TBMC Taiwan Bio-Manufacturing Corporation

A Next-Generation GMP Manufacturing Platform

Built for Speed. Designed for Flexibility. Ready for Commercialization.

TBMC specializes in CRDMO services for advanced therapeutics and complex biologics, committed to enabling biotech and pharmaceutical partners to seamlessly transition from development to manufacturing—with speed, flexibility, reliability, and cost-efficiency.

We deliver fully integrated CRDMO solutions, including:

- **End-to-End Support**
  Development to commercial supply
- **Multi-Modality Coverage**
  Drug substance & drug product across multiple modalities

- **Flexible, Modular Suites**
  Enable rapid reconfiguration and multi-product manufacturing.
- **Single-Use Technology Platform**
  Reduce contamination risk and increase operational flexibility.
- **Real-Time Raman Monitoring**
  Enable in-line control and real-time quality assurance.
- **Integrated Digital GMP System**
  Ensure data integrity, traceability, and compliance.

Taipei
- Headquarters
- PAD (Process Analytical Development)

Hsinchu
- GMP Manufacturing
- PAD

Nucleic Acids

mRNA/LNP
End-to-end platform from plasmid DNA to GMP production, enabling rapid clinical entry and accelerated timelines
Manufacturing:
0.1-6g/Batch, 68 batches/year

Cell Therapy

Autologous & allogeneic T cells and MSCs, adapting to diverse clinical and manufacturing
Manufacturing:
Autologous CAR-T: 480 patients/year
MSC: Approx. 100 batches/year, 2x 10' cell/batch

Analytical/QC

80+ qualified methods supporting development to GMP

Gene Therapy

Lenti & AAV
Integrated development to GMP manufacturing, reducing process and scale-up risk
Manufacturing:
Current: 200L
Expansion (2027): 2x 200L

Biologics

Scalable mammalian platform enabling efficient transition to commercial production
Proprietary CHO-C platform: HTP to GMP production, fast, stable, PAT-driven bioprocessing
Manufacturing:
Current: 200L
Expansion (2027): 2x 2,000L

GMP Service

- Enabling mRNA, Gene Therapy, Cell Therapy, and Biologics

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https://tbmcbio.com/

Overview & Design

Discover our modular, high-flexibility facility designed for speed, safety, and scalability.

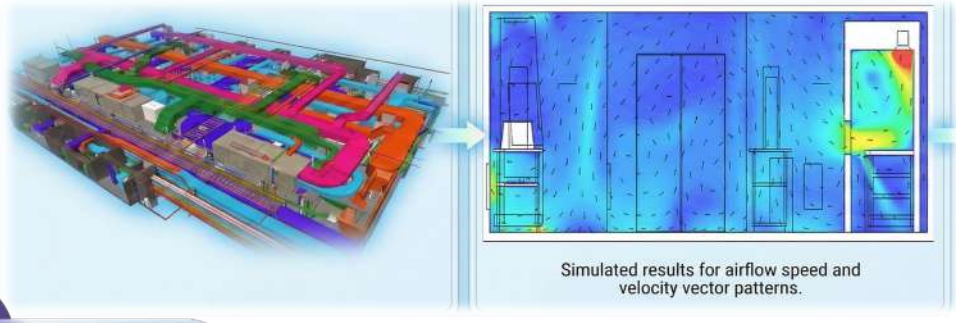
- **Cell Therapy** – 5 dedicated rooms
- **mRNA** – 1 specialized room
- **Viral Vectors** – 2 suites 200 L each (2027)
- **Proteins** – 1 suite with 2×2,000 L bioreactors (2027)
- **Fill & Finish** – small-scale (500 vials/hour, 2R~10R)

GMP facility features include

- **Unidirectional** personnel & material flow
- **Single-use bioprocessing** – minimize cross-contamination
- **Independent HVAC** per zone – zero air mixing
- **BSL-2 compliant** – ideal for vaccines & viral vectors

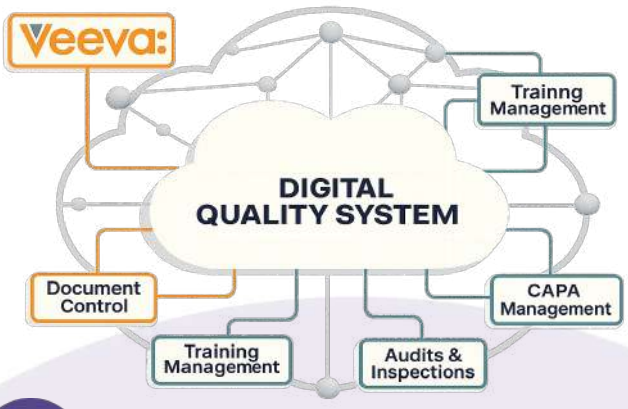
Digital Twin Visual Models Enable Design Validation, Performance Enhancement, and Risk Prediction

3D Virtual Model | Computational Fluid Dynamics | Real Time Monitoring on Process Environment



Quality

Quality Assurance



Global Regulation Conformance

Quality Control

Service

Tox/Clinical/Commercial Production | MSAT Tech Transfer/Regulatory Submission Services

