tanvex
CDMO

Our Experience, Your Vision

Tanvex CDMO

Your Strategic GMP Manufacturing Partner

Tanvex offers comprehensive contract development and manufacturing services tailored to the biologics sector. Our campus is conveniently located in the Sorrento Valley of San Diego, California – at the heart of Southern California's biotech hub, providing both microbial and mammalian full-service resources and capacity to expedite your program. Our FDA registered facilities include 100,000 square feet of R&D and GMP manufacturing space, housing a dynamic team of over 100 experienced professionals.

With a proven track record spanning preclinical to Investigational New Drug (IND) applications to Biologics License Applications (BLA) to commercialization, and a U.S. FDA and Health Canada approved biosimilar, Tanvex's dedication to quality, innovation, and regulatory compliance makes us a reliable partner.

TANVEX GMP MANUFACTURING BY THE NUMBERS

2011
Year Founded

100,000
sf of R&D and GMP manufacturing facilities

>100
experienced professionals

14,000
sf GMP warehouse storage

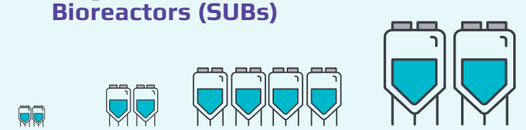
3
GMP suites

Mammalian GMP Manufacturing

Utilizing innovative, scalable, and compliant processes, Tanvex maximizes success through streamlined tech transfer and batch records to ensure superior quality, safety, and regulatory compliance.

Equipped with advanced technology for efficient production, our mammalian facilities meet stringent GMP guidelines, minimize cross contamination risks, and facilitate rapid change.

Single-Use Bioreactors (SUBs)



2 x 50L | **2 x 250L** | **4 x 1000L** | **2 x 2000L** (future)

- Two Mammalian GMP Manufacturing Suites
- Single-Use GMP Facility
- Standardized Cell Culture SUBs
- In-House WFI
- AKTA Chromatography Systems
- Automated TFF Skids
- Viral Filtration Skid

Microbial GMP Manufacturing

Tanvex has met the demand for speed and cost-effectiveness in microbial-derived biologics through optimized strain selection, fermentation, and purification processes since 2011.

State-of-the-art fermenters, harvesting equipment, and a variety of downstream purification options permit our microbial facilities to support the production of secreted and intracellular products from pre-clinical to commercial scale.

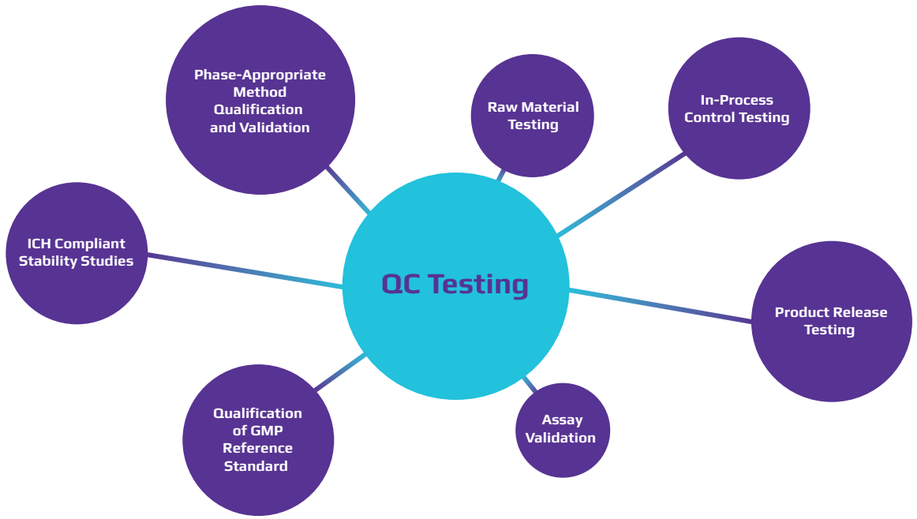
Stainless Steel Fermentors

150L | **300L** (SUF)

- State-of-the-art Fermenters
- Downstream Purification Options
- Pre-clinical to Commercial Scale
- AKTA Ready
- Automated TFF Skids

Robust Quality Assurance and Quality Control

Quality is non-negotiable at Tanvex. Our mature quality management system employs rigorous testing protocols, ensuring the safety, identity, strength, and purity of every product.



Meticulous testing, validation, and monitoring ensure your product meets or exceeds regulatory benchmarks.

Quality Assurance

QA Systems

- Supplier Management
- Quality Agreements
- Training
- Document Control
- Internal/External Audits

QA Operations

- RM Disposition
- Lot Number Assignment
- Lot Disposition
- QC Data Review
- QA Hold
- NCMR
- Material Review Board

QA Engineering

- Quality Events Management
- Investigations
- Change Control
- CAPA
- Validation Support

Supply Chain Management

A robust supply chain is the backbone of a successful biopharmaceutical program.

GMP Warehousing

- 14,000 sf of Warehouse Space
- Controlled Storage Condition:
  - Ambient
  - 2-8˚C
  - -20 ˚C
  - -70 ˚C

Vendor Management

- Vendor Qualification and Monitoring
- Change Notification System
- Audit Program
- Quality Event Trending Analysis

Inventory Management

- Validated ERP System – QAD
- Status, Lot and Expiration Tracking
- Material Segregation by Client

Program Management

Our timeline driven collaborative approach ensures your vision is realized, expectations are met, and projects progress seamlessly.

- Designated Program Manager
- SME Selection
- Governance Structure
- Escalation Pathway
- Onsite Kick Off
- Ongoing SME Collaboration

Our Experience, Collaborating on Your Vision

Tanvex BioPharma USA, formerly La Jolla Biologics, Inc., founded in 2011, has successfully navigated the path from concept to market. With recent drug approval success, we share our experience and know-how with the global biopharmaceutical community.

We look forward to working with you.

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