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A sponsor of DCAT Week expands on **Parenteral CDMO services**

Grifols has emphasised its commitment to expanding its parenteral CDMO services, predominantly in the small molecules injectable field. What strategies is the company adopting to reinforce its position in this market? And how does this align with the growing demand for small molecule injectable therapeutics?

Grifols is actively expanding its contract development and manufacturing services, particularly focusing on small molecule injectables. Here are some key strategies we are adopting:

High specialization in fill-finish small molecule injectables: Grifols is enhancing its capabilities in the development and manufacturing of sterile injectable drugs, including both concentrated and diluted parenteral formulations. This specialization allows us to cater to the growing demand for high-quality, terminal-sterilized injectable drugs.

Manufacturing sites are equipped with *automated multi product lines* to ensure efficiency and high standards in the production process. This automation supports the scalability and flexibility needed to meet diverse client requirements.

Global experience and partnerships: leveraging over 100 years of expertise, Grifols collaborates with mid-size, big, and generic pharmaceutical companies. These partnerships help us deliver substantial value and maintain high standards of quality.

Commitment to innovation and improvement: CDMO business is aligned with corporate values such as innovation and continuous improvement ensuring it stays ahead in the competitive CDMO market.

These strategies align with the growing demand for small molecule therapeutics by providing agile and flexible outsourcing solutions, ensuring high-quality pharmaceutical development, and addressing the needs of both human and veterinary pharmaceuticals.

How do you plan to differentiate Grifols from other CDMO providers?

We prioritize building long-term partnerships with clients by offering personalized services, flexibility, and responsiveness to meet their specific needs.

These initiatives and differentiators help us stand out in the competitive CDMO market and attract clients looking for reliable and innovative partners.

Grifols offers end-to-end solutions, from development to commercial manufacturing, ensuring seamless project execution and reducing time-to-market for clients. With a strong emphasis on quality and regulatory compliance, we ensure high quality standards for all products, which is crucial in the increasingly regulated pharma/biotech industry.

Recently, Grifols revealed details of technology investments that enhance its CDMO capabilities. Can you go into more detail as to how these investments will improve efficiency, scalability, and client satisfaction in small molecule manufacturing?

Grifols operates two FDA-and GMP-approved manufacturing sites in Spain, located in Barcelona and Murcia. These facilities are equipped with advanced technologies, including form-fill-seal (FFS) lines for flexible polypropylene (PP) bags, which optimize drug manufacturing costs, reduce lead times, and enhance patient safety. Facilities are designed with sustainability in mind, incorporating energy-efficient technologies and waste reduction strategies. This not only reduces the environmental footprint but also aligns with the sustainability goals of many clients. The in-house engineering division, Grifols Engineering, provides additional support, helping in terms of control over the entire process.

The new investments include additional FFS lines and high-capacity autoclaves for terminal sterilization. This expansion allows Grifols to scale up production efficiently to meet increasing client demands. New integrated artificial vision OCR systems (Optic Recognition of the characters) for particle detection ensures a high quality standard for injectable solutions assuring 100% vials inspected. This technology minimizes human intervention, reducing contamination risks and errors.

These investments improve efficiency by streamlining production processes and enhancing quality control. Scalability is achieved through expanded capacity and advanced technologies, allowing us to handle larger volumes and more complex projects. Client

satisfaction is boosted by the company's commitment to quality, sustainability, and comprehensive service offerings, making Grifols a reliable and innovative partner in the CDMO space.

Grifols has also been clear about its sustainability goals, including reducing its environmental footprint. How are you integrating sustainable practices into your CDMO operations, particularly in small molecule production? What impact will this have on client partnerships?

Grifols is actively integrating sustainable practices into its contract manufacturing operations. Some of the initiatives are:

- Setting up energy efficiency technologies and processes to reduce energy consumption across its manufacturing facilities.
- Implementing waste reduction strategies, including recycling programs and waste minimization techniques (water recycling systems), to lower its environmental impact.
- Ensuring that suppliers adhere to environmental and social responsibility standards, Grifols also shows its commitment to sustainable sourcing of raw materials.

These sustainable practices not only help Grifols reduce its environmental footprint but also enhance its reputation as a responsible and forward-thinking partner. This commitment to sustainability can strengthen client partnerships by aligning with the values and goals of clients who prioritize environmental responsibility. It also helps clients meet their own sustainability targets, creating a mutually beneficial relationship.

With stricter regulatory scrutiny in the pharma/biotech industry, how is Grifols drawing upon its expertise to ensure compliance and streamline approvals for small molecule products manufactured under its CDMO services? Can you share any recent successes in this area?

Grifols employs a quality by design (QbD) approach, integrating quality into the design and development of manufacturing processes from the outset. This ensures that products meet regulatory standards consistently.
The company has a dedicated team of regulatory experts who stay abreast of the latest regulatory requirements and guidelines. This team provides comprehensive support, including technical documentation, safety sheets, and certificates of analysis, to facilitate smooth regulatory submissions and approvals.

Each production site maintains stringent quality control measures including raw materials control, bioburden testing, and final product control. This rigorous oversight ensures that all products comply with Good Manufacturing Practices (GMP) and other regulatory standards.

Grifols has secured authorization for parametric release of parenteral solutions, which allows for product release based on data collected during manufacturing rather than end-product testing. This enhances efficiency and ensures consistent product quality.

Grifols manufacturing facilities are accredited by major regulatory bodies, including the FDA, the EMA, and Health Canada. This global compliance framework ensures that products meet the highest regulatory standards across different markets.

By integrating these practices, Grifols not only ensures regulatory compliance but also enhances the efficiency of the approval process, thereby strengthening client partnerships and fostering trust.

Grifols CDMO parenteral business has stated its intention to increase visibility in 2025. Are there any initiatives or campaigns the company is planning to raise awareness of its CDMO services, notably in the small molecule space?

We actively work on several initiatives and campaigns to raise awareness of our CDMO parenteral services. For instance, we regularly participate in major industry conferences and events, such as CPhI worldwide and DCAT, to showcase our CDMO capabilities and network with potential and existing clients.

Our team publishes articles in leading industry journals to highlight its expertise and innovative solutions in small molecule production.

Grifols leverages digital marketing strategies, including targeted online advertising, social media campaigns to reach a broader audience and educate them about its CDMO services.

Sharing client testimonials and success stories helps build credibility and demonstrate the value we bring to our partners.

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