Grifols Partnership

Better together

PARENTERALS CDMO

Manufacturing of Complex Parenterals

SUPPORTING SMALL VOLUME AND SMALL MOLECULE PARENTERAL PROJECTS

GRIFOLS

Grifols vital statistics

Year founded: **1909**
Number of employees: **More than 25,000**
Annual worldwide revenues: **More than € 6 billion**

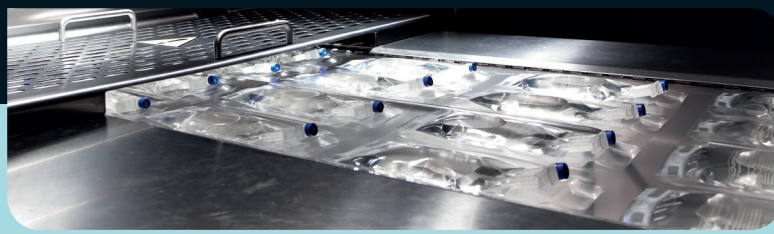
Grifols, a global healthcare company and leading producer of plasma-derived medicines, has a presence in more than 30 countries and regions and provides its innovative healthcare products and solutions in more than 110.

Who we are

We are a contract development and manufacturing platform (CDMO) specializing in added-value injectable products (small molecules). We have an extensive global experience developing and manufacturing various sterile drug products, primarily in flexible bags and vials.

What we do

Our high level of specialization allows us to offer pharmaceutical development and manufacturing for products that require advanced technology and complex production processes, such as sterile solutions.
We are experts in development and contract manufacturing (CDMO), with long-standing satisfied customers.
Grifols Partnership has two FDA-and GMP-approved manufacturing facilities in Spain for intravenous solutions that have parametric release certification.
In our cGMP facilities, we can handle a variety of complex molecules, ensuring that production can be tailored to specific needs.



Our customer approach

Grifols Partnership works together with the customer from the early stages of development until commercial manufacturing.

Pharmaceutical and analytical development

- Design and optimization of formulations
- Technology transfer
- Manufacturing and sterilization process development
- Scale-up from pilot plant to production facilities
- Development, transfer, and validation of analytical and microbiological methods

Plastic components and container closure system (CCS) development

- Selection of materials
- Capability for injection, welding and assembling
- Sterilization process development by gamma radiation and ethylene oxide
- Design verification

Stability studies

- Preliminary stability studies
- ICH stability studies
- Shipping studies

Manufacturing

- Engineering batches
- Registration batches
- Clinical batches

Qualifications and regulatory support

- Equipment
- Cleaning process
- Manufacturing process
- Container closure integrity (CCIT)
- Technical documentation

Industrialization for commercial batches

- Manufacturing process validation
- Manufacturing of commercial batches
- Small- and large-scale manufacturing
- Labelling and packaging: tailored to your specifications
- Serialization

TECHNOLOGICAL CAPABILITIES BY SITE	FACILITIES (Spain)	
	Parets del Vallès (Barcelona)	Las Torres de Cotillas (Murcia)
Drug product development	✔	
Small molecule drug products	✔	✔
Terminal sterilization	✔	✔
Light and O_2 sensitive products	✔	
Vials (2,5 to 50 mL)	✔	
Diluents	✔	
Glass bottles (50 to 500 mL)	✔	
Flexible containers (PP bags, 50 to 1000 mL)	✔	✔
FFS technology for PP bags	✔	✔

Major markets

Over the years, we have established successful relationships with customers in global markets, including North America, Canada, Australia and Europe in the following areas:

- **Human and veterinary fields**
- **New and generic drug development**
- **Rare diseases and orphan drug development and manufacturing**

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