# PARENTERAL CDMO

your lyo drug & our diluent:

# The match



**Grifols Partnership:** your CMO for filling vials. Because diluent is as important as your API

**GRIFOLS** 

## **Laboratorios Grifols, S.A.: your trusted partner**

Grifols is a leader in the Spanish pharmaceutical market for Large Volume Parenteral solutions. The company has over 75 years of experience in manufacturing parenteral solutions, diluents, clinical nutrition and medical devices.

Grifols Partnership was conceived as a business-to-business platform, through which we offer our experience, knowledge and manufacturing capability to other companies in the pharmaceutical sector.

A highly automated and specialized production process with cutting-edge technology for parenteral solutions means that we are able to offer a product with the highest levels of quality.

## We focus on quality to deliver safety

At Grifols, we work hard to ensure maximum levels of quality in our production processes. We continuously strive to improve our quality systems, which has earned us the highest levels of accreditation and certifications.

We manufacture our products following strict GMP standards and US and European Pharmacopeia requirements in order to aim at the highest quality of the final product. In 2007, Grifols obtained

authorization for the parametric release of its parenteral solutions in glass and flexible containers from the manufacturing plants in Spain, making the company one of the first in Europe to obtain this authorization.



- Experience in intravenous products since the 1940<sub>S</sub>
- Specialists in parenteral solutions
- Experts in formulation, filling, terminal sterilization, labeling and packaging
- Experts in contract manufacturing, with long-standing satisfied customers





Drug master file for water for injection as a diluent in glass vials is available.

#### New automated fully integrated filling line for vials from 5 mL to 50 mL:

- 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

#### **Technical Features**

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

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

Grifols Partnership

Better together