PARENTERAL CDMO

Grifols Partnership

Better together

for **sterile solutions**
and **lipid emulsions**

GRIFOLS

We care about your product as if it were our own

Grifols Partnership is a business to business contract development and manufacturing platform (CDMO) for sterile solutions and lipid emulsions for the pharmaceutical industry.
Grifols Partnership undertakes all commitments with great enthusiasm; our objective is that your product reaches the market on time, and in optimum conditions.

"We are delighted to be expanding our relationship with ***Grifols*** *on a new product launch for the U.S. health systems market.* ***Grifols*** *truly exemplifies what we value in a partnership: technical expertise, collaboration, reliability, and service excellence. Most importantly, we feel as though we are part of the* ***Grifols*** *team, and not just another customer."*

Mylan

*"****Grifols*** *are very collaborative on our project and have excellent technical knowledge and experience, which they bring to the team"*

Mallinckrodt

Our service and approach to the customer

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.

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

- **Proformulation** and **pharmaceutical development**
- **Development support** for components

- **Scale-up & technology** transfer methods
- **Validation** batches
- **Process scale-up and pilot** production including 10/300L 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

Our areas of expertise: sterile injectable fill-finish

We specialize in small molecule intravenous solutions and offer high quality pharmaceutical development and product manufacturing. Our portfolio also includes products which require careful design and assembly including medical devices and bags for blood storage and collection.

STERILE MANUFACTURING SOLUTIONS

- **Large volume parenterals** (100ml-1000ml)
- **Small volume parenterals** (5ml-50ml)
- **Diluents for reconstitution**
- **Emulsion technology**
- **IV specialties**

PARENTERAL DELIVERY SYSTEMS

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

TECHNOLOGICAL CAPABILITIES

- **Aqueous LVP and SVP**
- **Emulsion technology**
- **Form Fill Seal (FFS) technology for PP bags**
- **Manufacture and filling of oxygen and light sensitive products**
- **Terminal sterilization**

Life cycle management

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 the right approach when choosing a CDMO should be to consider those that are able to offer 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, money and being able to rely on someone you already trust.

We have already helped other pharmaceutical companies make the switch from a concentrated formula to a pre-mixed solution in a ready-to-use flexible bag.

What sets us apart from other CDMOs

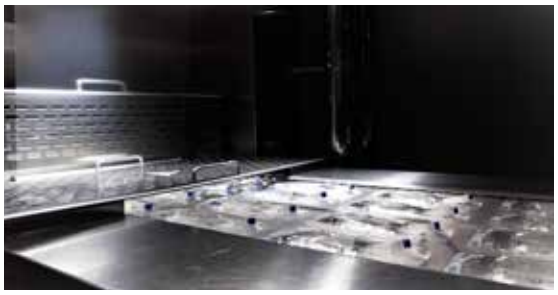
WE FOCUS ON QUALITY

At Grifols we work hard to ensure 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. 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 | ISO 13485 | FDA | ISO 14000

GMP | OSHAS 18001 | 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**
- **Three Form-Fill Seal lines have been designed to manufacture PP bags**

A global healthcare company

GRIFOLS IS PRESENT IN MORE THAN 100 COUNTRIES AND HAS 14,000 EMPLOYEES

GLOBAL EMPLOYER

Grifols employs more than 14,000 people worldwide – more than 10,000 of whom are based in the U.S. With each employee essential to our mission for continued growth, we strive to hire and retain the best employees.

GLOBAL MANUFACTURER

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

INNOVATIVE

According to Forbes magazine, Grifols is among the top 100 most innovative companies in the world. 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.

For more than 75 years, Grifols has improved the health and well-being of people around the world by producing life-saving plasma medicines and by providing healthcare professionals with the tools they need to deliver expert medical care.

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Grifols Partnership

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