Goodwin Biotechnology: Delivering Impeccable Outcomes to BioPharmas

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Karl Pinto, CEO

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The biologics space is rapidly attaining new heights by developing products like antibodies (monoclonals, bi-specifics tri-specifics, polyclonals), recombinant proteins, antibody-drug conjugates (ADCs), radio-immunotherapies, conjugated vaccines, extracellular vesicles (exosomes) and more, that are revolutionizing disease treatments. However, these high valued new products and techniques are extremely complex to develop and manufacture at scale, and often require a number of components to build. As a result, pharmaceutical companies are dependent upon CDMOs (Contract Development & Manufacturing Organizations) to develop, manufacture and move their products through the clinic. The pharmaceutical companies seeking such CDMO services are challenged with finding a CDMO partner that can manage the whole supply chain smoothly. The more individual contractors a company needs to use, the greater the complications that could often cause delays, potential quality issues, and unexpectedly high costs. Such risks can often jeopardize the entire clinical campaign if the final drug product (DP) is not ready in time to treat patients. There is also a continued consolidation within the CDMO space, resulting in fewer, much larger CDMOs who cannot work as efficiently with the smaller, highly innovative biotech product companies. This creates a gap.

For almost three decades now, Plantation, Florida based Goodwin Biotechnology mitigates these challenges by internalizing and being responsible for most of what is required to make the final drug product. With its Single Source Solution boasting a wide portfolio of services, Goodwin develops and manufactures complex biologic therapeutics second to none in the industry. The company is the pre-eminent provider of high-quality, cost-effective, flexible, and timely cGMP compliant manufacturing solutions, from pre-clinical development through clinical, and is expanding into commercial product supply.

Goodwin has remained relatively small in size while building its area of expertise into a variety of fields. Because Goodwin offers expertise in Bioconjugations, for example, the batches required are not typically large and Goodwin's 500L (liter) bioreactor scale is well-positioned to achieve efficiencies at this scale or smaller. In addition, Goodwin manufactures both Bulk Drug Substance and Vialed Drug Product at the same facility, and this feature which is appealing to many clients, is often an important factor that converts a prospect to a customer. "Unlike large CDMOs that may not be as flexible and don't undertake products that are at smaller scale, Goodwin is small and agile, and partners with the client in every step of the process to bring the drug, at the appropriate scale and regulatory requirements, to the clinic and eventually towards the market," says Karl Pinto, CEO, Goodwin.

Goodwin has broken ground on an expansion that provides greater flexibility and scale to take on multiple projects from early-stage process development to the full cGMP manufacturing of complex biopharmaceuticals, sterile Fill & Finish, and supporting analytical services.

In addition, the company has invested in expanding its regulatory acumen such that its quality systems support clients as they move towards commercialization. Goodwin's team of scientists, engineers, and operators have decades of experience working with a large number of projects and products (almost 500 over its history) that require the scale-up, process economics and compliance of complex molecules to ensure an efficient manufacturing process that can support a larger scale in a timely manner. "We have established process knowledge and platforms that can be applied to several complex molecules that include fusion proteins, antibody fragments, multi-specific antibodies, exosomes and complex bioconjugations of the same," says Pinto.

In one instance a few years ago, a small biotech client with a cutting-edge new photoimmunotherapy platform for treating cancer needed their technology to be further developed, refined, scaled up, and manufactured compliantly in order to conduct their very first clinical trial. Goodwin successfully provided this client with material for their clinical trials which continue to be successful, currently in late studies. The company now works with this client on multiple products which leverage their specialized technology platform. This client has grown in size more than one hundred-fold and is worth hundreds of millions of dollars, all pivoting around this proprietary and highly valuable technology.

Goodwin has been providing CDMO services since 1992, making it one of the oldest existing and most experienced CDMOs globally. "Our process development and manufacturing experience together with our regulatory and product characterization have been borne from our longevity, during which time nearly 500 projects pertaining to biologics products have been completed with over 150 clients," says Pinto. Today, Goodwin continues to have more than 80 percent of its business from existing or referred clients, which is a testament to the level of client satisfaction that it enjoys. 'Goodwin Delivers' is one resounding feedback from its clients based upon the well-rounded portfolio of services offered by the company, which validate its Single Source Solution uniqueness.

Currently, Goodwin is in the midst of a major expansion that will increase its capacity and efficiently meet regulatory compliance. While the company continues to execute Fill & Finish campaigns to generate clinical materials, its new and increased Fill & Finish capacity, to be ready in a few months' time, will enhance its Filling capacity by a factor of four and will also support late stage clinical and commercial products manufacturing. At the same time, Goodwin is expanding its manufacturing capacity from 500L to 2,000L single-use bioreactors, which will be in place in 2022. "Our regulatory compliance and Quality Systems are continually being expanded and upgraded, with an eye on achieving commercial product readiness by next year," says Pinto.

Company
Goodwin Biotechnology

Headquarters
Plantation, Florida

Management
Karl Pinto, CEO

Description
Develops complex biologic therapeutics by being the pre-eminent provider of high-quality, cost-effective, flexible and timely cGMP compliant manufacturing solutions