Thousand Oaks Biologics Co. Ltd.

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THOUSAND OAKS

More Accessible, Affordable

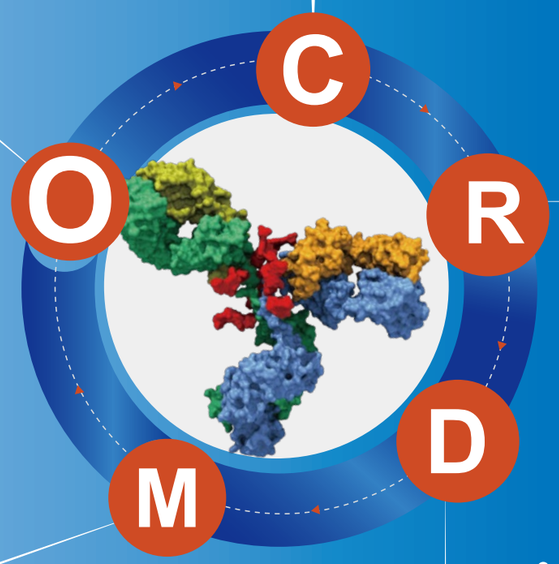
Biologics for Humanity!

An Integrated CMC Organization

Integrated CMC Solution Provider

- Serving Customers

- Integrated CMC Solution Provider



- Target Selection
- Antibody Preparation
- Media Supply for early-stage antibody preparation
- Druggability & Developability Assessment
- Candidate Molecule Screening
- Innovative Molecule Collaboration
- Regulatory Support

- **Process Development**
  - Cell Line Construction
  - Screening and Customizing of Cell Culture Media
  - Upstream, Downstream, and Formulation Process Development
  - ADC Conjugation Process Development
  - Analytical Method Development and Characterization Studies
  - Small-Scale CMC Support

- **Manufacturing**
  - Toxicology Batch Production
  - Manufacturing of Drug Product for Early and Pivotal Clinical Trials (Liquid / Lyo / Pre-filled Syringe)

- **IND&NDA Submission Support**

- Commercial-scale Media Manufacturing
- Commercial Drug Substance Manufacturing
- Commercial Drug Product Manufacturing
- Commercial Product Release and Stability Testing
- Commercial Product Packaging and Labeling

About Us

Thousand Oaks Biologics Inc. (TOBio), a premier Integrated CMC Solution Provider, focuses on comprehensive solutions for large - scale, compliant biopharmaceutical production. Its business covers three main segments: Biopharmaceutical CDMO, Cell Culture Medium, and Early - Stage Research Services. Its products and technical services find extensive applications in the production of recombinant proteins, antibody - based drugs, human and veterinary vaccines, and cell therapy products.

In CDMO, TOBio offers end - to - end CMC solutions at its Shanghai and Nantong GMP bases, serving diverse biopharmaceuticals. JSBio, under TOBio, excels in serum - free cell culture media, providing R&D, production, and customized services with kiloton - scale capacity across China and South Korea. Ginspire Biologics drives early - stage research, offering molecular design, evaluation, and optimization to boost complex molecule development success. This dedication across its business segments underscores TOBio’ s unwavering commitment to making biologics more accessible and affordable for humanity.

Integrated Reg-CMC Solns for mAbs, Proteins and ADCs

Discovery >> IND Enabling >>

Molecular Assessment:

- Druggability & developability assessment
- Drug candidate in silico analysis
- Transient transfection for sample preparation
- Affinity, in vitro binding activity and MOA-related cell-based functional activity
- Physiochemical analyses and biological analyses, mass spectrometric structural characterizations and post-translational modification (PTM) analysis
- Thermal stability (Tagg, Tm) and forced degradation studies

IND Enabling CMC:

- Stable cell line construction, GMP cell banking (RCB, MCB, and WCB)
- Media screening and cell culture process development and qualification
- Purification process development and qualification
- ADC conjugation screening & process development
- Formulation development
- Analytical method development and qualification
- Toxicology material production
- GMP manufacturing of DS and DP (liquid / lyo / pre-filled syringe)
- Product characterization, impurity analysis, stability studies
- IND dossier preparation in Chinese and English

Phase Ⅰ/Ⅱ >> Phase III >> BLA >> Commercial

During Clinical Studies:

- Phases Ⅰ/Ⅱ clinical supplies: GMP manufacturing, release and stability studies
- Process optimization, quality change control and comparability studies, define product CQAs
- Filing strategies and CMC communications with regulatory agencies
- Process and quality profile lock for phase III or pivotal trial materials and stability studies
- Risk analysis and PC to define process parameters (CPP, KPP & GPP)
- Establishment of scale-down models and virus clearance validation
- Development of product-specific HCP kits and HCP coverage study
- INN applications to WHO & Chinese Pharmacopoeia
- Scale-up, manufacturing efficiency improvement, and cost reduction

BLA and Commercial Manufacturing:

- Process characterization and validation for BLA filing and commercial GMP manufacturing
- Optimization and validation of analytical methods for commercial release of DS and DP
- Compatibility studies and transportation stability studies
- Detailed process descriptions, DS and DP materials specifications, and method SOPs for BLA filing
- Preparation of Module 3 for BLA and Pre-BLA Prep
- Pre-approval inspections (PAI)
- Supplier management program for commercial production
- Commercial product manufacturing, packaging and coding
- Post-approval studies (PAS) and process change control strategies
- PAS comparability studies and regulatory filing

A Development

- Offer authenticated CHO K1, CHO K1 GS-/-, and CHO K1 Fut8-/- cell lines at competitive licensing rates, paired with proprietary media to meet diverse functionality needs in antibody and fusion protein production, achieving up to 9 g/L monoclonal antibody yield in a 14-day batch process
- Implementing a streamlined two-step chromatography process, achieving >80% purification recovery, effectively reduces costs and enhances production output and efficiency for clients
- Advanced ADC platform offers a range of conjugation techniques, including non-site-specific cysteine/lysine conjugation and enzyme-assisted transpeptidase/glycosidase conjugation. The platform is supported by state-of-the-art equipment, such as scalable reaction vessels, ESCO isolators, AKTA avant systems, and Cytiva/Merck TFF systems
- Our adaptable process development platform concurrently supports multiple antibody and ADC drug research projects

B Capacity

Nantong Large Molecule CDMO Manufacturing Campus

- 5 DS Lines (Batch & Intensified Fed-Batch): Configured with disposable bioreactors ranging from 200L to 2000L, suited for both fed-batch and intensified fed-batch operations
- Perfusion-Based DS Line: Features single-use bioreactors of 200L and 500L capacities, optimized for continuous fed-batch and perfusion processes
- Formulation Line #1: Offers sterile fill-finish capabilities for glass vials and freeze-dried products, equipped with a 10 square meter lyophilizer and capable of processing batches of 2R to 20R vials, yielding up to approximately 100,000 filled units per batch
- Formulation Line #2: Specializes in prefilled syringe (PFS) production, ranging from 1mL to 3mL volumes, with a single batch capacity of approximately 64,000 units

Shanghai ADC R&D and GMP Center

- OEB-5 Containment Isolator (ESCO): Versatile facility fitted with an OEB-5 level isolator compatible with diverse ADC conjugation equipment from leading providers like Cytiva and Merck
- ADC Naked Antibody Production Line: Scalable with single-use bioreactors in 50L, 200L, 500L, and 2000L sizes for efficient production of ADC precursors
- ADC Conjugation Suites: Conjugation Suite #1: Features a hybrid setup with 50L glass and 200L stainless steel reactors, complemented by enzyme-mediated conjugation technologies such as iLDC and Igdc
- ADC Conjugation Suites: Conjugation Suite #2: Outfitted with flexible, single-use 50L, 200L, and 500L reactors specifically designed for ADC conjugation procedures

ADC Formulation Production Capacities

- Isolator-Based Vial Filling Line: Incorporates a state-of-the-art OEB-5 level isolator with eight-channel peristaltic pumps, online cleaning-in-place (CIP), vaporized hydrogen peroxide (VHP) sanitization, 100% inline process control (IPC), and nitrogen gas flush, supporting versatile filling operations
- Filling Speed: Adaptable to vial sizes 2R through 50R, with throughput capacities of 18,000 vials per hour (2R), 13,800 vials per hour (10R), 9,000 vials per hour (20R), and 3,600 vials per hour (50R)
- Freeze-Drying Capability: Employs a combination of 10 square meter and 25 square meter freeze dryers integrated with automated loading and unloading systems. Maximum batch sizes can accommodate up to 100,000 vials (2R), 43,000 vials (10R), 27,700 vials (20R), and 15,400 vials (50R) respectively.