Feature/Modality	mRNA-LNP	Cell Therapy	Viral Vectors (AAV/LVV)	Complex Biologics
Process Platform	- Plasmid linearization - *In vitro* transcription (IVT) mRNA production - LNP formulation	- Integrated process & analytical development (PAD) team - Single-use system	- Proprietary HEK293 host cell - Suspension production platform	- Proprietary CHO-C cell line - Fed-batch/ Intensified fed-batch
Production Capacity & Clinical Scale	- 6.0 g per batch - Up to 68 batches/ year (13 million doses)	- Up to 480 patients per year	- 200 L production capacity - 200 L x2 (2027)	- 200 L production capacity - 2,000 L x2 (2027)

RNA Service

Concept to Clinical Production — Accelerated by Integrated RNA Platforms

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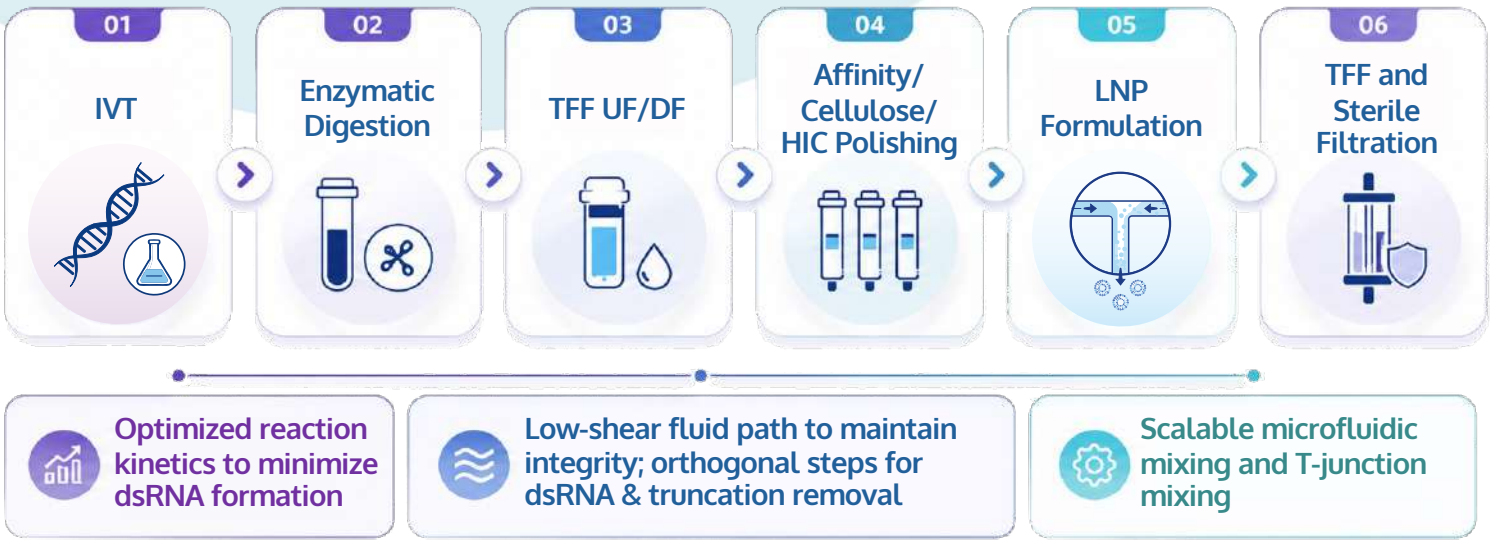
Overview

Ultimate Scalability: Seamlessly scaling production from personalized cancer vaccines to large-scale pandemic vaccine manufacturing

Customer-Driven Formulations: Expert LNP manufacturing using client-specific lipids and tailored mixing conditions

Optimized Workflow: Rapid turnaround with high-quality results delivered in as fast as 2 weeks

Highlight



Final Product

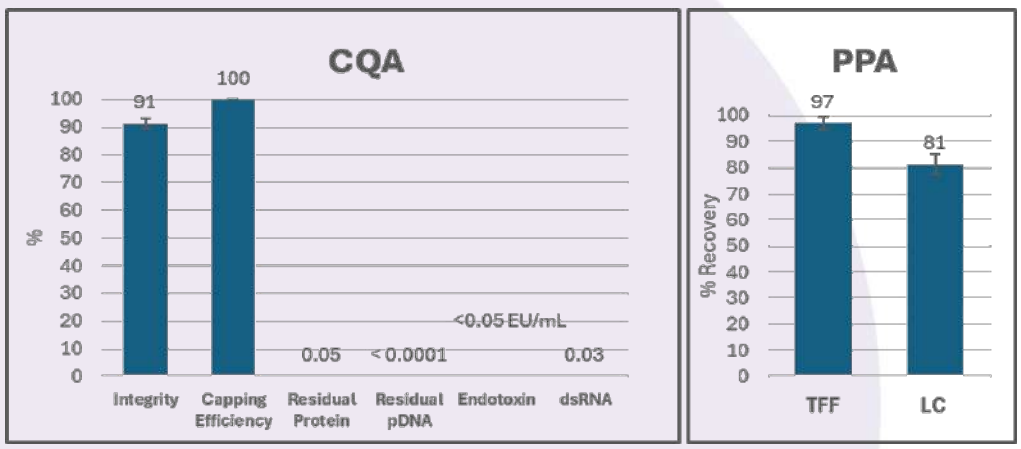
- High Integrity mRNA & saRNA
- Low Immunostimulatory Impurities
- Consistent CQAs

