

PARENTERALS CDMO

# Your CDMO for glass bottles and vials

THE TRUSTED MATERIAL FOR INERTNESS,  
COMPATIBILITY AND SUSTAINABILITY

GRIFOLS

## Grifols Parenteral CDMO

Grifols Partnership is a contract development and manufacturing organization (CDMO) focused on added value injectable products (small molecules), with a large international experience in the development and manufacturing of many types of sterile drug products. We are able to leverage the resources and experiences of the larger Grifols organization to provide significant value to our partners.

## Safety Through Quality

We manufacture our products to stringent GMP standards and the requirements of the US and European Pharmacopeia, targeting excellence in the finished product.

The production of sterile parenteral products requires not only a culture of quality, but effective quality systems to consistently meet the highest safety standards. Our culture of quality is reflected in our commitment to continuous improvement, and underscored by our integration of quality into manufacturing processes from the outset.



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**From small-volume vials to large-volume parenteral solutions, Grifols offers end-to-end sterile manufacturing capabilities for glass primary packaging systems.**

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**Laboratorios Grifols, S.A. produces high-quality vials of water for injection which are also used by its sister companies Instituto Grifols, S.A., Grifols Therapeutics LLC and Grifols Biologicals LLC. to reconstitute the company's lyophilized plasma-derived products.**



## GLASS VIAL

Automated fully integrated filling line\* for glass vials from 5 mL to 100 mL

- Bottle neck size: 20 mm
- Minimum filling volume: 2.5 mL
- Intermediate volume filling
- Automatic machine inspection (particulate matter, filling volume, glass defects and capping)
- One line for labeling and packaging
- Drug master file for water for injection as a diluent in glass vials is available in CDER and CBER



### TECHNICAL FEATURES

- Washing process with WFI80
- Depyrogenation ensuring at least a 3 log reduction in endotoxin levels
- Filling through peristaltic pump with 2 steps filling to achieve accurate dosing and precise timing
- Vials are laser-etched on the cap
  - Provides a unique identification number for every single vial
  - Ensures traceability
  - Permits flexibility in shipping without a label
- Automatic variable data marking inspection
- Terminal sterilization
- Compatible with different types of glass vials
- Serialization

## GLASS BOTTLE

Automated filling line type II glass bottles available in 250 mL and 500 mL

- Bottle neck size: 32 mm
- Halogenated butyl rubber stopper
- Aluminum cap with a pull-off tab that, when removed, exposes the top of the stopper for infusion or medication preparation
- Batch number and expiry date information



\* Filling line was designed by Grifols Engineering, S.A., resulting in an advanced technological solution that complies with the strict manufacturing standards required by the US FDA, the EMA and other world health authorities.

Grifols Partnership



**Better together**

Contact us at  
[partnership@grifols.com](mailto:partnership@grifols.com) | [www.partnership.grifols.com](http://www.partnership.grifols.com)



Sales Spain: **+34 670 923 382**

Sales US: **+1 972 841 4495**

**GRIFOLS**

**Grifols International, S.A.**

Parc empresarial Can Sant Joan  
Av. de la Generalitat, 152-158  
08174 Sant Cugat del Vallès, Barcelona - SPAIN  
Tel. +34 935 710 500  
[partnership@grifols.com](mailto:partnership@grifols.com)  
[www.partnership.grifols.com](http://www.partnership.grifols.com)