C Manufacturing

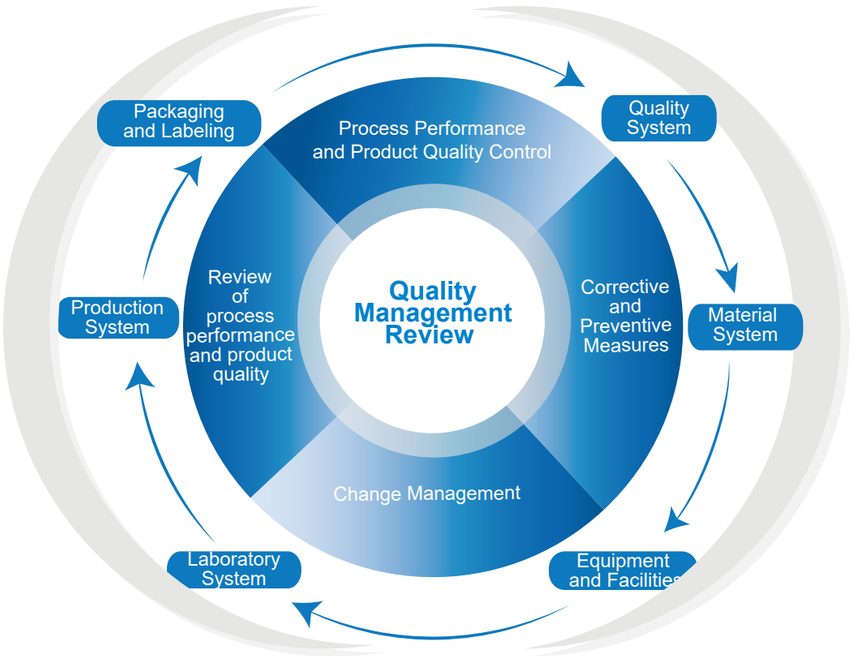
- A globally acclaimed team of process engineering and production technology experts guarantees the forefront technological advancements and consistent production performance
- Our holistic cost optimization solutions enable partners to minimize expenditure, thereby augmenting the accessibility and affordability of biopharmaceuticals
- Characterized by "versatility", we excel in devising tailored, modular process strategies to address a wide spectrum of client-specific needs
- Backed by a proven track record in multi-batch large-scale fed-batch and perfusion production, we have honed our capabilities in commercial-scale continuous manufacturing
- Operating multiple dedicated antibody drug substance and finished dosage form production lines, we are adept at concurrently handling multiple projects in parallel streams
- Our production facilities are meticulously designed to conform to the rigorous GMP standards of NMPA, FDA, and EMA, catering to synchronized regulatory submissions across China, the United States, Europe, and Australia
- We fully meet the demanding requirements for the provision of essential clinical trial supplies and commercial-scale manufacturing of both antibody-based therapeutics and Antibody-Drug Conjugates (ADCs)

Quality System

Thousand Oaks Biologic's quality management system was established with a foundation in Chinese GMP standards and incorporates significant modules from both the FDA and ICH guidelines. The entire quality framework is organized into six distinct subsystems, with risk management and knowledge management being integral components woven throughout the establishment and ongoing operation of these systems. Upholding the principle of continuous improvement, the company systematically updates and refines its systems in practice. By the end of 2025, TOBio had successfully undergone over hundred of audits, testament to its dedication to quality control and assurance.

Risk Management and Knowledge Management are the cornerstones of the Quality Management System, which is divided into six distinct subsystems:

Risk Management (RM)



Knowledge Management (KM)

Cell Culture Media Platform

High capacity: Installed blending capacity of 600 kg

Cost-Saving: Continuously improve upstream affordability

High efficiency: Exceptional turn-around with significantly reduced lead times compared to current Industry standard

Stability: Stable supply chain in long-term

Personalization: Customized services for raw materials and packaging

Compliance: Complies with EP/ USP/ ACS / JP / CP and BR standards

- Serum free, chemically defined media for CHO cells
- CHO cell line selection, process development and scale up
- Development of suspension cell culture process for vaccine production
- Media customization and process development services
- Customized cell culture media for customer
- The research, development and production of customized culture media
- Low serum/ serum-free cell culture media for human or animal vaccine production
- Development of specialized cell lines media (e.g. HEK293, BHK21, MDBK, VERO, Insect.) for vaccine production

Services

Custom Media Manufacturing (Powder & Liquid)

JSBio provides cGMP-compliant media manufacturing services to our customers for small-scale custom media used in product testing and early development and also for commercial-scale media used in the production of biological products from IND to commercial stage. We use the same manufacturing technology and quality system for both small-scale production and commercial-scale manufacturing. We ensure the consistency of product quality in the two processes and improve the efficiency of technology transfer.

