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PARENTERALS CDMO

Manufacturing of Complex Parenterals

SUPPORTING SMALL-VOLUME AND SMALL-MOLECULE PARENTERAL PROJECTS

GRIFOLS

We care about your product as if it were our own

Grifols Partnership is a contract development and manufacturing organization (CDMO) specializing in high-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)

It's been fabulous, they have great expertise in project management and their technical expertise in the dosage form that we are working in, from start to finish, great transparency as far as communication wise great transparency.

GYMA (USA)

Our experience has been amazing, world-class CDMO partner, it's been a great partner for us.

Par Health (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.

Flexibility: Adapting manufacturing services to specialized and lower-volume injectable products is crucial due to the technical challenges in forecasting for these products with low patient populations.

Enabling Technologies: Necessary to address the challenges in the manufacturing and development of small molecule drugs, improving efficiency, precision, and scalability.

In our cGMP facilities, we can handle a variety of complex molecules, ensuring that production can be tailored to specific needs.

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

> **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 and 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	✔	✔

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.**

Lifecycle 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.

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 help 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 bags

- **US - FDA establishment identifier (Barcelona) 3009736169 (Murcia) 3010258616**
- **Spanish Health Authorities License Drugs (Number 1979E)**
- **Good Manufacturing Practices (GMP) Compliance certification (EEC and FDA)**
- **Spanish Health Authorities number 44PS**
- **ISO 13485 2016 and CE Mark issued by CNCSP (Medical Devices Notified Body 0318**
- **Environmental Management System Certification ISO 14001**
- **Occupational Health and Safety Management Systems Certification ISO 45001**
- **MDSAP Certificate for Canada, USA and Brasil / ISO 13485 2016 Issued by SGS**

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A Global Healthcare Company

GLOBAL EMPLOYER

Grifols, with more than 23.000 employees in over 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 US, 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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