



#### **Grifols vital statistics**

Year founded: 1909

Number of employees: More than 25,000

Annual worldwide revenues: More than € 6 billion

Grifols is one of the world's leading pharmaceutical companies with 30 subsidiaries, and operations in more than 100 countries.

## 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.

### Our customer approach

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

# **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

TECHNOLOGICAL CAPABILITIES BY SITE	FACILITIES (Spain)	
	Parets del Vallès (Barcelona)	Las Torres de Cotillas (Murcia)
Drug product development	<b>~</b>	
Small molecule drug products	<b>✓</b>	✓
Terminal sterilization	<b>✓</b>	✓
Light and O <sub>2</sub> sensitive products	<b>~</b>	
Glass vials (2,5 to 50 mL)	<b>✓</b>	
Diluents - Water for injection	<b>~</b>	
Glass bottles (50 to 500 mL)	<b>~</b>	
Flexible containers (PP bags, 50 to 1000 mL)	<b>✓</b>	<b>✓</b>

FDA, AEMPS, ANMAT, European Regulatory Authorities (Infarmed, BfArM, MHRA...)



- Pre-formulation and development
- Pharmaceutical and analytical development
- Scale-up and technology transfer of methods
- Validation batches
- Process scale-up and pilot production including 10/300 L reactors
- ICH stability studies
- Clinical batches
- Dossier support documentation
- Commercial manufacturing of industrial batches
- On going stabilities
- Labeling and packaging
- Serialization

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**GRIFOLS** 

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FFS technology for PP bags

Regulatory approvals