

“Quality is our pillar”: Grifols’ Marta Serra on regulatory readiness



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Grifols Partnership stands out from other CDMOs through our commitment to the well-being of patients and their quality of life.

Safety is elevated above regulatory obligation and is coupled with our holistic approach to quality. This Grifols philosophy encompasses not just our products, but also permeates our internal manufacturing, communication, and operational procedures.

Our commitment to quality has engendered a robust, dependable quality system, establishing Grifols Partnership as an ideal strategic partner.

Speaking to 24/7 BIOPHARMA, Marta Serra, Quality & Regulatory Director at Grifols, a leader in plasma-derived medicines and transfusion medicine, outlined how the company is preparing to meet future regulatory and market demands.

Quality systems for small molecules remain aligned with evolving global regulatory expectations, especially in markets like the U.S., EU, and emerging regions?

Grifols’ Quality System is one of the pillars of its operations, designed to establish and maintain high standards across all processes and products. The system covers quality planning, assurance, control, and continuous improvement, with constant monitoring of regulations in all key markets to ensure ongoing alignment.

What are the key challenges in maintaining consistent quality standards across different phases of small molecule development and manufacturing, and how does Grifols’ CDMO structure support this integration?

Our approach is based on customer focus, leadership, team commitment, integration, continuous improvement, evidence-based decision-making, and strong relationship management. These principles are applied throughout development, from technology transfer and scale-up to production, while adapting processes to address new challenges and integrating sustainability. Digitalization plays a key role, enabling automation, data analysis, trend monitoring, and ongoing improvement.

With the growing regulatory emphasis on data integrity, how is Grifols implementing digital solutions to ensure compliance and traceability across the lifecycle of small molecule

products?

Grifols is fully committed to data integrity and has developed a strategic plan for equipment specification requirements in all GMP processes. For equipment already in operation, corrective actions have been implemented to meet new regulations. Data integrity is also a major focus of internal audits.

What role does Quality Risk Management (QRM) play in decision-making for Grifols’ small molecule operations, and how do you balance risk mitigation with operational efficiency?

QRM is essential, built on the principles of identifying, assessing, controlling, and reviewing risks across the product lifecycle. A strong multidisciplinary team with deep process and product knowledge ensures effective risk communication and mitigation. Misapplication of QRM can directly impact process efficiency, so careful execution is critical.

How does Grifols maintain a state of inspection readiness across its small molecule facilities, and what recent trends have you observed in regulatory agency expectations during inspections?

Continuous quality improvement is central to our operations. Dedicated quality teams work directly within processes to identify areas for enhancement and to adapt to regulatory changes. Regulators increasingly expect to see proactive teams with a strong command of regulations and clear implementation of changes.

How do you foster a culture of quality and compliance across multidisciplinary teams, particularly when managing outsourced or client-sponsored

small molecule projects?

Quality is a core pillar at Grifols, so every process must be supervised by our quality team. Internally, we run extensive training sessions, and for subcontracted activities, we make sure Grifols’ quality principles are clearly communicated and enforced.

What are the most significant upcoming regulatory or quality trends you anticipate will impact small molecule development, and how is Grifols preparing to meet these future demands?

Future regulations will place greater emphasis on continuous improvement processes grounded in risk assessment carried out by experts. Systematic data analysis will also be crucial, helping to predict trends and prevent deviations during processes.

