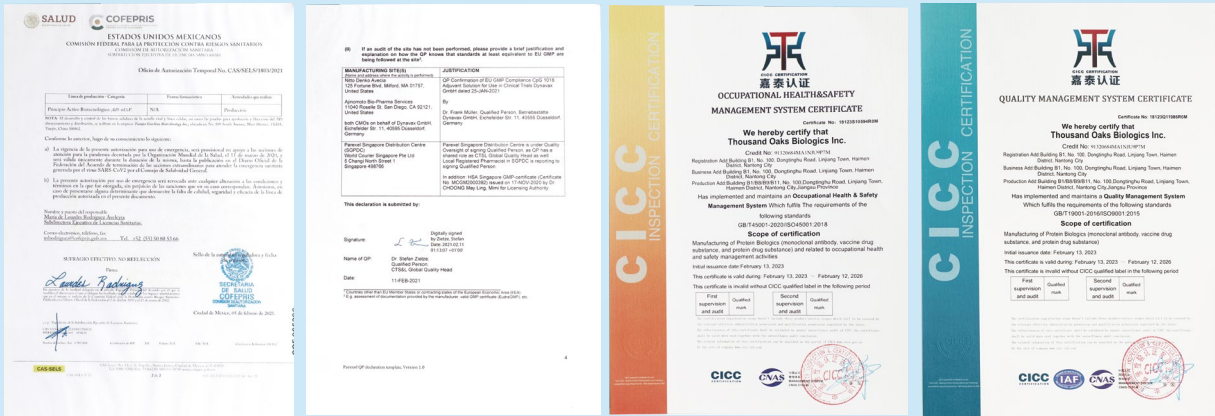


Quality System

Thousand Oaks Biologics adheres to the stringent requirements set forth by regulatory bodies such as the Chinese NMPA, US FDA, European EMA, and PIC/S. Our quality management system, aligned with the ICHQ series guidelines, covers the entire drug lifecycle across six FDA modules: research, technology transfer, clinical sample preparation, commercial production, and post-approval process changes. In recognition of our commitment to quality, we obtained the Manufacture License of Pharmaceutical Products in January 2019. Furthermore, Thousand Oaks Biologics has successfully passed three national drug registration production site inspections and GMP pre-approval inspections (PAI). Our quality system has undergone multiple audits by the National Medical Products Administration, the European Union, and international partners. Leveraging our extensive experience in research and development, production, registration, on-site verification, clinical trials, and post-approval changes, Thousand Oaks Biologics is well-equipped to provide comprehensive and high-quality CMC services, spanning from research and development to commercial manufacturing.



Quality Assurance Management

- File and Data Management
- Personnel training and qualification confirmation
- Deviation, Change, CAPA Management
- On site supervision and regular inspections
- Material/Product Release
- Audit and self inspection
- Confirmation/validation management, etc

Quality Control Management

- Instrument management and reagent management
- Management of standard and reference materials
- Sample/retention management
- Stability assessment
- Material Quality Standards/Inspection SOP/Records
- Product Quality Standards/Inspection SOP/Records
- QOS, OOT, UAR management
- Environmental monitoring and water quality monitoring
- Analysis method transfer and confirmation/validation, etc

Material Management

- material management (Acceptance, testing, release, inventory)
- Supplier Management (Evaluation, Audit, Approval)
- Warehouse management (Material and product storage)
- Logistics management, etc (Shipping of cells/materials/products)

Six major QA system

R&D management

- Data management
- Experimental record management
- Technical report management
- Measurement management, etc

Equipment and facility management

- Facility and equipment maintenance
- Daily inspection of factory buildings/public systems
- Measurement/calibration of instruments and meters
- Confirmation of factory buildings/public systems
- Equipment confirmation and pest control
- Computer system/access control system management, etc

Production management

- Cell bank management
- Process procedure/SOP/batch record/material list
- Simulated filling of culture medium
- Site clearance management and signage management
- Environmental cleaning and disinfection
- Production workshop personnel access control, etc

Thousand Oaks Biologics Co. Ltd.

contact us

Room 206-207, 2nd Floor, Building 8, No. 1043 Harley Road,China (Shanghai) Pilot Free Trade Zone
Building 5, 1215 Zhengjia Road, Lin-gang Special Area, China (Shanghai) Pilot Free Trade Zone
Building B1, 100 Dongting Lake Road, Linjiang Town, Haimen District, Nantong, Jiangsu Province, China
6960 Koll Center Parkway, Suite 306-307, Pleasanton, CA 94566, USA