Service

- **IVT RNA Production:** mRNA, saRNA, and circRNA synthesis
- **LNP Platform:** High-precision microfluidics & T-junction encapsulation
- **GMP RNA Production with Integrated Fill–Finish:** Supporting scalable production of mRNA, saRNA, and circRNA
- **Solid-Phase Synthesis:** Fully customizable oligonucleotide modifications and sgRNA

	Research-Grade	Tox/GMP Batch
Scale	mRNA: 0.1 – 1.0 g	mRNA: 0.1 – 10.0 g
	LNP: 0.1 – 0.5 g	LNP: 0.1 – 6.0 g
Time	Vector: 1.5 weeks	GMP plasmid production: 10 weeks (strategic partners)
	Plasmid production & linearization: 0.5 week	
	IVT mRNA synthesis and QC: 0.5 week	IVT mRNA and LNP production: 1 week
	LNP encapsulation and QC: 0.1 week	QC release: 2 weeks
Delivery	Approx. 2 weeks	Approx. 13 weeks

CQAs and PPAs



CQAs: Critical Quality Attributes **PPAs:** Process Performance Attributes

In-Process Control (IPC)

- Spectrophotometry
- pH/Conductivity
- Agarose gel electrophoresis
- RiboGreen assay
- NanoOrange assay
- Capillary electrophoresis
- FRET dsRNA assay
- Residual pDNA assay
- Endotoxin assay

One Biologic Platform: From Transient to Stable Clone, the Same Proprietary CHO-C

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Overview

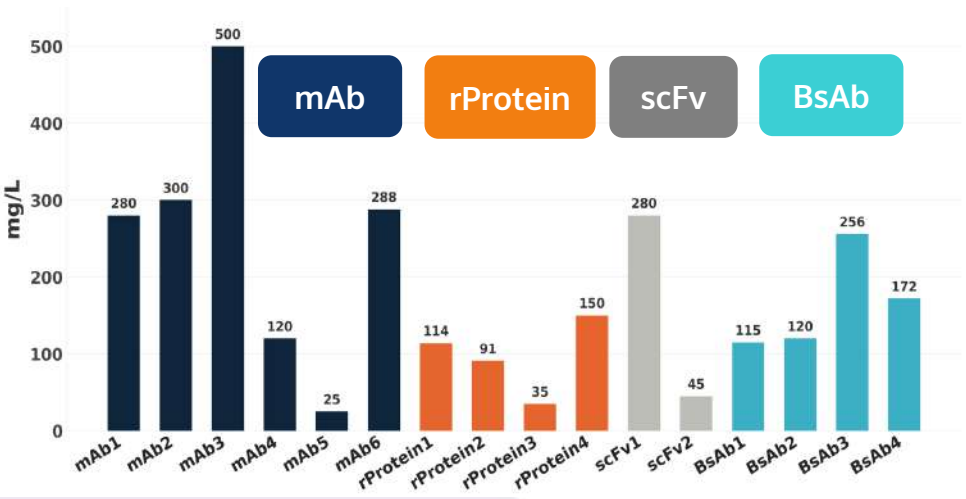
- **Rapid Protein Production**：Gene to 100s mg of purified mAb/BsAb in 1 month
- **BsAb Correct Pairing**：Boost correct assembly from 20% to 80% via vector design
- **Stable Cell Line Development**：3–5 g/L titer, stable over 100 generations; CHO-C 2.0 targeting >8 g/L
- **Real-Time Raman Monitoring**：30+ parameters for upstream and downstream

Transient to Clone Same CHO Host, Representative Quality			DNA to Tox-Grade Material in 6 Months		
Transient Production	**Stable Pools**	**Single Clone**	**Scale-up**	**Tox Material**	**GMP Production**
7-day production mAb/BsAb/ rProtein	Early stage materials supply > 95% purity, HCP & endotoxin compliant	3-5 g/L fed-batch 60-100 gen stable	250 mL to 200 L process transfer	QC-released tox material	

CHO-C Platform Capability

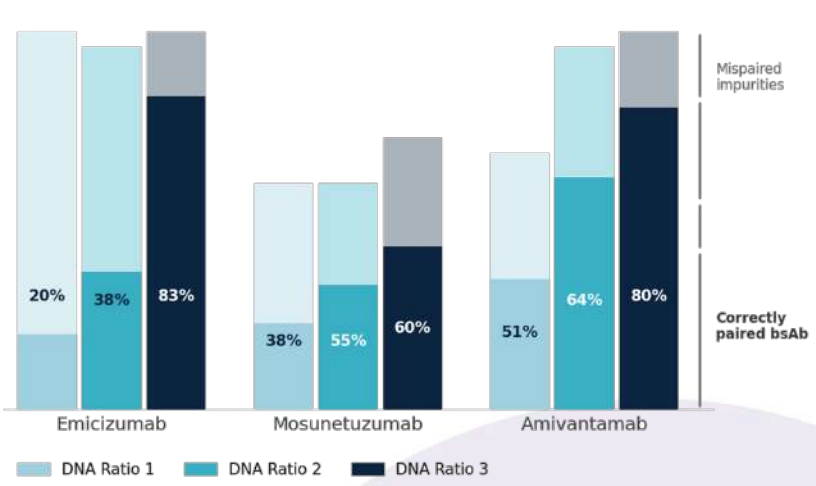
From gene to purified protein in 1 Month

