Yaohabio
耀海生物

Yaohai Bio-Pharma

About Us

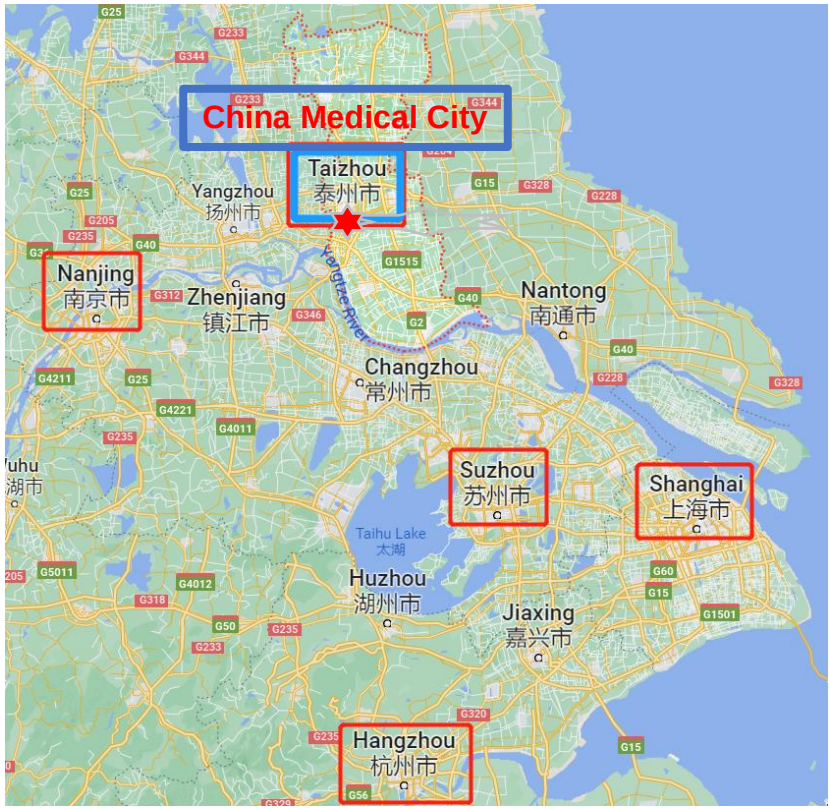
- Founded in 2010, located in **China Medical City**, originally as a spin-off of **GSK (GlaxoSmithKline)**
- The 1st and Biggest microbial CRTDMO, end-to-end solution provider in China

Services:

- Focus on recombinant proteins, peptides/polypeptides, enzymes, antibody fragments and nano-antibodies, plasmid DNA and mRNA, virus-like particle (VLP), IVT RNA design…
- Global clinical and commercial products supply in biological drugs, biosimilars, vaccines and diagnostics for human and veterinary use

Advantages:

- cGMP Production Platform **7500+ L**, 20, 000+ m² plant
- The largest GMP-level Plasmid supplier in China
- **Explosion Proof Facilities**
- **High-potency** Manufacturing Suite
- Bio-Safety Level 2 (**BSL-2**) lab for pathogenic bacteria
- Customer Technical Personnel allowed to be stationed on-site



Position in the Industry

Top 1 Number of serviced projects

Top 1 Scale of production capacity (7500+L)

