



GOODWIN BIOTECHNOLOGY, INC.
Your Partner To Market For Therapeutic Products



Your Time Is Our Essence™

OUR EXPERIENCE

- ▶ Pre-clinical, Phase-I, Phase-II, Phase-III and Commercial Manufacturing
- ▶ Over 20 Years as a Manufacturer of Therapeutic Antibodies
- ▶ Over 14 Years as a Contract Manufacturer of Recombinant Proteins
- ▶ 320+ Cell Lines / Products Manufactured
- ▶ 100+ Clients Served, 80% Repeat/ Referral Business
- ▶ 15 Regulatory Filings and INDs
- ▶ 85+ Successful Audits by Clients, Auditors and Regulators
- ▶ Expression Systems
 - Mammalian (CHO, NS0, 293, BHK)
 - Transgenic (Plant, Avian, Caprine)

YOUR PIPELINE



OUR BIOREACTORS

- ▶ Stirred Tanks (200L, 500L, Q3 2006)
- ▶ Packed Bed Reactors
- ▶ Hollow Fiber Reactors
- ▶ Perfusion/Batch



OUR SERVICES

UPSTREAM PROCESS DEVELOPMENT

GBI provides services from cell line evaluation, media selection studies and subcloning. Bioreactor process development is also performed prior to cGMP manufacture. If needed, GBI can partner for cell line development.

CELL BANKING

GBI provides cell banking services that include manufacturing of seed, master, working and post-production banks in accordance with FDA and ICH guidelines. Bank sizes of up to 200 vials can be manufactured.

MANUFACTURING EXPERTISE

GBI's senior Operational and Quality staff have an excellent track record and each have a minimum of 10 years of experience in cGMP environment. Staff experience includes working at several leading biopharmaceutical companies.

PROJECT MANAGEMENT

GBI assigns a Project Manager to all projects to facilitate client communication as well as track all project activities. This streamlines project execution and provides the client with a single contact point for project information.

PURIFICATION

GBI has experience of running pilot and process scale chromatographic operation with a wide range of medium that include affinity, ion exchange, hydrophobic interaction, and size exclusion. Batch sizes typically range from one to one hundred grams. GBI has proven expertise in developing viral filtration and inactivation steps.

Preclinical

Phase I

Phase II

Phase III

To Market

QUALITY AND REGULATORY SERVICES

Quality is what GBI takes pride in and has experienced staff developing and executing various analytic methods. GBI provides full regulatory services for projects that begin at initiation and conclude with the creation of the Chemistry, Manufacturing & Controls (CMC) section for the IND filing. GBI provides regulatory assistance for all phases of the client's project including meeting with regulatory agencies to discuss manufacturing and testing issues. The staff is knowledgeable in US, Canadian, European, and Asian requirements.

PRODUCT VIALING

GBI maintains a Class 100 vialing facility that provides economical and compliant filling of client material. This operation is fully validated for fill volumes up to 10mL/vial.

PROTEIN CONJUGATION AND MODIFICATION

Whether a client's protein requires a toxin, another protein or an isotope attached, GBI can develop a conjugation process that is efficient, stable, and regulatory compliant.

DOWNSTREAM PROCESS DEVELOPMENT

GBI helps clients develop and refine downstream purification processes. With an extensive background in the purification of monoclonal antibodies and complex recombinant proteins, GBI can quickly develop a robust and economical purification process while meeting current regulatory requirements. GBI has successfully developed protein purification processes for over 50 clients.



“ GBI is a pioneer and continues to lead by deploying its global development platform for therapeutic biologics processing, greatly reducing our client’s cost to market and time to market risks. Integrity, innovation and partnership take our clients where they need to be. ”

- Karl Pinto, Chairman



“ Goodwin’s more than 15 years of experience has entrenched in us a ‘never give up’ spirit, industry strength, performance and broad capability set, enveloped by a flexible and cost-conscious attitude towards our clients. This has ensured that we have successfully served over 80 clients on more than 300 cell lines and projects, a pedigree that few others can match. ”

- Stephanie C. Finnegan, CEO

Senior Management

- David Fischer, Executive Vice President and Founder
- Mike Cox, Senior Director, Process Development
- Storm Lefelar, Director, Manufacturing Operations
- Jay Madan, Director, Business Development
- Ellery Mangas, Director, Regulatory and Quality
- Muctarr Sesay, Ph.D., Director, Process Development

Contact Information

Business Hours

Monday-Friday 8:00 AM to 4:30 PM EST

Telephone : (954) 321-5300
FAX : (954) 587-6378
Postal address : 1850 N.W. 69th Avenue, Plantation, FL 33313

Electronic mail

General Information : info@goodwinbio.com
Business Development : bizdev@goodwinbio.com
Sales : sales@goodwinbio.com
Employment Opportunities : employment@goodwinbio.com