Materials for analytics, formulation & *in vivo* studies



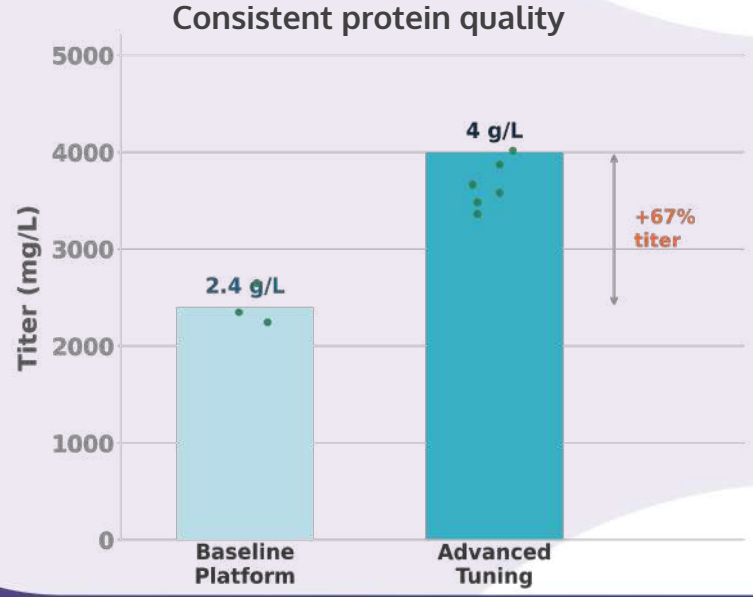
Strategic vector and ratio design boost BsAb correct pairing 20% to 80%

Fewer impurities, lower purification burden



Process optimization lifts titer 2.4 → 4 g/L

Consistent protein quality

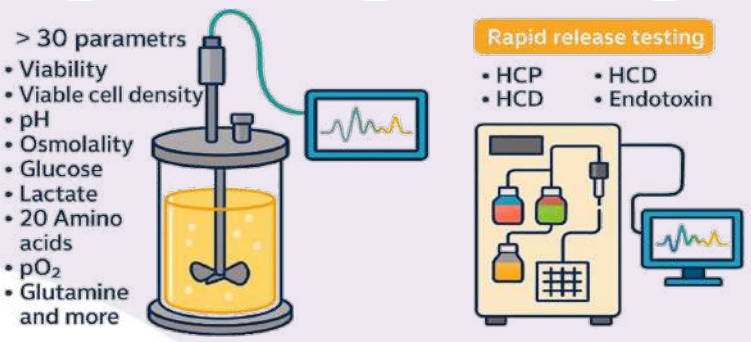


In-line Raman monitors 30+ parameters in real time: Data available < 1 min

90%
Reduced Workload
Manual sampling eliminated

30+
Parameters Tracked
VCD, Glucose, AA, Titer, Pairing & more

<1 min
Data Availability
vs. 2-6 hrs for conventional analysis



Biologics High-Throughput (HTP) Development

Faster Decisions, Consistent Quality

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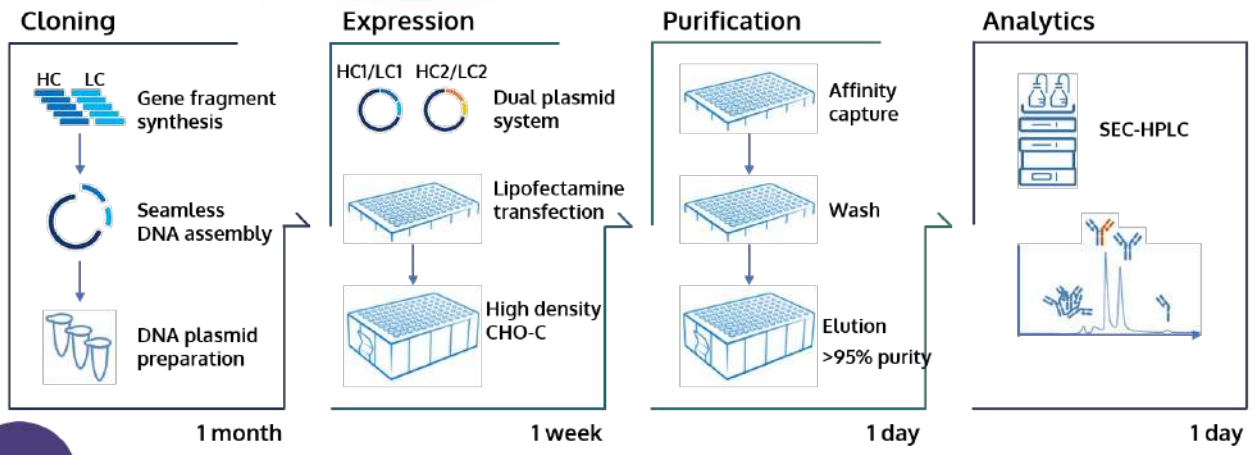
Overview

- **Speed** : Rapid lead identification with a 7-day HTP production cycle
- **Quality** : Same CHO-C host from transient to stable: consistent product quality, no system switch
- **Throughput** : 96-well HTP platform delivers flask-comparable performance