Email: services@tobiopharm.com Web: www.tobiopharm.com/en



Scan the QR code to follow us on LinkedIn



TOBio ADC Technology Platform Introduction

An Integrated CMC Organization

One-stop Technical Service Platform for CMC of ADC Drugs

- | | | | |
|---|--|--|---|
| <ul style="list-style-type: none"> • Antibody Preparation • ADC Drug Substance Preparation • CMC Feasibility Evaluation • ADC Conjugation Process Development | <ul style="list-style-type: none"> • ADC Purification Process Development • ADC Formulation and Process Development • Establishment of Analytical Methods for Antibodies and ADCs • Small Molecule Analytical Method Development | <ul style="list-style-type: none"> • Analytical Method Transfer and Validation in Compliance with GMP • Structural and Functional Characterization Studies of Biologics • GMP Manufacturing of Antibodies • GMP Conjugation and Purification Manufacturing • GMP Fill-Finish and Lyophilization | <ul style="list-style-type: none"> • GMP Product Release and Stability Testing • Technology Transfer and Gap Analysis • Process Change Management and Comparability Assessments • Domestic and International Regulatory Registrations |
|---|--|--|---|

Conjugation Process Development

TOBio's conjugation process development team boasts extensive experience in process development. Our platform technology is built on the principles of speed, cost control, and reproducibility. Notably, our platform technology eliminates the need for chromatography steps, resulting in improved yield, reduced costs, and shorter cycles. This accelerates the research and development process for conjugation. Additionally, we offer a range of conjugation platforms, including chemical conjugation (lysine, cysteine) and enzymatic conjugation (transpeptidase, glycosidase).



Our state-of-the-art facilities include reactors of various sizes (1mL, 25mL, 250mL, 500mL, 2L), negative pressure isolators (OEB-5 level), AKTA Avant chromatography system, and ultrafiltration fixtures/systems.

ADC DS Manufacturing

- Equipped with 50L, 200L, 500L and 1000L disposable/glass/stainless steel conjugation reactor, capable of producing up to 150 batches of conjugation per year;
- Jobio provides transpeptidase and glycosidase enzymatic conjugation production and online DAR value detection;
- Equipped with disposable chromatography and ultrafiltration equipment (Cytiva, Merck);
- Equipped with OEB5 level stainless steel isolator and disposable soft isolator;
- Use disposable consumables to effectively prevent cross contamination;
- Isolator and workshop with yellow light control, capable of producing photosensitive drugs;
- Meet the drug use and commercial production needs in key clinical trials of ADC.

ADC DP Manufacturing

- Using Tofflon isolator liquid vial filling line, equipped with OEB5 level isolator;
Rapid Transfer Ports (RTP) are implemented in the production line, equipped with VHP atmospheric clean sterilization, 100% online
PC weighing, refilling when the filling volume is insufficient, tunnel oven cooling section sterilization, and bottle outer wall cleaning
functions;
Equipped with the function of emptying the tail liquid of the filling machine, ensuring the filling yield;
Use disposable filling system to effectively prevent cross contamination;
The filling line is compatible with the production of 2R-50R specification injection and lyophilized formulations, with a maximum
operating speed of 300 bottles per minute;
Equipped with KYOWA 10m² and 25m² lyophilizers, both with independent fully automatic feeding and discharging system;
With the function of filling nitrogen before and after bottle filling, filling nitrogen and pressing the stopper of lyophilization, capable of
producing oxygen sensitive products;
Isolator orange light control and workshop yellow light control can be used for photosensitive drugs production.

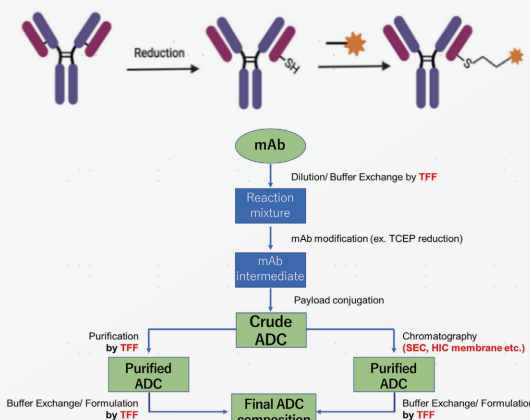
ADC R&D and Production Technology Platform

Antibody to ADC Drug Substance (DS) to ADC Drug Product (DP) are all produced within the same premises, mitigating the potential risks associated with segmented manufacturing

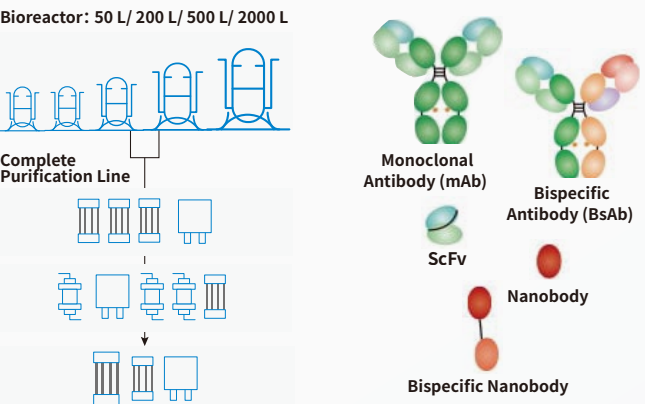


Fed-batch DS & iDS line: 200L / 500L / 2000L
 ADC DS line: 50-200-500L conjugation reactor
 ADC DP line: liquid vials (2ml-50ml, 144,000 vials / batch)
 lyophilized product (25m² lyophilizers, 2ml-50ml, 100,000vials/batch)

