Biologics cGMP Manufacturer of the Year 2018

Goodwin Biotechnology, Inc. is a US-based, uniquely qualified, and flexible full GMP Contract Development and Manufacturing Organization (CDMO) that offers a fully integrated Single Source Solution™ from cell line development, process development, cGMP contract manufacturing and aseptic Fill/Finish of mammalian cell-culture derived monoclonal antibodies, recombinant proteins, vaccines, and Antibody Drug Conjugates (ADCs) for early-and late-stage clinical trials. We explore the secrets behind the firm's success so far.



1992, Goodwin
Biotechnology was
one of the first
fully integrated
CDMOs. Since then, Goodwin
Biotechnology has been a
customer-focused, flexible
strategic partner for companies

Established in

customer-focused, flexible strategic partner for companies of all sizes. SooYoung Lee, Ph.D, and the company's COO, discusses the firm's recent developments.

"At Goodwin Biotechnology, we have developed and optimized bioreactor and purification processes for a number of industrially important cell lines including CHO, NS/0, BHK, 293, as well as murine hybridomas, and have completed more than 400 projects, the majority of which were for Phase I through Phase III clinical trials."

The firm also develops a number of other innovative solutions, as Muctarr Sesay, Ph.D, CSO and VP of Bioconjugation, highlights.

"Alongside our work with bioreactors, Goodwin Biotechnology is one of the pioneers in providing development and cGMP manufacturing of ADCs, including Cytotoxic-immunoconjugates, Radio-Immunoconjugates, Peptide-Immunoconjugates, and other Bioconjugates for over 15 years. We provide random and proprietary site-directed conjugation of payloads to antibodies or proteins to improve conjugate binding, and with our high containment SafeBridge® level 4/5 ISO7 facility for handling highly cytotoxic, small molecule drugs and the receipt of a DEA manufacturer's license for the

development and manufacturing of controlled substances such as opioids, we can meet the special needs of a variety of clients."

In conclusion, CEO Karl Pinto outlines Goodwin Biotechnology's future plans as the firm looks towards a bright and exciting future.

"Ultimately, based on this success and coupled with the needs of our current and prospective clients, Goodwin is embarking upon our next stage of growth in 2018 with a commercial facility build out plan in progress. The conceptual design is in process and we plan to be ready to provide commercial manufacturing services by mid-2019.

"Overall, this award is testimony to how we enhance the value of our clients' product candidates with clear development and manufacturing strategies by providing a road map to meet the appropriate quality requirements from the milligram and gram range to hundreds of gram quantities as their product candidates move along the clinical development pathway in a cost-effective, timely, and cGMP compliant manner."



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