High-Throughput Fast Track Platform

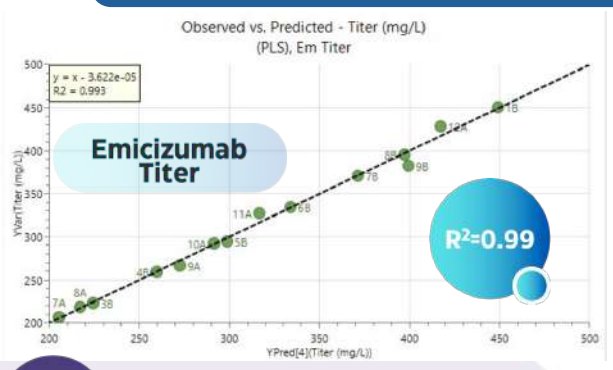
From gene to analytical-grade protein in **1.5 Months**
Fully integrated cloning, expression, purification & analytics on one platform

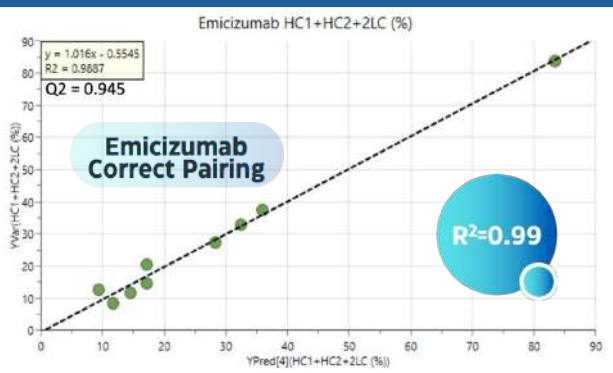


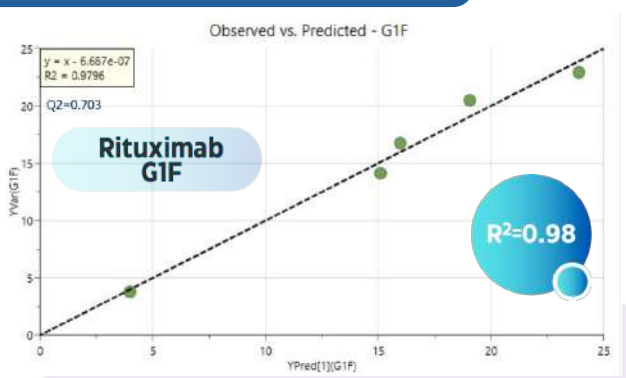
Automated sample preparation

Predictive Modeling with Raman PAT

Raman PAT predicts titer, BsAb correct pairing, & glycan profiles with $R^2 \geq 0.98$
Real-time quality prediction without offline analysis

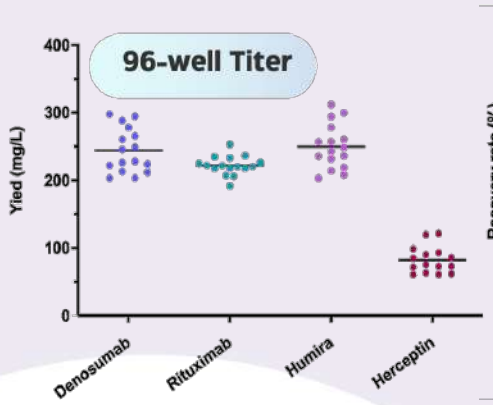


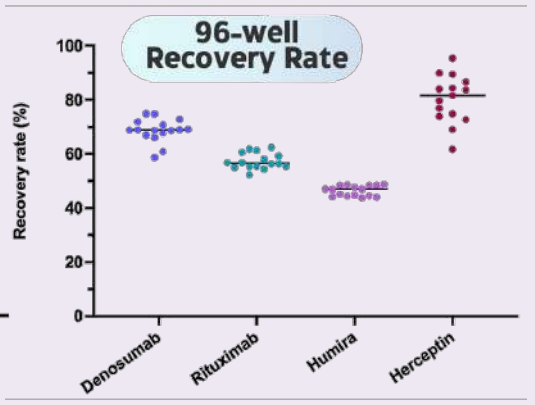




A 7-Day HTP Rapid Production System

Same CHO-C system at HTP scale; flask-comparable titer and purification recovery across mAbs