The No. 1 and Largest microbial biologics CRDMO in China

Fill & Finish

Microbial Strain Engineering
MCB/WCB Establishment

Contract Manufacturing

Process Development & Optimization

Facilities

Building #1

107,700 sq. ft

DS Workshop III: **50-100L**, DS Workshop IV: **50-500L**,

DS Workshop V: **50-200-500-2000L**,

DP Workshop II, Quality Control center

Building #2

86, 000 sq. ft

DS Workshop I: **50-500L**, DS Workshop II: **50-200-1000-2000L**

DP Workshop I

Beijing Branch

FDA/EU Industrialization Standard

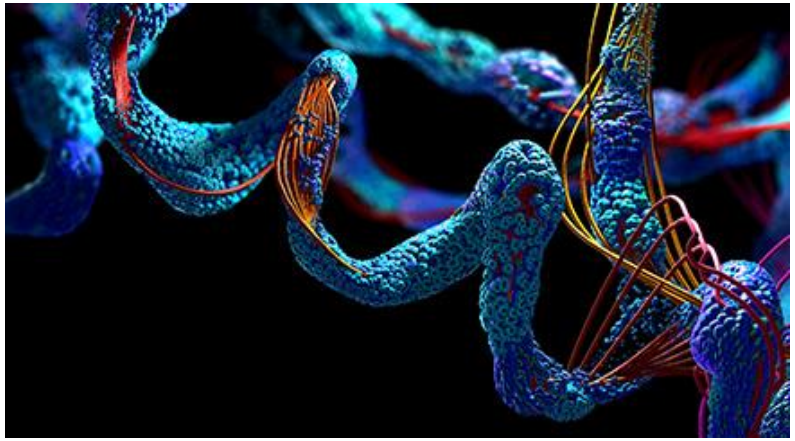
Process Development Center

Nucleic acid drugs and Nano-bodies CRO/CDO

Quality research service

Technical Capacities

Yaohai Bio-Pharma delivers end-to-end biopharmaceutical services, with focuses on recombinant protein, nucleic acid drug and nanobody. With high efficiency and flexibility, Yaohai provides global biotechnology companies with CDMO services such as process development, IND-CMC pharmaceutical research, GMP production of clinical samples, registration application, etc., to serve customers with solutions for the whole process from DNA to commercial production. Yaohai is engaged in providing efficient and feasible CDMO services and solutions to customers and facilitate the R&D of new drugs.

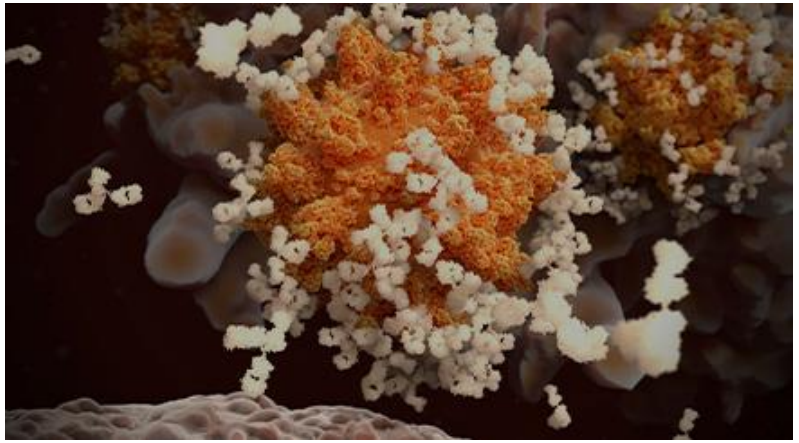


Recombinant Protein

End-to-end CDMO service platform for recombinant protein/polypeptide drugs

Nucleic Acid Drug

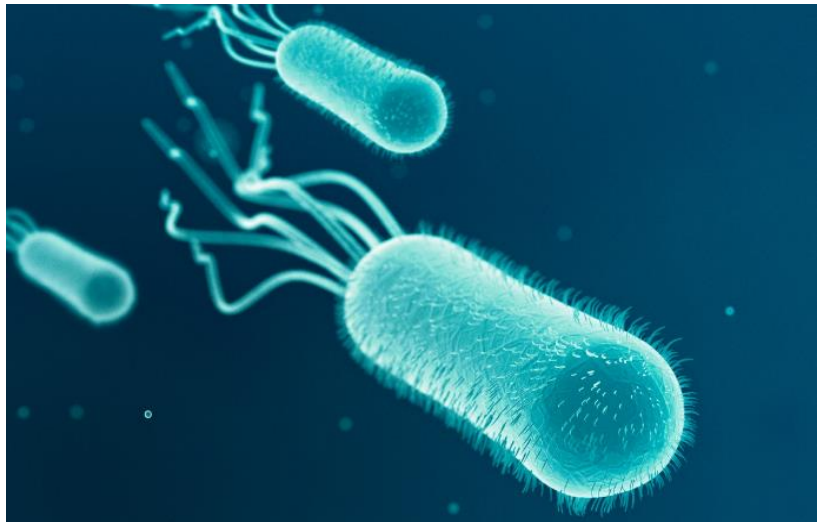
Focusing on the use of plasmid and mRNA, accelerating the progress from R&D to clinical application



