tanvex CDMO

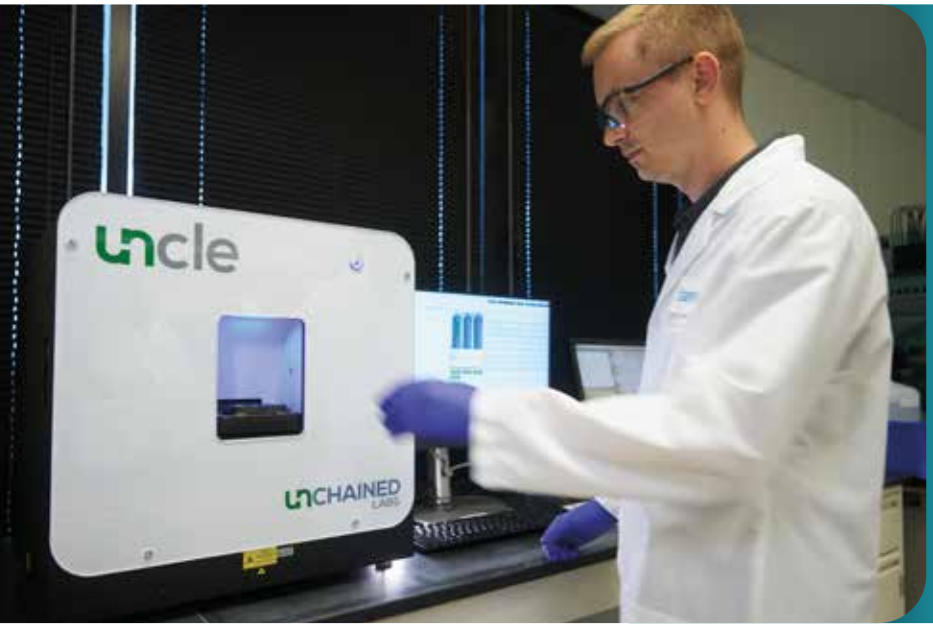
Our Experience, Your Vision

Tanvex CDMO

Your Strategic Formulation Development Partner

As the global demand for accessible biologics continues to soar, the need for capacity, competence, and capabilities in development and production has never been more critical. At Tanvex, we are ready to rise to this challenge. Tanvex is proud to offer contract development and manufacturing services to the biologics sector. Pairing our proven track record of successfully advancing biologics from Investigational New Drug (IND) application to Biologics License Application (BLA) with our state-of-the-art facilities and high-throughput workflows, our expert team is poised to serve as your collaborative partner.

Formulation and Drug Product Development Services



At Tanvex, we understand that transforming biologic drug substances into safe, stable, and cost-effective products requires a unique blend of talent and science. Our formulation team excels at resolving complex development challenges, utilizing precise and high-throughput (HT) formulation capabilities.

Drug Product Development Capabilities

With a focus on innovation and optimization, Tanvex crafts tailored solutions that ensure the creation of safe, effective, and stable biopharmaceutical products.

- High throughput pre-formulation screening
- Drug product and formulation development
- Biophysical characterization
- Spectroscopy-based assay development
- Thermal and kinetic stability assessment
- Excipient compatibility studies
- Pooling and mixing characterization
- Filter comparability and compatibility assessment
- Filter integrity assessment (Vmax, flush volume, Bacterial Retention Support)
- Filtration process characterization
- Filling process characterization and assessment
- Extractable and leachable assessment of manufacturing production components
- Drug product (DP) package selection, assessment, compatibility, and testing (functional studies for syringes using Instron, photostability, CCIT)
- DP Shipping assessment and testing
- Regulatory drafting and audit support
- DP Administration / IV bag compatibility