Optimal ADC Candidates in 28 Days

DOE-Driven Conjugation + Full Analytics | From Candidate Screening to Scale-Up

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Overview

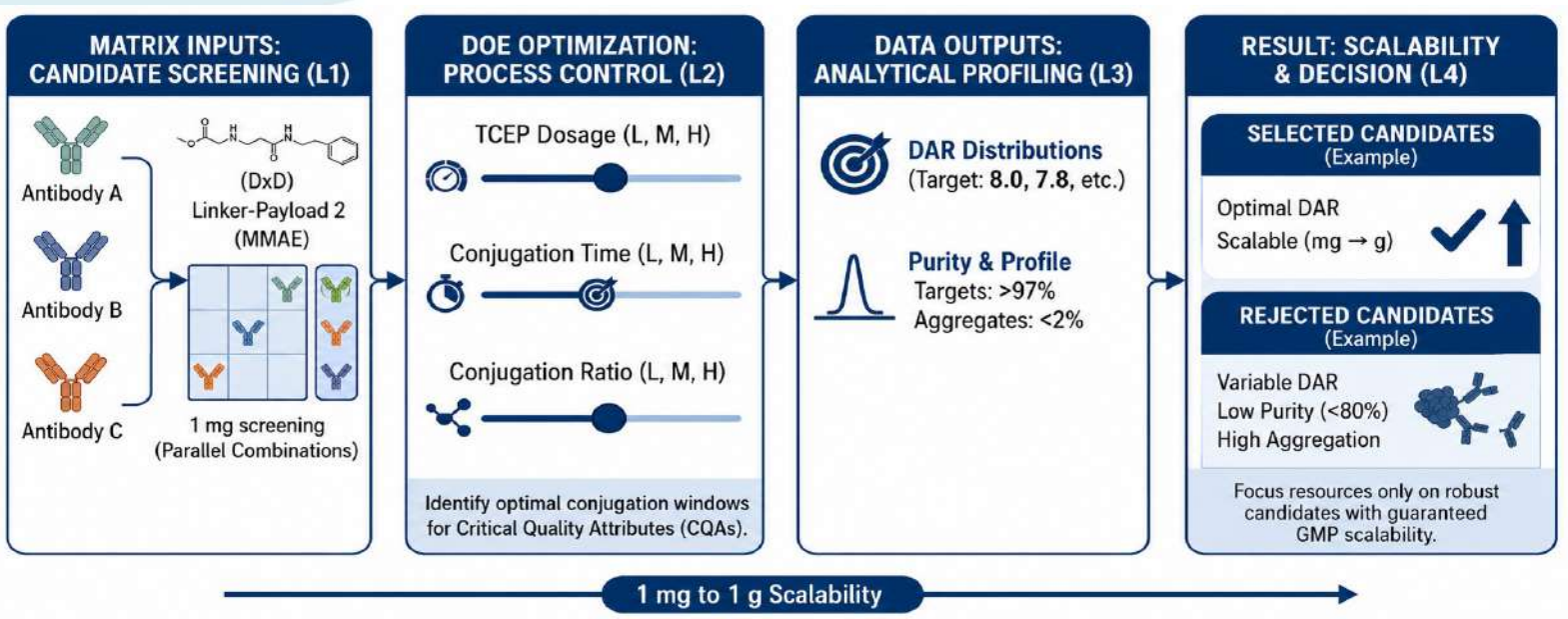
- Antibody generation for ADC development
- ADC conjugation (cysteine and site-specific)
- Linker-payload compatibility evaluation
- Analytical & bioassay support
- GMP manufacturing supported via strategic partners

Service Highlight

Integrated ADC DOE & Candidate Selection Platform

17 Days
mg Scale

28 Days
g Scale

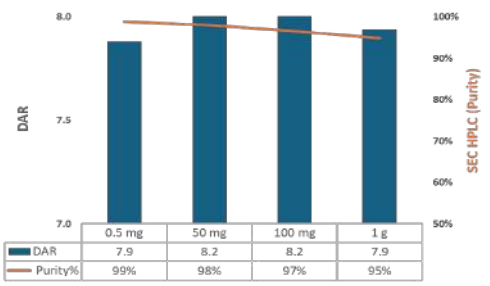


ADC Platform Capabilities

Scale-up does not compromise quality - DAR remains consistent from 0.5 mg to 1 g
Scalable and Reproducible

Rapid candidate screening can be performed without full analytical characterization, with Raman-based DAR prediction achieving an accuracy of $R^2 \geq 99$ %

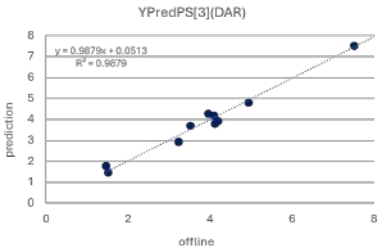
Consistent DAR Across Scales



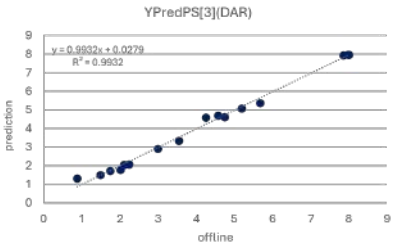
	0.5 mg	50 mg	100 mg	1 g
DAR	7.9	8.2	8.2	7.9
Purity%	99%	98%	97%	95%