	Rapid Small Scale	Commercial Scale
Capacity	• Liquid: 1 - 200 L • Dry powder: 1 - 50 kg	Dry powder: 50 - 6000 kg
Lead Time	18 days	30 - 45 days
cGMP-Compliance	Yes	Yes
Raw Materials	• cGMP-qualified raw materials • Customized raw material sourcing	
Manufacturing Technology	Continuous pin-milling for powder	
Release Testing	Standard or custom testing by request	
Packaging	Foil Bags, Drums (1 - 50 kg), Bulk Bags (100 - 1000 kg)	

Custom Media Manufacturing

Customer's Formulation

JSBio Customized Formulation

Services Flow Chart

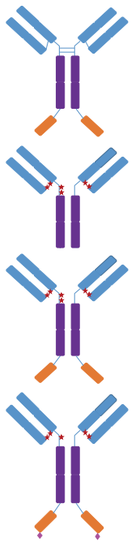
01 Request
- Preliminary Communication
- CDA
- Formula Evaluation

02 Test
- 100L-200L sample

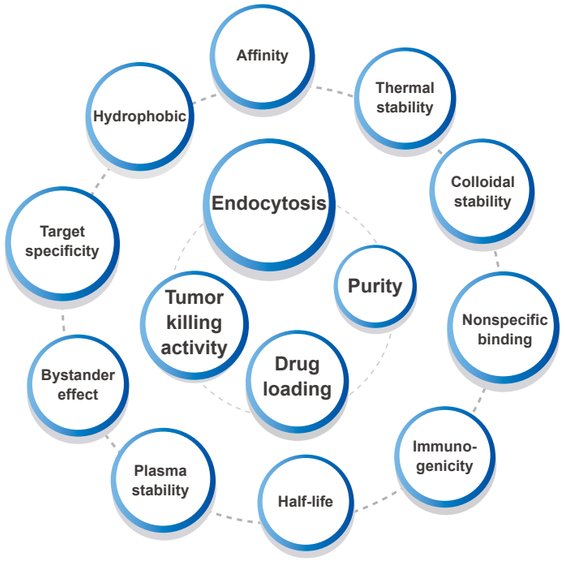
03 Contract
- Confirm product release standards
- Quality agreement
- Purchase agreement
- Packing specification
- Logistics

04 Purchase
- Confirm media quantity
- Delivery time

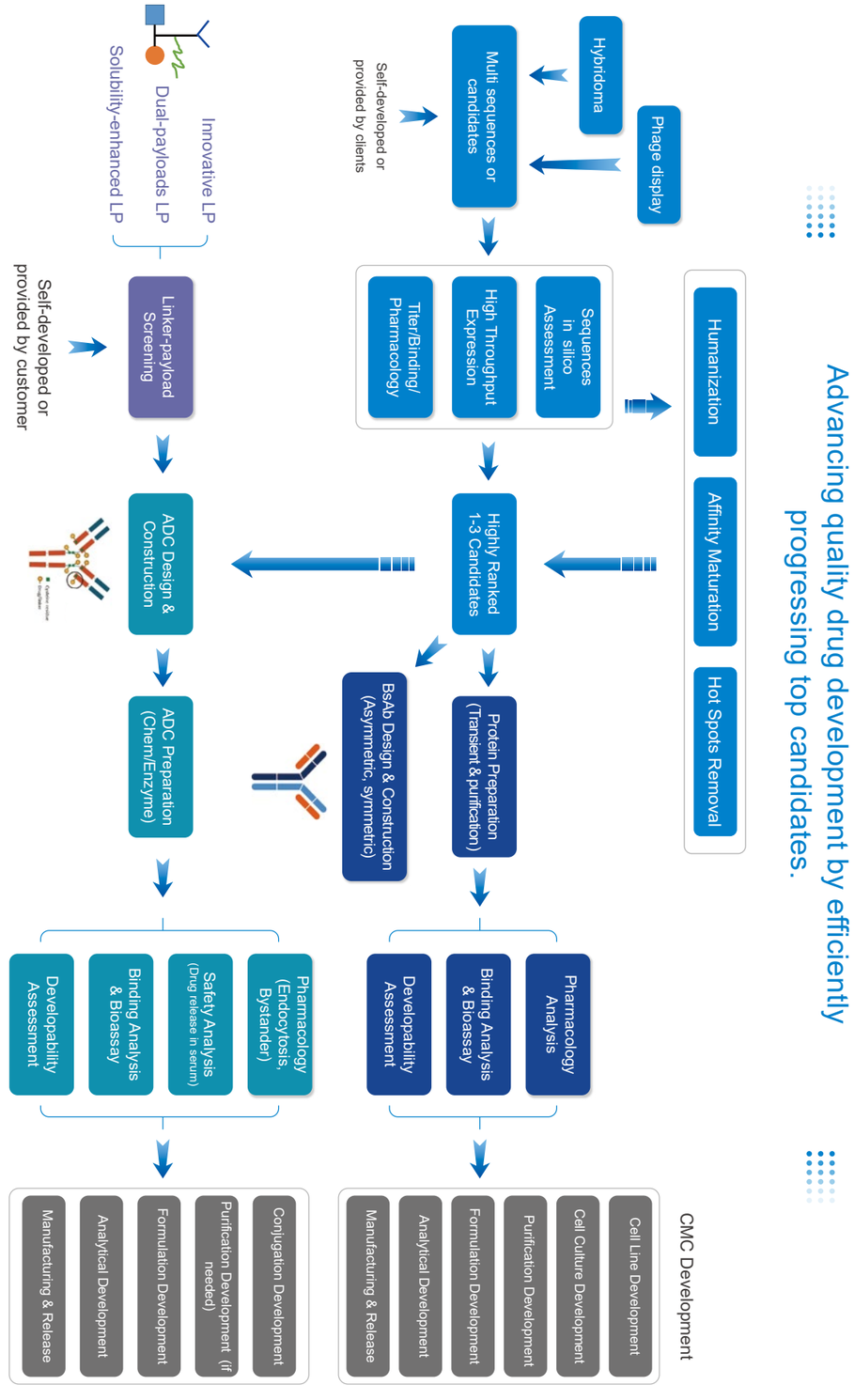
The Development Challenges of Innovative Complex Molecules



