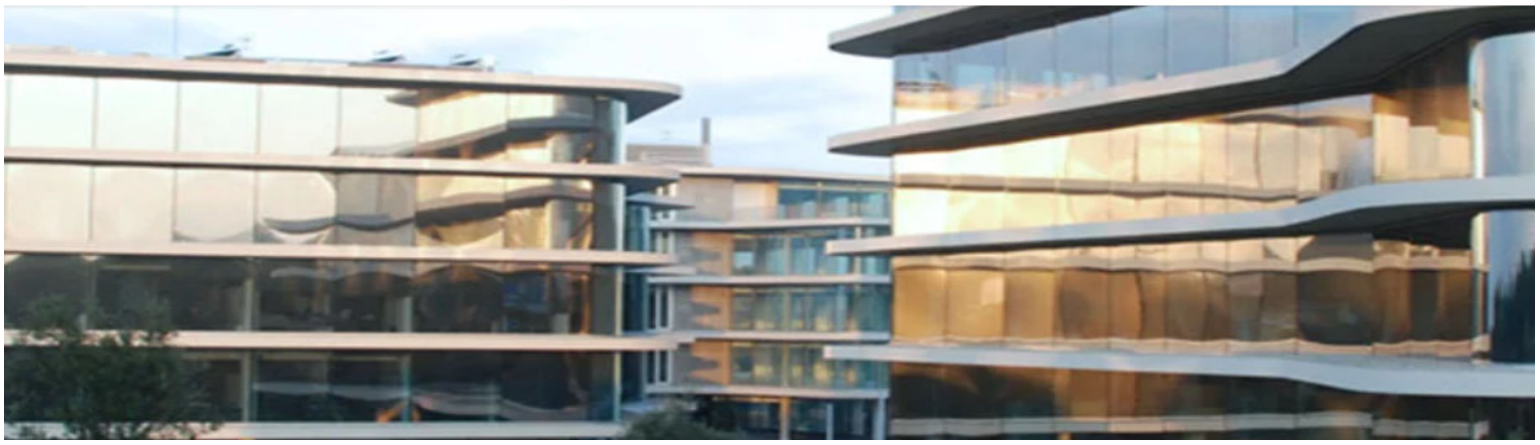

A CDMO Dedicated to Supporting Small-Volume, Small-Molecule Parenteral Projects

February, 2022 **PAO-12-21-CL-02**

Tags: **Parenterals Small Molecule Grifols Small Volume Q42021**

Oriol Prat
Director Contract Manufacturing & IV Solutions, Grifols

Oriol Argemi
Managing Director, Laboratorios Grifols, Grifols

Marga Viñes

Business Development Manager, Contract Manufacturing, Grifols

Oriol Prat, Director of Contract Manufacturing and IV Solutions at Grifols, Oriol Argemí, Managing Director of Laboratorios Grifols, and Marga Viñes, Business Development Manager for Contract Manufacturing at Grifols, spoke with Pharma's Almanac Digital Marketing Director, Phill Neill, about trends in parenteral manufacturing and how Grifols is maintaining its leadership in the small-volume parenteral manufacturing market.

Phill Neill (PD): What gives Grifols its strong position in the CDMO marketplace?

Oriol Prat (OP): Grifols is in the CDMO market because of our leadership in intravenous (IV) therapy and our focus on IV solutions, which is supported by deep knowledge in sterile manufacturing. With the extensive experience we have in producing our own parenteral drug products, we wanted to leverage these capabilities for customers in the pharma industry that have IV drug products but lack the specialized expertise and equipment, because these types of products are not part of their core businesses.

PD: As you look forward to the next decade, what trends do you see or anticipate in the parenteral manufacturing space?

Marga Viñes (MV): I see two main trends: the rise in orphan drugs and the expansion of manufacturing capacity. The rise of orphan drugs to treat rare diseases and the increase in the development of more targeted therapies with small patient populations results in increased manufacturing needs for low-volume drugs. These products create both opportunities and challenges for contract manufacturing organizations (CMOs). Most existing manufacturing capacity in the pharmaceutical industry is designed for the production of large volumes of drug product. For orphan drugs, these manufacturing plants must be converted or rebuilt so that they can accommodate lower scales. Some pharmaceutical companies are not able to make the necessary investments and, therefore,

must outsource. Grifols is well-positioned to help them with small-volume parenteral manufacturing.

The increase in parenteral manufacturing capacity is due to expansions, as well as acquisitions and the creation of partnerships. The market is highly fragmented, and as a result there is significant M&A activity from the big players, which are both expanding their capabilities and significantly increasing the range of products they offer. That has led to increased competition among smaller CMOs, who are forced to establish niche positions within the market. Each company has to strengthen its position in the segment in order to be able to provide significant and differentiating value to sponsors.

PD: How has the shift toward smaller-volume, niche, and personalized medicines affected the approach to parenteral drug manufacturing?

MV: Perhaps the biggest challenge for CMOs is the cost associated with manufacturing small-volume parenteral. That has created a perception for some that CMOs do not want to participate in this segment of the market. That is not true. There are specialized CMOs, such as Grifols Partnership, that are devoted to these types of projects and excel in managing the complexity behind them. We support our customers with a combination of long-term experience, knowledge, and real agility, which helps them be successful in the market, even with highly complicated projects.

PD: What are the inherent challenges with small-volume manufacturing?

MV: Other than cost, the biggest issue is accommodating a larger number of products in the processing line, which requires a lot of product changeovers. Managing this activity is only possible for CMOs that have teams with extensive experience in parenteral manufacturing and that are really customer-focused.

PD: What is Grifols' approach to continuous improvement of parenteral manufacturing?

Oriol Argemí (OA): First of all, let me say that, within the larger Grifols Group, we have Grifols Engineering, which is a pharma engineering company focused on engineering development and automation. They are responsible for all our facilities, but also offer services to third parties. For sterile manufacturing, automation is a must in order to reduce the need for human interventions, and thus the risk of contamination. Even though we already have state-of-the-art facilities at Grifols, we are always pioneering new automation solutions and committed to continuous investments and enhancements that ensure continuous improvement of our automated systems.

OA: We actually continue to improve our technologies across the board. For instance, we have increased our storage capacity and added a cutting-edge particle revision technology and a new, fully automated manufacturing line for the filling of specialty products in polypropylene bags. We are also adapting and upgrading our software and document management capabilities to increase the efficiency of project management, ensure data integrity, and meet the evolving needs of our customers.

PD: Overall, what is Grifols doing to stay ahead of the curve and remain a leader in the orphan drug space?

MV: Grifols has been participating in the orphan drug market since it was first established. Our manufacturing lines are quite flexible and able to accommodate low-volume demand. From the start, each project is managed and structured, taking into account its industrial scale. Thanks to our experience and knowledge in technology transfer for high-volume products, it is quite easy to adapt to this newest scenario dealing with low-volume drugs.

OP: The success of our customers is our success. If they achieve their goals, we achieve our goals. That's why transparency in all our activities ensures that our focus remains centered

on the customer. Our ultimate goal is that we, at Grifols, and our customers achieve our objectives for every CMO project.

In addition, because the CMO business is a part of the Grifols Group, we have strong financial support and comprehensive resources, which gives customers peace of mind.

GNL-CM-2200001

https://www.pharmasalmanac.com/articles/a-cdmo-dedicated-to-supporting-small-volume-small-molecule-parenteral-projects