Raman-based DAR Prediction

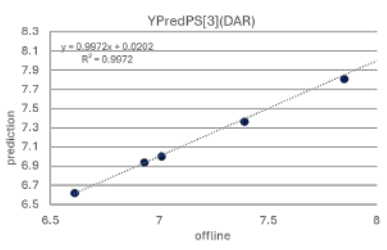
Enhertu



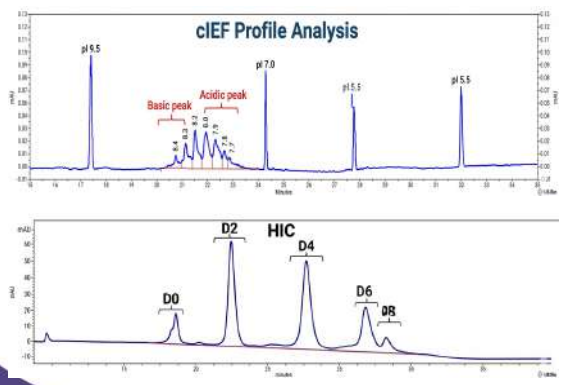
Adcetris



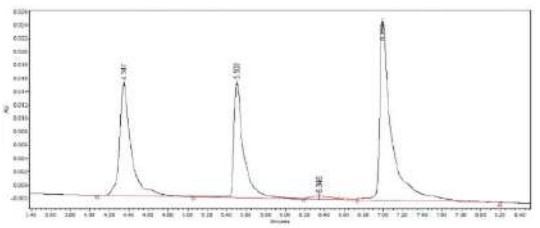
Trodelvy

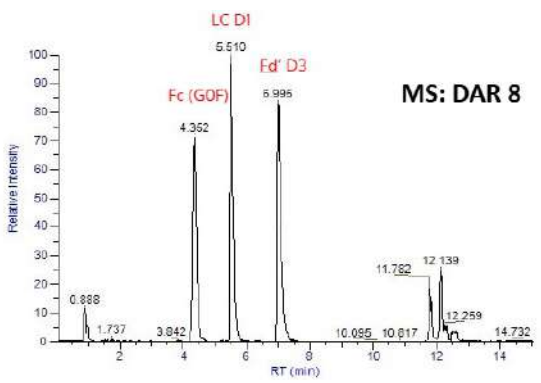


cIEF confirms charge homogeneity; HIC resolves DAR species distribution



DAR confirmation: LC+MS
Unambiguous DAR characterization





Integrated Cell Therapy Service

- Accelerating Cell Therapies from R&D to Commercialization

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Overview

- We provide one-stop cell therapy CRDMO solutions, integrating the development, manufacturing, quality, and clinical translocation
- Technology coverage：
  Autologous and allogeneic MSC/T-cell therapies (e.g., CAR-T)
  Immune cell and somatic cell therapies
  Exosome- and secretome-based therapeutic products

Why Choose TBMC

One-Stop Integration

Unified services from raw material to final clinical manufacturing

GMP Suites

5 Grade B/A suites with 9 independent AHUs and segregated personnel/ material flows

Comprehensive Analytics & Quality

Sterility, potency, and safety testing for regulatory compliance

Fill & Finish

Automated process ensuring sterility and consistent production

Dual-arm Automation

High-throughput system for scalable and consistent production

Core Manufacturing Capacity & Delivery Efficiency

High Capacity
Fast Delivery
Reliable Release

CAR-T Cell Therapy	MSC Cell Therapy
480 batches/year	100 batches/suits/year
Manufacturing Time：7-9 days	Manufacturing Time：6 days
Per Patient：3×10^9 cells	Per Batch：$0.5\text{-}2 \times 10^9$ cells
QC Release：4 days	QC Release：4 days

Shorten the Path to the Clinic

Accelerating timelines through integrated workflows and regulatory support across CMC, IND, NDA, and BLA

Reduce Cross-Stage Transfer Costs

Standardized SOPs and platform integration minimize repeated validation.

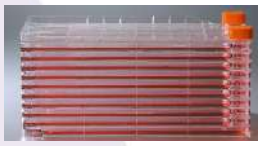
Improve Delivery Efficiency & Product Consistency

Automation and digitalized control support stable and consistent quality.

Seamless Support Workflow

Starting Materials	Cell Isolation & Activation	Lenti Viral Vector Provision	Cell Expansion	Storage & Analytical Testing	Clinical Manufacturing & Release
Patient tissue, blood, bone marrow, umbilical cord, leukopak, and PBMC	Density system and magnetic separation system	Plasmid production, purification, QC, titer, and potency test	Multilayer, wave system, and scalable system	Ensuring safety, identity, potency, and consistency	Manufacturing suites, process execution, and final product release



Analytical & Testing Platform

Flow Cytometry	ELISA/ELISPOT	qPCR/Digital PCR
T-Cell Phenotyping	Cytokine Release Analysis	Vector Copy Number
MSC Phenotyping	MSC Lymphocyte Modulation Assay	Replication Competent Lentivirus
CAR Antigen Analysis		

Automated Cell Manufacturing Platform

- Cell Culture 
- Imaging Analysis 
- Media Exchange 
- Cell Passage 

Gene Therapy Service

- Research and Tox/GMP Grade Viral Vector Production

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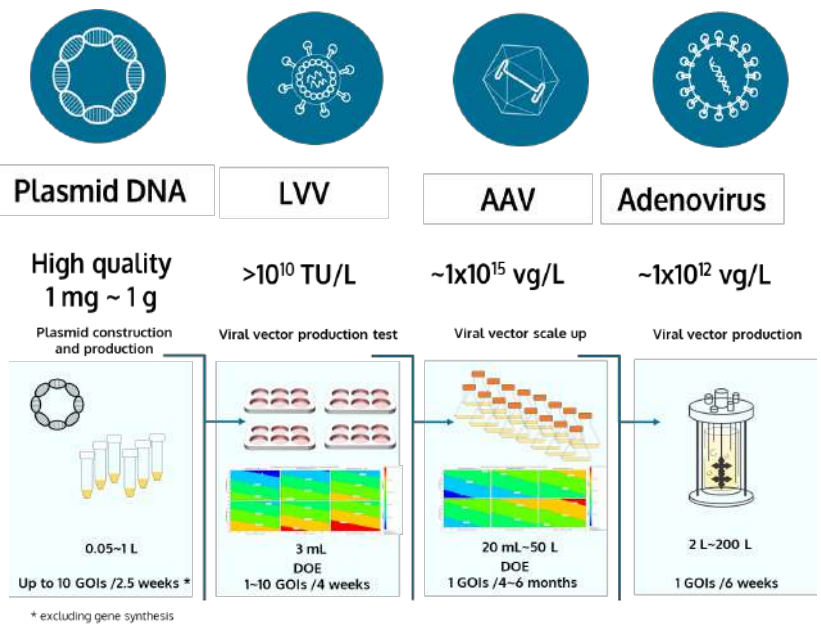
Overview

