SCORPIUS BIOMANUFACTURING

PROCESS DEVELOPMENT & CLINICAL MANUFACTUREING

Process development & cGMP contract manufacturing with American-made equipment and reagents for creating large molecule biologics and new cell and gene therapies.

Our clinical biomanufacturing services accelerate product development timelines from preclinical evaluation, to first-in-human studies and beyond, in support of commercial manufacturing programs. By integrating bioassay and analytical method development, process development, cGMP manufacturing, and QC lot release testing, we efficiently assemble client-specific manufacturing solutions that enable a faster path to clinical trials and product commercialization.

Work With Us.

cGMP Biomanufacturing Facility

Clinical biomanufacturing for preclinical, clinical scale, and limited commercial-scale biologics.

San Antonio, Texas

Multi-Product Manufacturing Capabilities

- Allogeneic Cell and Gene Therapies
- Microbial Fermentation
- Mammalian Cell Culture
- Viral Vectors
- Vaccine Production

Facility Designed for Maximum Flexibility and Efficiency

~2,000 sq. ft.
of analytical development space

~8,000 sq. ft.
of cGMP-compliant cleanroom manufacturing space

1,000 L
scale capabilities for mammalian and cell-therapy based products

200 L
scale capabilities for microbial-based products

SCORPIUS BIOMANUFACTURING

Email: hello@scorpiusbiologics.com | www.ScorpiusBiologics.com

Full Product Lifecycle Analytical, Regulatory Support, and Process Development Capabilities

Analytical Methods Development

Scorpius employs a "phase-appropriate" approach to method development, qualification, and validation using key criteria (e.g., accuracy, linearity, precision, specificity, system suitability, etc.) to establish a baseline for subsequent qualification or validation studies.

- Drug Product Characterization and QC Release Testing
- Protein Characterization & QC Release Testing
- Plasmid DNA Characterization & QC Release Testing

Regulatory Support

Scorpius works closely with CDMO clients to develop effective regulatory drug development strategies for advanced biological therapies from the early stages of product development to market authorization.

- Evaluate and Guide Regulatory Strategy
- Represent Clients in Interactions with FDA or Other Regulatory Agencies
- Author and Review CMC Materials for Regulatory Applications and Submissions
- Leverage Experience with Global Regulatory Agencies Including FDA, EMA, PMD

Process Development

Our process development programs span all phases of product development and process optimization. We can handle small-scale, preclinical evaluation and "proof-of-concept" studies to the development of cGMP-compliant, clinical-scale processes to commercial-scale process development.

- Creation of Master & Working Cell Banks
- Mammalian Cell Culture
- Microbial Fermentation
- Cell and Gene Therapy
- Upstream Optimization
- Downstream Purification
- Formulation