Single Domain Antibody

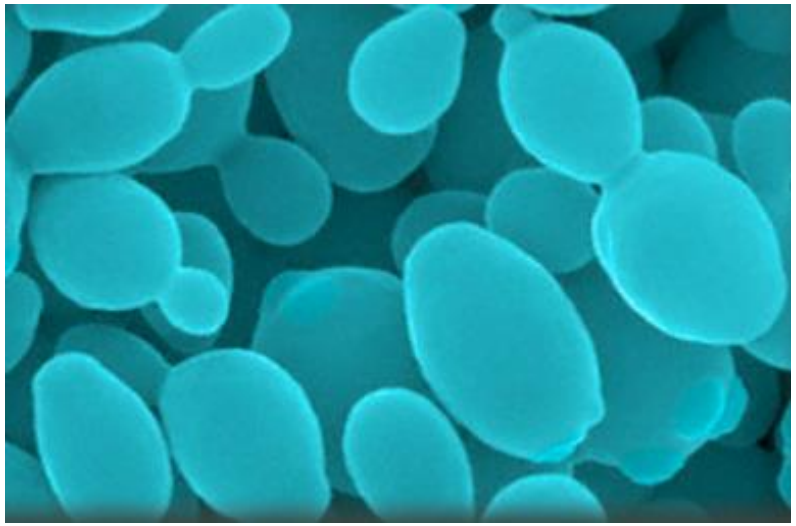
Global expression platform

Expression Systems



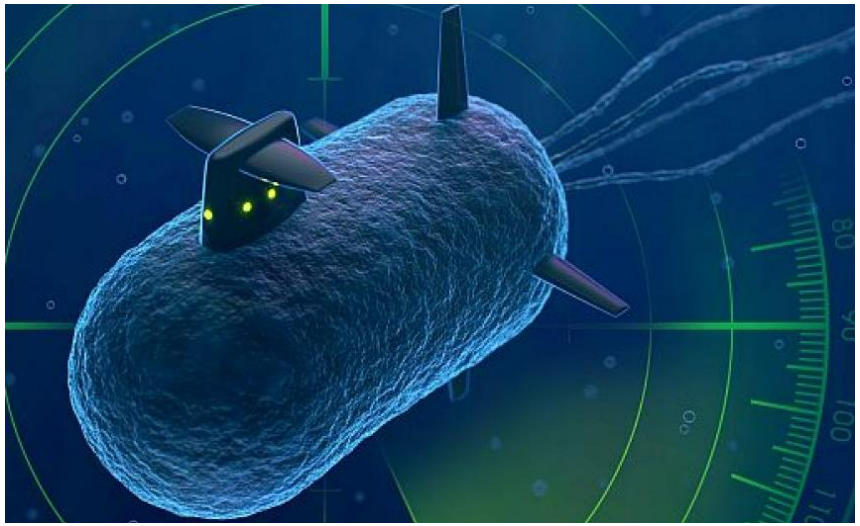
E. coli

K-12 strains & derivatives (DH1, DH5α, RV308, W3110, MG1655, JM109, BW25113…)
B strains (BL21, BL21(DE3), BL21(DE3) pLysS, BL21(DE3) Rosetta…)



Yeast

Pichia pastoris, Hansenula polymorpha, Saccharomyces cerevisiae, etc**.**



Tailor constructed Strains

Other microbe/microbiota/microbiome provided by clients
Microbial strains engineering and construction

Yaohai has an integrated CMC development and cGMP production process platform to produce recombinant proteins, plasmids, and antibody fragments with *E.coli* and yeast expression systems, or any microbial strains provided by clients or engineered in-house.