Flexible and Scalable Production

- **End-to-end services**: From plasmid DNA to GMP production, proprietary HEK293 host cell
- **Easily scalable**: s3T AAV and s4T LVV suspension platform, from 2 L to 50 L and up to 200 L
- **Flexible**: Small-scale, high-throughput research production and large-scale manufacturing
- **Fully quality control**: Comprehensive analytical capability & PAT system with Raman spectroscopy

Highlight

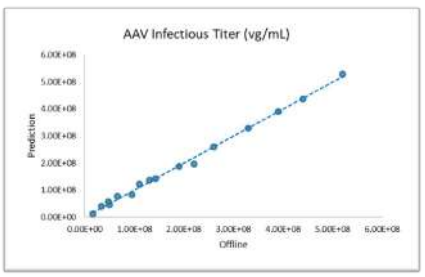
Gene Therapy PAD Lab Capacity

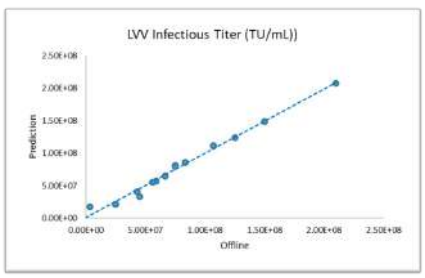


Save Time. Save Money. Achieve More

	Raman System				
	vg, copy number (ddPCR)	Capsid (ELISA)	P24 (ELISA)	Infectious (Flow)	Empty/Full (AUC)
AAV	V	V		V	V
LVV			V	V	

Short-Time **Cost-Effective** **Reduce Labor**





Service

Research, TOX, and GMP grade

- Research to Tox batch
- GMP manufacturing for clinical and commercial
- Single-use bioreactor 50 L, 200 L

LVV Production

- > 10^{10} TU/L — High productivity
- 4 plasmid — Transient transfection
- > 30% — High recovery rate
- 2 L – 200 L — Scalable process
- 16+ — Release specification

AAV Production

> 10^{15} vg/L High productivity	> 85% High full capsid ratio	> 60% High recovery rate
2 L – 200 L Scalable process	5+ Serotype	26+ Specified characterization assay

Integrated AD/QC Analytical Service

- For Advanced Therapies & Biologics

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Accelerating Product Characterization to GMP Release & Stability
TBMC provides analytical development and GMP-ready QC testing services for mRNA/LNP, cell therapy, gene therapy, viral vectors, and biologics from early development to clinical release.

Two Flexible Service Models

EXTERNAL CLIENT SOLUTIONS

For Customer Programs
Analytical Strategy Consultation

- CQA mapping & testing panel
- Method development/qualification/validation
- Product characterization & comparability support
- Troubleshooting for impurities, residuals, potency, and stability

INTERNAL GMP SUPPORT

For TBMC Manufacturing Operations

- Raw material/in-process/release testing
- Stability testing
- Environmental and microbiological support
- Deviation/OOS/investigation support
- Method transfer and routine QC readiness

Through Our Analytical & Testing Services

LC-MS

Capping and poly(A) analysis, impurity profiling, and PTM analysis

AUC

Full-to-total AAV ratio and higher-order characterization

CAD

Lipid composition and detergent quantification

dPCR

Vector copy number and residual DNA analysis

BacT/Alert

Automated sterility testing and microbial detection

Cell assay

Cell potency, phenotyping, and functional assessments

Four Advanced Therapies

mRNA/LNP

- RNA purity and integrity
- Encapsulation efficiency
- Lipid composition
- Particle size and distribution
- Residual DNA/enzymes/solvents
- Stability-indicating methods

CELL THERAPY/CAR-T

- Cell count and viability
- Immunophenotyping by flow cytometry
- Identity and purity
- Potency/functional assays
- Vector copy number by ddPCR
- Sterility/mycoplasma/endotoxin support

GENE THERAPY/ VIRAL VECTOR

- Vector titer
- Genome integrity
- Residual host cell DNA/HCP
- Empty/full ratio support
- Transgene expression
- Purity and impurity profiling

BIOLOGICS

- Protein identity and purity
- Aggregation and stability support
- Charge variants
- PTM/glycosylation support
- Potency assays
- Stability and comparability support

Stability Testing Support

- Real-time and accelerated stability studies
- Region-specific storage condition support
- Flexible temperature conditions based on market requirements
- Sample management, pull-point testing, trending, and reporting

Stability studies performed under different regional temperature requirements with protocol-defined sampling time points

-80°C | -40°C | -20°C | 2-8°C | 25°C | 40°C

Protocol-defined sampling time-points support: initial, 1M, 3M, 6M, 9M, 12M, 18M, and 24M (additional time-points available per study protocol)

HIGH QUALITY FAST SPEED COMPETITIVE PRICE