HT Pre-Screening

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Formulation / Development

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Characterization

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Filtration / Purification

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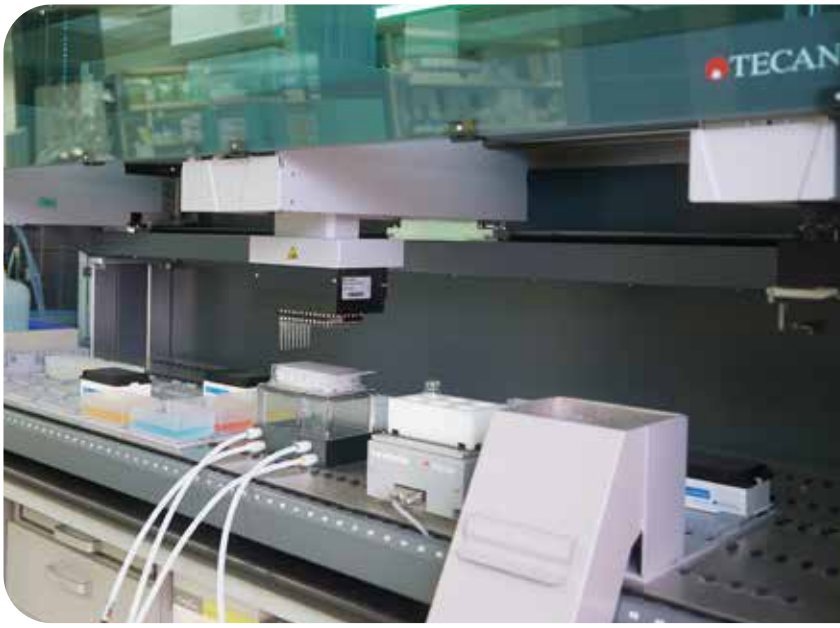
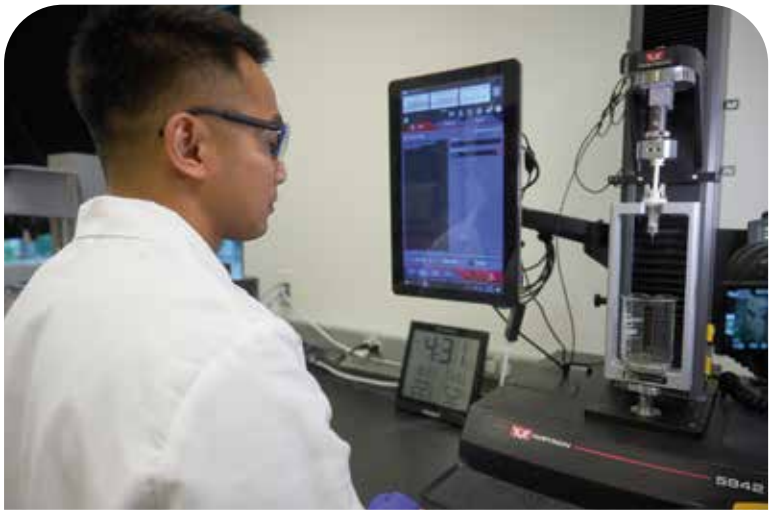
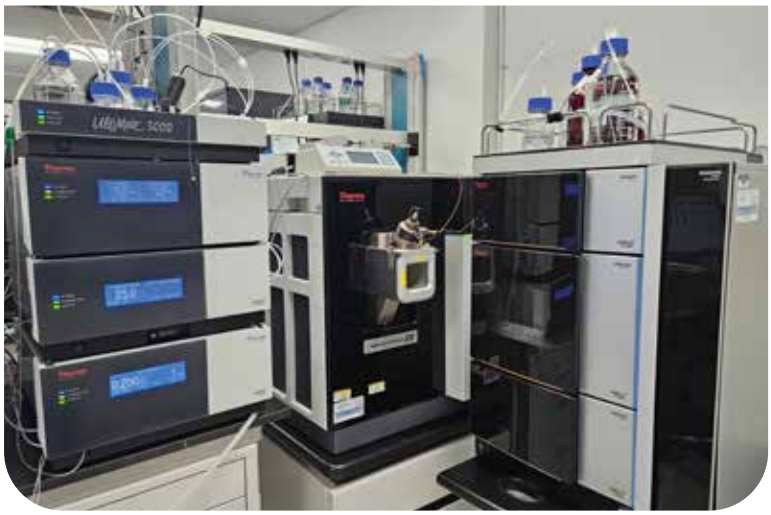
Administration
Packaging
Shipping

Integrated Allosteric Formulation Development Platform

Discover the cutting-edge, original, and powerful allosteric formulation screening platform employed by Tanvex for fast, economic, and precise formulation development of multiple types of biologics, included but not limited to all formats of monoclonal antibodies and their fragments, ADC, cytokines, enzymes, growth factors, synthetic peptides, recombinant fusion proteins, liposomes, LNPs, micelles, polymers, etc. Our unique allosteric formulation platform has been designed to adapt to a wide range of biologics, and it is applicable to all stages of clinical and preclinical drug development.







Biophysical HT Platform

- Spectroscopy Techniques: Fluorescence, CD, NMR, ESR, FTIR, Raman, LS
- Biophysical Techniques: DSC, AUC, SPR
- Structural analysis and computational approach

Analytical Platform

- Variety of HPLC-based methods (e.g., SEC, RP, CEX, HIC, HILIC), MALS, cIEF, CE-SDS, MS, osmolality, HIAC, MFI, photostability, pH, viscosity, protein concentration/solubility $A_{280/350,}$ Instron, and cell-based biological assays
- DOE and statistical analysis: JMP, GraphPad

What Sets Tanvex Apart

Experience and Success

With a history dating back to 2011 and recent drug approval success, we bring a wealth of experience to your project.

Client-Centric Collaboration

We understand innovators' needs because we have been there, ensuring a deep understanding of your vision.

Innovation and Efficiency

Our commitment to innovation and efficiency empowers clients to navigate the complex path from concept to market with precision and speed.

Our State-of-the-Art Facility

Located at the heart of the US Biotech Innovation Hub in San Diego, California, our 100,000 square feet of Research and Development (R&D) and Good Manufacturing Practice (GMP) manufacturing facilities house a dynamic team of over 160 experienced scientists. Equipped with cutting-edge technology, we provide streamlined mammalian and microbial biologic development, scale-up, and GMP manufacturing services catering to every stage of drug development from pre-clinical to commercialization.

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.

Embark on your formulation development journey with Tanvex CDMO, where innovation, efficiency, and precision converge to bring your vision to life.

Contact Us

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