Grifols Partnership
Better together

PARENTERALS CDMO

FLUID DELIVERY OF PREMIUM PRODUCTS

Sterile Manufacturing
Delivery Systems
Parenteral Technologies

GRIFOLS

We care about your product as if it were our own

Grifols Partnership is a contract development and manufacturing platform (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.

Customers who have chosen Grifols as CDMO range from local, medium-sized pharmaceutical companies, to global industry leaders in the human and veterinary sectors.

Each customer is unique and we have learned a great deal from them over the years. We realize that what works for one company may not necessarily work for others.

*"**Grifols** has the resources of a large organization, but it is also able to provide a personal detailed level of service and quality."*

Cumberland (USA)

*"My company's project with **Grifols** was delivered on time and on budget. The **Grifols** team were responsive and flexible to our project needs and communication between our companies was excellent."*

Medicure (Canada)

*"Trust in a business relationship is as important as in personal relationships. It is built over the years and it is what makes us select a partner for a long term project versus another one. As it happened with **Grifols**, we wanted to work together as, over time, we had the possibility to appreciate each other."*

GYMA (USA)

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Collaborating with Grifols as a CDMO

Grifols actively seeks out projects with small and emerging pharma companies. The key to successful project completion is to develop understanding and alignment of the commercial strategies of both organizations.

Grifols Partnership offers you an integrated project management strategy during the development and supply of products. The team involves people from all relevant areas to implement the new processes and products at the manufacturing sites.

Our team carefully plans the project and follows it step by step keeping you informed every step of the way.

Flexibility and Understanding Matter

With many new drug candidates receiving designations allowing for accelerated approval pathways, CDMOs supporting small and emerging pharma companies developing small molecule injectable drugs must have the process understanding and physical capability to implement projects within dramatically shortened timelines.

Familiarity with project management and quality systems at both companies can also facilitate rapid completion of product developments and tech transfer projects.

Preformulation and pharmaceutical development

Development support for components

Scale-up & technology transfer methods

Validation batches

Process scale-up and pilot production including 10/300 L reactors

ICH stability studies

Analytical development & validation

Clinical batches

Regulatory support: providing technical documentation, certificates of analysis, safety sheets

Commercial manufacturing industrial batches

Small- and large-scale manufacturing

Labeling and packaging: tailored to your specifications

Serialization

Grifols Partnership **works together with the customer** from the early stages of development until commercial manufacturing, from **small scale to high production scale.**

A CDMO Dedicated to Supporting Small-Volume, Small-Molecule Parenteral Projects

Combining the focus on parenteral with the expertise of an established pharmaceutical leader, the contract manufacturing business is agile and flexible in its service to companies outsourcing the development and manufacture of injectable drugs.

We specialize in small-molecule intravenous solutions and offer high-quality pharmaceutical development and product manufacturing. Our portfolio also includes products that require careful design and assembly, including medical devices.

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

Sterile manufacturing solutions

- Large volume parenterals (100 mL - 1000 mL)
- Small volume parenterals (5 mL - 50 mL)
- Diluents for reconstitution
- IV specialties

Parenteral delivery systems

- Premixed solutions in IV Fleboflex® PP bags (50, 100, 250, 500 and 1000 mL)
- Premixed solutions in customized IV PP bags (50, 100, 250, 500 and 1000 mL) (One port, two ports, twist-off, luer valve)
- Premixed solutions in IV Fleboflex® Luer PP bags (50 mL - 1000 mL) Needle-free access valve
- Glass vials (2,5 mL - 50 mL)
- Glass bottles (50 mL - 500 mL)

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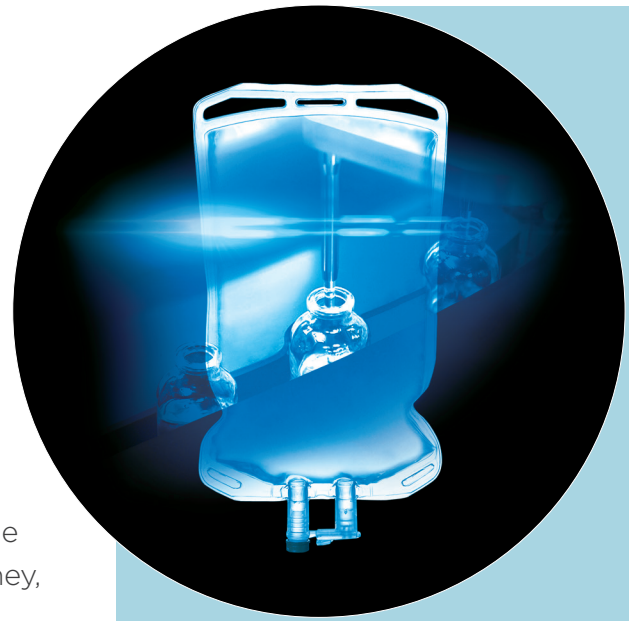
Expertise in Premixed Solutions to Specifically Treat Rare Diseases

