



Comprehensive Capabilities from Discovery to
Commercial Manufacturing for Large Molecule
Biologics and Cell and Gene Therapies

COUNT ON US

Experienced CDMO Team.

Developed by a staff with extensive expertise in cell and gene therapies and large molecule biologics, Scorpius BioManufacturing's client-specific manufacturing solutions enable a faster path to clinical trials and commercialization.



End-to-End Process Development

Our **process development and optimization programs** span **all phases of product development**, from pre-clinical evaluation and proof-of-concept studies through cGMP-compliant clinical and limited scale commercial manufacturing.

This includes creating cell banks, mammalian cell culture development, microbial fermentation, upstream optimization, downstream purification, and managing formulation and fill-finish.



Data-Driven Analytical Method Development

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

We offer characterization and QC release testing for drug products, proteins, and plasmid DNA.



Informed Regulatory Support

Our experienced regulatory support team works closely with clients to develop **effective regulatory strategies** for advanced biological therapies from the early stages of product development through market authorization.

We offer a wide range of **regulatory services**, from representing clients with the FDA and other agencies to authoring and reviewing CMC submission materials.

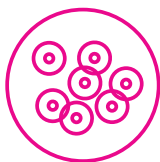
AVAILABLE BIOLOGICS CAPACITY. START FASTER WITH US.

Our state-of-the-art cGMP biomanufacturing facility for pre-clinical, clinical-scale, and limited commercial-scale biologics in San Antonio is the heart of our operation.



Adaptable, Multi-Product Manufacturing Capabilities

We are proud to prioritize American-made and sourced equipment, reagents, and materials in our state-of-the-art facility in San Antonio. Our brand-new equipment features enabling technologies for:



Mammalian cell
Culture Development



Microbial
Fermentation



Producing Vaccines
and Viral Vectors



Manufacturing
Allogeneic Cell and
Gene Therapies

Flexible Facility Design

The space's largely reconfigurable design allows customized layouts that maximize manufacturing efficiency, allowing clients to take advantage of an available:

~2,000 sq. ft.

of analytical development space

~8,000 sq. ft.

of cGMP-compliant cleanroom space

~8,000 sq. ft.

of process development laboratories

50 to 2,000 L

single-use bioreactors, for clinical-scale manufacturing

50 to 200 L

scale capabilities for microbial-based products

SECURITY IN US

American facility and supply chain.

We use American equipment and reagents to develop purpose-built analytical packages including assays that profile your molecule and test clinical trial samples throughout your product's lifecycle. This ensures the continued production of safe, effective, and consistent products that meet the standards of leading global regulatory bodies.



Broad Bioassay & Developmental Assay Selection

We offer **assays for all stages of the product development lifecycle** from pre-IND through CMC and clinical trials, including bioanalytical sampling, cell-based potency, comprehensive immune profiling, and molecular detection.



Extensive CMC Testing

In addition to **product stability testing**, Scorpius BioManufacturing also provides **cGMP lot release testing** including sterility, potency, purity, concentration, and adventitious agent testing such as viruses, endotoxin, mycoplasma, and DNA.



Reliable Clinical Trial Support

Our array of **clinical trial support services** include automated whole blood fractionation, clinical PK/bioavailability studies, flow cytometry-based assays, functional immune profiling, immunogenicity testing, and PK/PD analysis.

About Scorpius

Scorpius BioManufacturing is an integrated contract research, and contract development and manufacturing organization (CDMO) focused on rapidly advancing your mammalian and microbial large molecule biologics. With an experienced team and new, purpose-built, U.S. facilities, Scorpius is dedicated to transparent, accessible, collaboration and fully customizable biomanufacturing and bioanalytical services.