

# Grifols

## A reliable and trusted partner in the injectable field



# GRIFOLS

Grifols Partnership



Better together

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As an expert parenteral CDMO, Grifols Partnership is aware that the high cost of manufacturing injectable drugs, as well as quality issues and compliance requirements, forces companies to outsource these products. For an increasing number of companies, seeking technically and operationally superior contract-service partners to deliver capacity and resources is becoming a key component of their patient-centric strategy and the fastest path to market.

### WHAT SETS GRIFOLS PARTNERSHIP APART FROM OTHER CDMOS IN THE INJECTABLE FIELD?

Our commitment with customers and credibility has positioned Grifols Partnership as a reliable and trusted partner in the injectable field.

From both a commercial and production perspective, we have historically invested in the delivery of safe and high-quality products to the market in a timely manner. Our holistic approach to quality has resulted in a robust and reliable quality system and positioned Grifols Partnership as an ideal strategic partner in the contract manufacturing of sterile products.

The history of Grifols is the history of a team, which has grown as new members have joined our project.

Although some team members contribute very specifically to certain projects, it's the cooperation and collaborative efforts of everyone here at Grifols that leads to the final outcome. We call it "One Grifols". Under the "One Grifols" concept, we are committed to serving our customers and delivering safe and high-quality products to the market. It is important to remember that behind each parenteral product is a patient, and at Grifols, we never lose sight of that fact.

### IS GRIFOLS PARTNERSHIP FOCUS MAINLY IN INJECTABLE PRODUCTS?

Grifols Partnership is focused solely on the development and manufacturing of sterile solutions. Our expertise with and extensive knowledge of intravenous products has positioned us as a leader in the contract manufacturing injectable market. There are few companies in this space and our experience is an added value to our customers. We have acquired broad expertise in the development of robust processes for the production of numerous types of injectable products and we apply this knowledge to each new client project.

There is a clear trend among all manufacturers to look for niche and special technologies that could be essential in the commercialization of new injectable products. As an example, Form-Fill-Seal Technology involves formation, filling and sealing of polypropylene bags in one step. The process is fully automated, with no human interaction, thereby avoiding potential contamination and minimizing particulates in the final solution.

To ensure complete control of the process, Grifols manufactures components, including ports and stoppers, employed in the Form-Fill-Seal process and uses equipment developed and manufactured by Grifols

Grifols has a more than 75-year history developing plasma-derived medicines, and during all this time, our work with nurses and doctors has provided us with extensive knowledge regarding their preferences for parenteral product design. We also have insight into how changes in process or product design might impact final product acceptance.

This knowledge can be highly beneficial for drug manufacturers seeking to differentiate their small molecule parenteral products, whether they are introducing a new branded therapy in a glass vial or attempting to extending the life cycle of a generic premixed solution in flexible plastic packaging.

### HOW HAS GRIFOLS PARTNERSHIP WORKED TO ADDRESS THE EXISTING SHORTAGE OF INJECTABLE PRODUCTS IN THE US?

The majority of drug shortages in the US are associated with injectable products. Grifols is currently working with several pharmaceutical companies seeking to mitigate drug shortages and their significant impacts on patients. We are prioritizing such products above other requests. As a reliable CDMO with a long track record of excellent quality performance, extensive expertise and knowledge in parenteral manufacturing and the ability to rapidly implement manufacturing processes, Grifols can help customers address drug shortage situations by accelerating the time to market.

Customers who have chosen Grifols as a CDMO range from big pharma to small companies, from human to veterinary and from global to domestic. Our customers are quite different between them and we always learn from them along years. We know that what it works for one company doesn't mean it fits to another one.

Working in this field requires an understanding not limited to the process and product being analyzed. Knowledge of each party's expectations and limitations is essential. Familiarity with project management and quality systems at both companies can also facilitate rapid completion of product development and technical transfer.

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