We have already **helped other pharmaceutical companies** switch from a concentrated formula to a premixed solution in a ready-to-use, flexible bag, and we continue **to help companies develop and manufacture drugs to treat rare diseases.**

Life Cycle Management

We extend the product lifecycle by improving features, reformulating or switching from one type of container to another (for example, by switching from a vial to a flexible PP bag). Product lifecycle management should start as early as possible and be part of the product strategy portfolio in order to remain competitive. For this reason, when choosing a CDMO, it is important to consider a company that offers both development and manufacturing. This will enable a long-term relationship between both companies as strategic partners. Working with the same CDMO for both containers means saving time and money, and being able to rely on someone you already trust.

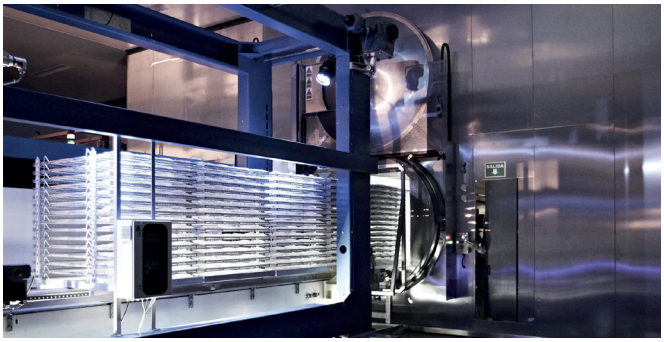


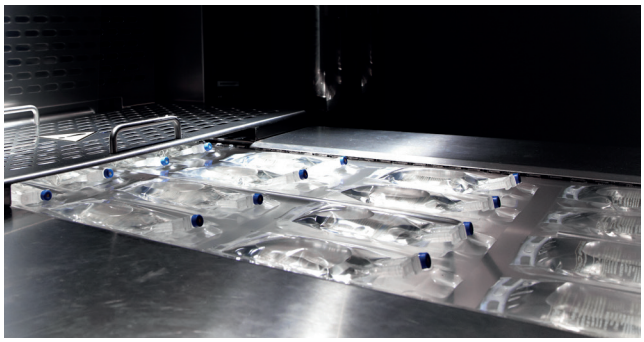
What Sets Us Apart from Other CDMOs?

We focus on quality

At Grifols, we aim at 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. A culture of absolute quality is at the root of our company business and it branches out through all of our manufacturing activities, including our sterile fill-finish operations. We manufacture our products following strict GMP standards and US and European Pharmacopeia requirements in order to ensure 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.





EMA

FDA

GMP

OSHAS 18001

ISO 13485

ISO 14000

CE

Parametric Release

A vertical integration model

Grifols Partnership also develops and manufactures its own flexible bags on site to obtain a perfect match between the drug and its container. This vertical integration model enables us to control the entire process from the very start and ensure the highest standards of quality to our customers.

We focus on automation

- Automation technologies offer safeguards to patients from contamination
- Artificial vision is used to determine the absence of particles
- Four Form-Fill Seal lines have been designed to manufacture polypropylene (PP) bags

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A Global Healthcare Company

GLOBAL EMPLOYER

Grifols, with more than 24.000 employees in 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership in the industry.

GLOBAL MANUFACTURER

Grifols has the infrastructure to meet the needs of patients and customers worldwide including manufacturing facilities located in the U.S., Spain, Germany, Ireland, Switzerland, Brazil and Australia.

INNOVATIVE

We conduct our own R&D programs and make strategic investments in promising start-ups and novel technologies. We also modernize our manufacturing facilities and develop novel processes to help ensure product safety and efficacy.

Grifols is a global healthcare company that since its founding in Barcelona in 1909 has **enhanced the health and well-being** of people around the world.

We produce essential plasma medicines for patients to treat chronic, rare and, at times, life-threatening conditions. The company provides a comprehensive portfolio of solutions in transfusion medicine and also offers hospitals, pharmacies and healthcare professionals information and services that deliver efficient, expert medical care.

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