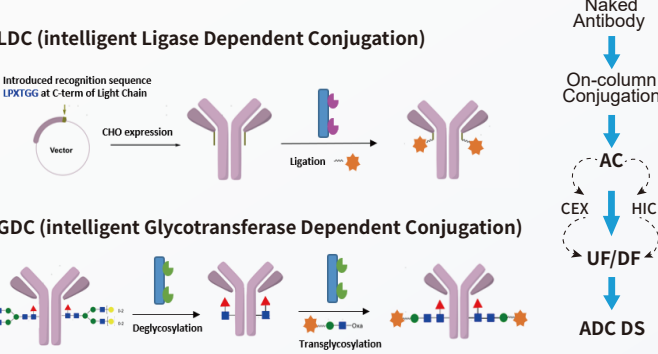
Support based on sulfhydryl, amino and other different ways of chemical conjugation preparation and production



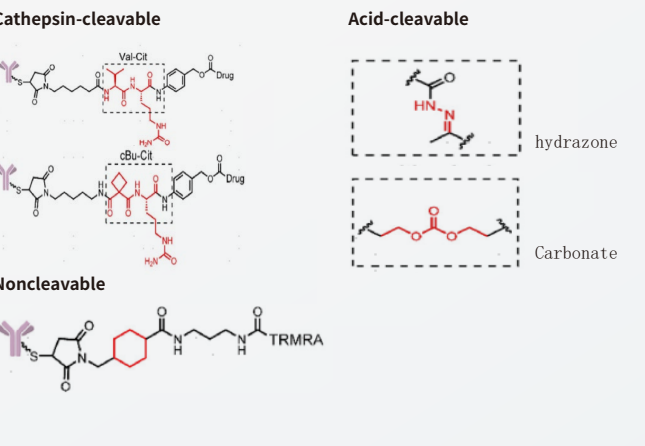
Support the preparation and production
various forms of naked antibodies



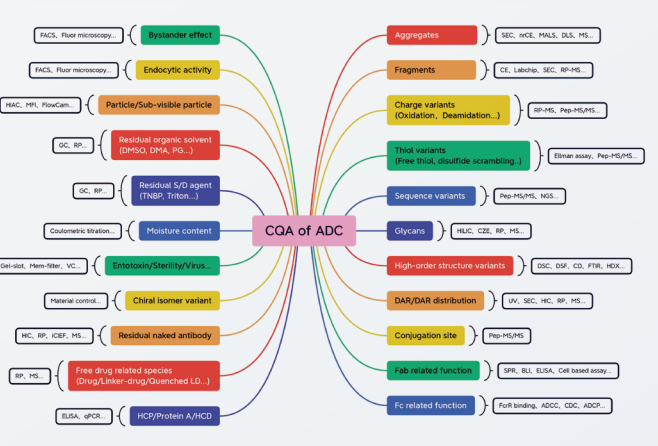
Support enzymatic conjugation preparation and production based on different methods such as transpeptidases and glycoside transporters



Support the conjugation use of multiple different forms of linker toxins



Support comprehensive analysis of ADC release, stability, structural and functional characterization, etc



Integrated Reg-CMC Solns for mAbs, Proteins and ADCs

At TOBio, we offer comprehensive R&D and production services for monoclonal antibodies, bispecific antibodies, fusion proteins, ADCs, and other drugs. For more detailed information, please refer to the following details.

Discovery >>

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
- Physicochemical analyses and biological analyses, mass spectrometric structural characterizations and post-translational modification (PTM) analysis
- Thermal stability (Tagg, Tm) and forced degradation studies

IND Enabling >>

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 >>

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

Phase III >>

BLA >>

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

Thousand Oaks Biologics has consecutively passed the dynamic GMP compliance inspections (PAI) and obtained the European Union Qualified Person (QP) certification.

The therapeutic biologics manufactured under contract by Thousand Oaks Biologics have successfully passed the marketing authorization registration and dynamic GMP compliance inspection. From 2021 to 2025, the company has successfully passed multiple consecutive Pre-Approval Inspections (PAIs), setting a new record for domestic Contract Research, Development and Manufacturing Organization (CRDMO) enterprises in consecutive passes of the combined "two-in-one" inspections, and has become one of the very few domestic enterprises specializing in biologics CRDMO services.

Meanwhile, Shanghai Thousand Oaks Biopharmaceuticals (ADC manufacturing site) successfully passed the European Union Qualified Person (QP) audit in 2025 and officially obtained the QP Declaration of Compliance. This marks that the quality management system and commercial manufacturing capabilities in the ADC field have fully met the EU GMP standards. This achievement positions the company among the few CDMOs in China with international service qualifications for ADCs.

The company provides end-to-end services covering Phase III process lock, clinical material manufacturing, commercial process validation, NDA filing and commercial-scale production. It has delivered exceptional results in close collaboration with its clients, and its robust technical capabilities have been frequently validated by authoritative industry certifications.



▲ CDMO signature and seal after verification