- **Target Selection and Validation**
  - Lead target screening
  - Preclinical and clinical research validation
- **Bispecific Antibody Design**
  - Structural engineering (scFv, VHH domains)
  - Linker chemistry optimization
  - Structure-activity relationship (SAR) analysis
- **CMC Challenges**
  - Multistep conjugation processes
  - Impurity clearance validation
  - API stability enhancement
- **PK/PD Considerations**
  - Nonlinear PK modeling
  - Dual-target synergy quantification
  - Immunogenicity risk mitigation
- **Toxicity Profiling**
  - On-target/off-target toxicity screening
  - Cytokine release syndrome (CRS) monitoring
- **Clinical Strategy**
  - Biomarker-driven patient stratification
  - MTD/Phase-adaptive trial design

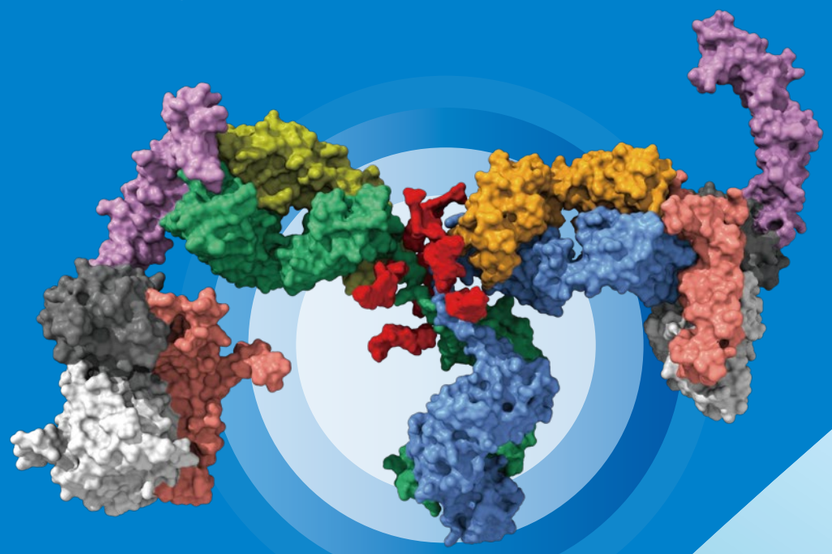


Consider all aspects of the design/screening/evaluation/optimization/development of innovative complex molecules
Source intervention to improve the development efficiency of innovative complex molecules!



About Ginspire

- Ginspire Biologics, an early research services subsidiary of Thousand Oaks Biologics.
- Currently employs 20 people, with over 60% holding master's or doctoral degrees. Average tenure exceeds 6 years.
- Offers molecular design and optimization, linker-payload and antibody screening, pharmacological efficacy and drug evaluation, and other services.
- Collaborates with clients on demand to develop differentiated innovative molecules and licenses self-developed molecules.



Technology Platform of Ginspire