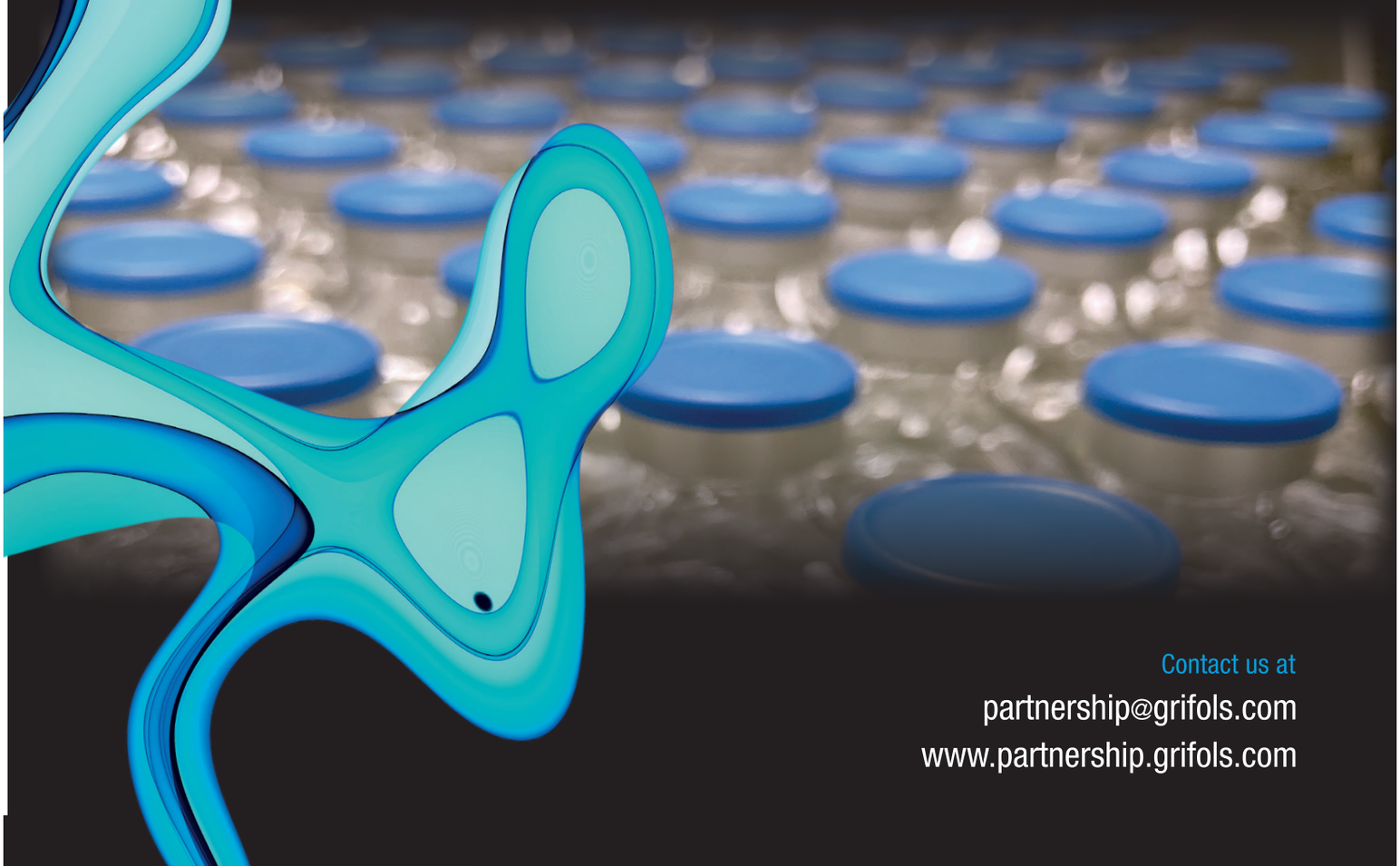
Grifols Partnership
Better together

PARENTERALS CDMO

YOUR CDMO FOR FILLING VIALS. BECAUSE DILUENT IS AS IMPORTANT AS YOUR API

Sterile Manufacturing | Delivery Systems | Parenteral Technologies



Contact us at
partnership@grifols.com
www.partnership.grifols.com

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.

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.

One of Grifols state-of-the-art filling lines in our sister company Instituto Grifols, S.A. in Barcelona

Drug master file for water for injection as a diluent in glass vials is available in CDER and CBER

New automated fully integrated filling line for glass 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 2 steps filling 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 variable data marking inspection
- 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 the US FDA, the EMA and other world health authorities.

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Contact us at:

partnership@grifols.com

Phone:

+34 935 712 199

Visit us at:

www.partnership.grifols.com

GRIFOLS

Grifols International, S.A.
Parc empresarial Can Sant Joan
Av. de la Generalitat, 152-158
08174 Sant Cugat del Vallès, Barcelona - SPAIN
www.grifols.com

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