R vials in nest & tub format.
- from 2R to 30R vials in tray format, standard or upside-down configuration.
- 3 ml 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, especially for the emerging biotech and small-batch needs such as orphan drugs, it could happen to face a stand-by-phase or a delay due to the limited availability of containers for direct filling options and formats at existing aseptic lines. EZ-fill® is the perfect solution from the clinical stage to industrialization because it provides glass containers

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

### Same filling process during all the Development Process

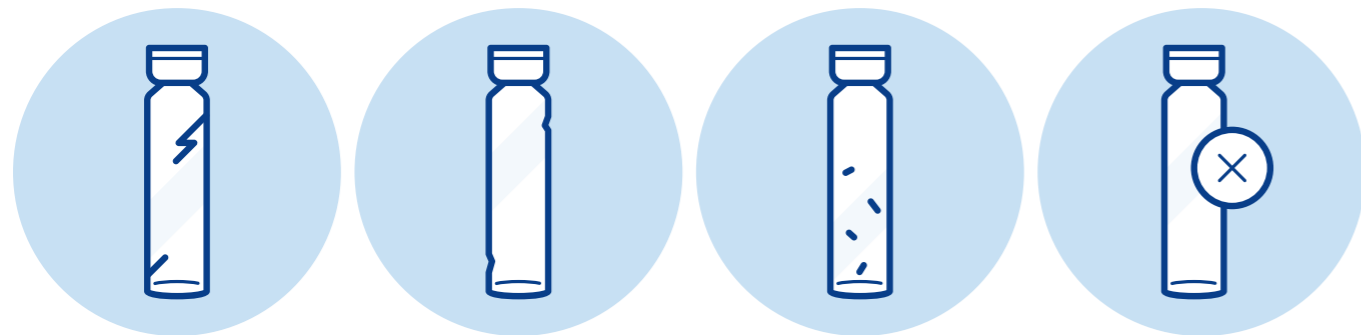
- Faster Revenue Gain
- Reduced risk of entry of new competitors
- Reduced risk of failures during tests/clinical phases

## More Flexibility

## A flexible aseptic process with a common multi-product line

Providing the nest & tub format for all sterile containers (vials, cartridges and syringes), EZ-fill® allows pharmaceutical companies to maximize flexibility in aseptic filling using a common filling platform (multi-product line). The flexibility of EZ-fill® is a proven concept, 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

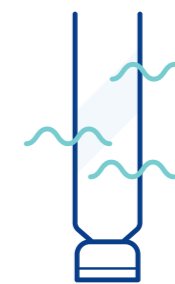
Less rejections



Packaging



Washing



Sterilization



Filling

EZ-fill®

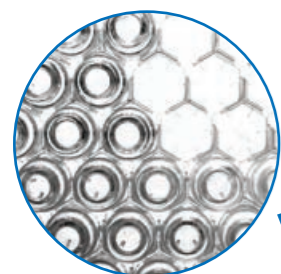
PharmaCo

## Increased Quality

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

Ompi 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 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



## 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 Ompi 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

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

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



### Steam and EtO sterilization

Ompi EZ-fill® adopts steam sterilization in addition to Ethylene Oxide (EtO) sterilization method. Ompi developed in-house steam sterilization for cartridges and vials in

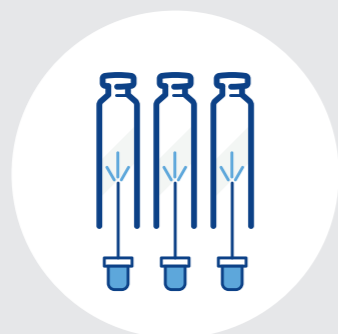
order to be even more and more close to authorities and customers' needs, giving an important alternative for this crucial phase of the production without changing final packaging configuration.

### The EZ-fill® process



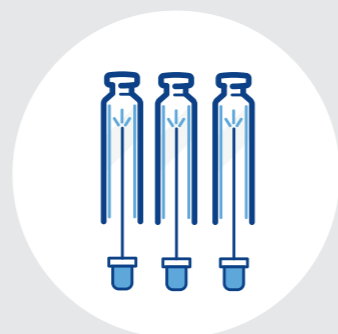
#### Incoming material

All the raw materials for Ompi 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 Ompi 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.



#### 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

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

\* Vials steam sterilization is currently under development.



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