Grifols Partnership Parenterals CDMO. Rare specialist for tomorrow's medicines

Growth in the pharmaceutical industry is no longer exclusively driven by large pharmaceutical companies. The switch in the marketplace from a focus on blockbuster drugs to an emphasis on therapies that treat orphan and rare diseases has led to the rise of small and emerging pharma companies founded to advance novel medicines for specialized patient populations. These innovators require the support of contract service providers that recognize their unique requirements.

Recent successes in the development of orphan drugs coupled with productivity challenges in the classic pharma R&D model for indications with a higher prevalence have resulted in a number of major pharmaceutical companies establishing business units focused on rare diseases.

Sponsor firms developing orphan drugs as parenteral products should only work with CDMOs that have the necessary expertise to produce these complex products and those that are committed to conducting extensive risk assessments before beginning any new project.

COLLABORATING WITH GRIFOLS AS A CDMO

Grifols Partnership is a contract development and manufacturing platform for sterile solutions (small molecules) within a large international pharmaceutical experience in the development and manufacturing of many types of sterile drug products. We are able to leverage the resources and experiences of the larger Grifols organization to provide significant value to our partners, from guiding new drug applications through regulatory approval to determination of patient and caregiver reactions to product delivery systems.

While many CDMOs are disinclined to pursue small-volume projects focused on developing and manufacturing orphan drugs for unmet needs, others, such as Grifols, actively seek out such projects with small and emerging pharma companies. The key to successful project completion is to develop an understanding and alignment of the commercial strategies of both organizations.

CDMOs must understand the commercial strategy of the sponsor to be able to accurately structure the timeline and to guarantee production of the product on time. In addition, knowledge of the sponsor's commercial strategy allows the CDMO to better support management of its life cycle and prepare for new market demands.

FLEXIBILITY AND UNDERSTANDING MATTER

With many new drug candidates receiving designations allowing for accelerated approval pathways, CDMOs supporting small and emerging pharma companies developing small molecule injectable drugs must have the process understanding and physical capability to implement projects within dramatically shortened timelines. They must also have flexible capacity to support projects as they move from the clinic to commercialization.

In many cases, specialized products developed as orphan drugs or therapies designed to treat rare diseases, will target small patient populations. The quantities of these drug products required at the clinical stage, and even for commercial production, can be much smaller than those for more traditional medications — as low as 100,000 units, for instance. The ideal CDMO for clients developing these products welcomes these smaller volumes but also has the ability to expand production to millions of units if or when the volume demand increases.

THE VALUE OF QUALITY

The processes involved in the manufacture of sterile parenteral products are usually more intricate than those required for the production of oral dosage forms. A culture of quality, and effective quality assurance systems are essential for the successful production of complex products such as sterile intravenous therapies. It is imperative that all parenteral products be manufactured to the highest quality standards, regardless of whether they are branded drugs or generics. Grifols' heritage as a major supplier and manufacturer in the plasma-derived proteins market includes an unconditional commitment to quality. A culture of absolute quality is at the root of our company business and it branches out through all of our manufacturing activities, including our sterile fill-finish operations.

Grifols was one of the first companies in Europe to obtain approval for the parametric release of parenteral solutions.