# Innovating to Optimize Quality in Injectable Drugs

Michael Howell, Site Director of Albumin Manufacturing, Grifols

**Grifols Partnership has decades of experience in the production of small molecule parenteral drug products and has built an extensive body of knowledge surrounding the relevant processes and the needs for products targeting both conventional and rare diseases at clinical to commercial scales. Michael Howell, Site Director — Albumin Manufacturing, at Grifols facilities in Grange Castle, Ireland manufacturing site, recently spoke with Pharma's Almanac about Grifols' forward-looking vision and the role of automation and other innovative technologies in driving quality in parenteral drugs.**

**Pharma's Almanac (PA): How is Grifols working to realize the future of healthcare?**

Michael Howell (MH): Healthcare as we know it today will no longer exist. We should be prepared for a new scenario driven by emerging technologies, highly engaged customers, and new business models.

At the global level, Grifols is preparing to face the new challenges that the future brings. At the level of our contract manufacturing business, we are clear that optimizing processes, projects, investments, and resources are key axes to structure healthy growth.

We have always promoted the personal growth of our teams, and now, more than ever, this is a key point of commitment and continuity that our clients greatly value.

**PA: How is Grifols approaching the challenge of running the CDMO business within the broader Grifols holding company?**

MH: Grifols has a long history in the pharmaceutical sector, and our great experience and knowledge in the manufacture of pharmaceuticals encouraged us in the past to offer all this know-how as an outsourced part-

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ner to pharmaceutical customers. In 2004, the Grifols Partnership business area was founded, which is dedicated to the development and manufacture of injectable drugs (small molecules) for third-party companies in the pharmaceutical sector. This business is now quite well known in our sector, but probably few know that Grifols also manufactures products for the companies within the group (e.g., water for injection [WFI], albumin, bags, etc.), acting as a contract manufacturing service for the group's own internal projects.

This approach allows us to have full control of all manufacturing and quality processes and reduces risks in terms of the supply chain and lead times.

### PA: What can you tell us about the kinds of cutting-edge solutions that Grifols Partnership offers your customers?

MH: The performance of a comprehensive risk analysis is crucial to the development of effective processes for sterile injectables. These risk analyses allow for identification of sources of potential problems, along with the implementation of measures that may prevent those issues from arising. The goal of risk management is not to eliminate downside risks but to control them within an acceptable range. Once the limits and potential areas of concern have been identified, the next step is to determine the process conditions and controls needed to ensure that the process will be robust and scalable.

As a CDMO, Grifols specializes in injectables, with a focus on the fill/finish of small molecule injectable products. Grifols offers both concentrated and diluted small molecule parenteral formulation options. As a business unit within a global pharmaceutical manufacturer, Grifols Partnership has access to financial, technical, regulatory, and other resources that are not readily available to standalone CDMOs. In addition, we use the same equipment, which is designed specifically for Grifols, for both internal and external projects. This vertical integration also fits with Grifols' quality culture; it enables us to control the entire process, ensuring achievement of high quality.

### PA: What is the overall approach that Grifols takes to manufacturing injectable drugs?

MH: Grifols is currently manufacturing many of the same products that were produced 20 years ago, but in an entirely new manner and in an upgraded, state-of-the-art facility. The new manufacturing plants rely extensively on automated processes, from production of the plastic containers to the preparation of drug product solutions, to filling, sterilization, and final packaging. Advances in technology have made the implementation of many of these automated solutions possible – one important example is form-fill-seal technology for flexible bags.

Our automated systems significantly reduce human interactions with the product and process, thus reducing the risk of contamination. Robots can be programmed to perform the same motion in exactly the same way every time, something that is not possible for humans to accomplish. They also enable the collection of large quantities of data that can be analyzed and used to make process improvements, which will in turn lead to even greater productivity. Overall, the automated processes employed by Grifols are robust and efficient and lead to more consistent and higher-quality products.

### PA: How are new and innovative technologies changing quality assurance for parenterals?

MH: Now more than ever before, innovations in technology are allowing Grifols to enhance the level of security around our people, processes, and practices as we manufacture and deliver critical products to our customers. Advances in automation and engineering principles allow us to develop unique manufacturing process, such as the robotic Grifols Filling System, ensuring that our products are filled to very high standards of cleanliness and quality. This is achieved by removing the human interface from the most critical points of the manufacturing process, thus ensuring that any potential risk of contamination is eliminated from our production environment.

The use of data analytics tools and integrated business enterprise systems with manufacturing executions systems means that we now have the information we need at our fingertips, ensuring better and more timely decision making regarding our products and processes, which leads to increased productivity, higher standards of quality, and demonstrated delivery of our products to our customers, all of which work toward our overarching goal of putting out patients first. ■

## ABOUT THE AUTHOR


**Michael Howell**

Site Director of Albumin Manufacturing, Grifols


Michael Howell holds a degree in mechanical and manufacturing engineering from Munster Technical University in Ireland. He has over 20+ years of experience in various senior leadership roles in the pharmaceutical and biopharmaceutical industries, working in the areas of oral solid dosage, sterile manufacturing, and biologics. Michael joined Grifols in 2019 and today leads the development and commercialization of a new, state-of-the-art albumin purification and aseptic filling facility in Dublin, Ireland.


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