tanvex CDMO

Our Experience, Your Vision

Tanvex CDMO

Your Trusted Partner In Analytical Development, QC GMP Testing and Stability Studies

Tanvex CDMO can help you excel in analytical development and product characterization, by deploying advanced methods to comprehensively analyze your product and ensure the quality of your biologics. Committed to precision and innovation, we offer tailored solutions for profound insights into your products.

Our analytical and QC laboratories are equipped with the same latest instrumentation so that methods can be seamlessly developed and qualified/validated to support timely lot testing and release. Our team of experts is dedicated to guiding you through each phase of your product's journey, from pre-clinical, clinical, and through commercialization.

Our Analytical Capabilities

- **Identity and Purity**
- **Product Related Impurities:**
  - Aggregation size variants: by SE-HPLC, SEC-MALS, CE-SDS
  - Charge variants: by IEX, cIEF
  - Other: hydrophobicity variants such as oxidation and Drug-Antibody Ratio (DAR) variants by RP-HPLC, HIC; released glycans by HILIC; post-translational modification (PTM) analysis by LC-MS
- **Process Related Impurities:**
  - Host cell proteins (HCP)
  - Host cell DNA (hcDNA)
  - Antifoam and surfactants
  - Protein A
- **Structural Characterization:**
  - Primary structure
    - Intact mass
    - Peptide mapping
    - Sequence variant analysis by LC-MS
  - Higher order structure
    - Disulfides
    - Free thiols
    - Far- and near-UV CD (Circular Dichroism)
- **Biological / Functional Characterization (Mechanism of Action):**
  - Cell-based potency assays (Proliferation, Inhibition of proliferation, Reporter gene assays)
  - ADCC (Antibody Dependent Cellular Cytotoxicity) using DELFIA (TRF) or Reporter gene assays
  - Characterization of signaling pathways
  - Ready-to-thaw cell banks
  - ELISA
  - AlphaLISA®
  - SPR
- **Microbiology (bioburden, endotoxin)**
- **Excipients and Other Miscellaneous**
  - Polysorbate
  - Amino acid analysis
  - PEG
  - Particulates
  - Titer

Our Equipment

Leveraging state-of-the-art equipment and innovative techniques, we can ensure your program remains compliant at every phase of its lifecycle. Our San Diego facility is equipped with:

- **HPLC & UPLC Systems**
- **High-Resolution Mass Spectrometers**
- **CE-SDS System**
- **icIEF System**
- **MALS**
- **Semi-Preparative HPLC System**
- **Plate Readers**
- **Vi-CELL Automatic Cell Counter**
- **qPCR**
- **Biacore™ SPR Systems**
- **UV/Vis Spectrophotometer**
- **HIAC Particle Counter**
- **Sievers Total Organic Carbon Analyzer**
- **ICH Compliant Stability Storage**
- **Cryo Freezers**
- **Photostability Chamber**
- **Tecan Liquid Handler**

Our team of experts follow the latest regulatory guidelines to provide tailored solutions for your products.

- **Incoming Raw Material Testing:** Ensures material suitability and conformity to our stringent quality standards
- **Phase-appropriate method qualification / validation** per ICH Q2R2
- **Analytical method transfers** per USP〈1224〉
- **Establishment of interim and GMP reference standard & characterization:** to enhance the accuracy of testing methodologies
- **Generation & Qualification of Assay Cell Banks:** to support accurate and reliable analytical testing
- **In-Process Control Testing:** Real-time monitoring during production safeguards product consistency and compliance
- **Product Release Testing:** Final products undergo meticulous testing to guarantee readiness for distribution
- **ICH Compliant Stability Studies:** We design, execute, and analyze stability studies in accordance with ICH guidelines, ensuring product shelf-life determination
- **Product related variant isolation and characterization** by semi-preparative HPLC and in-depth characterization techniques
- **Comprehensive comparative analytical assessment** for 351(k) submission
- **Development of bioassays** for mechanism of action per USP〈1032〉
- **Comparability assessment** for process changes per ICH Q5E

What Sets Tanvex Apart

Scientific Creativity

Innovative approach in developing precise methods for product characteristics and efficacy.

Dedication to Precision

Commitment to accuracy in method development for reliable results and regulatory compliance.

Comprehensive Offering

Fluent in all standard test methods, offering a one-stop solution for diverse testing needs.

In-Depth Insights

Beyond routine testing, Tanvex provides profound insights into product performance and integrity.

Experience and Expertise

Seasoned scientists specializing in method development, qualification, validation, and analytical testing for biologics with successful experience in developing multiple biologic products including commercialized biosimilar products.

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 experienced scientists. Equipped with cutting-edge technology, we provide streamlined mammalian and microbial biologic analytical development, process development, scale-up, GMP manufacturing, and QC lot release and stability services, catering to every stage from pre-clinical to commercialization.

Contact Us

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