Bespoke Integrated Solutions

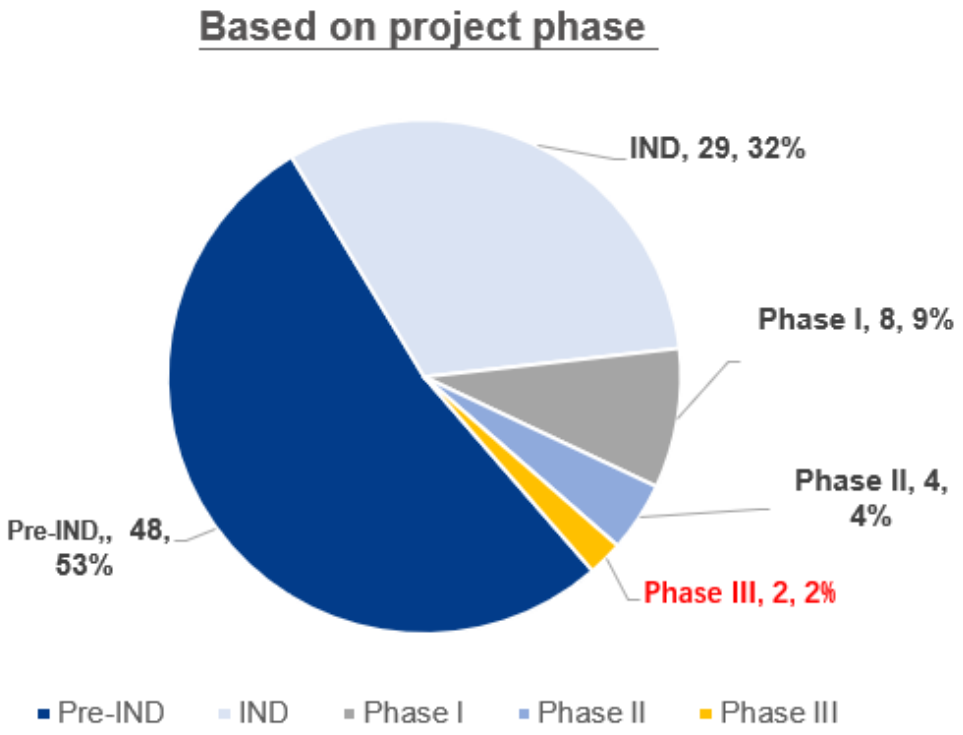
ONE-STOP CRTDMO

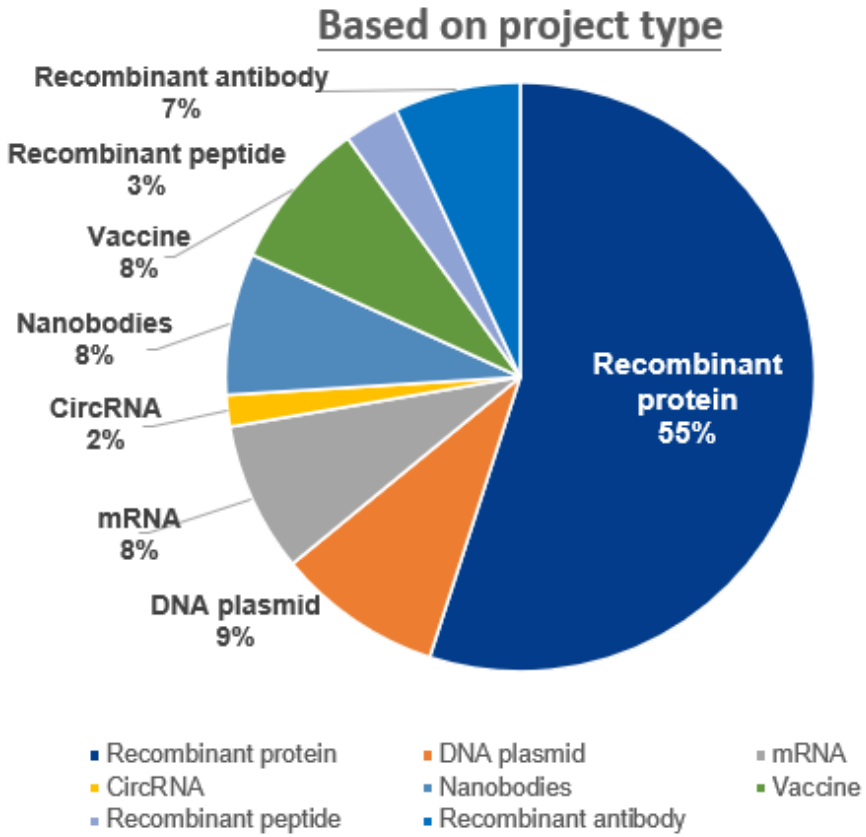
- **CRO**
  - Selection of nucleic acid drugs & Nanobodies
- **CTO**
  - Analysis Method Development
  - Stability Research
- **CDO**
  - Strain Construction
  - lab-scale process development & optimization
  - Process scale-up &optimization
  - Quality Standard Research
  - Registration & Application
- **CMO**
  - IND application
  - Sample production in Phase I/II/III
  - Commercialized production
- **Quality Management**
  - GMP Quality Management
  - Verification

Customized R&D services → **Strain / MCB Establishment** → **Process Development & Optimization** → **Registration & Application** → **IND batches** → **Production in Phase I~III** → **Commercial-ized production**

Cooperated Projects

US application	EU application	AUS application	CAN application
7	1	2	1





Standalone Services

Strain Engineering & Strain Bank Establishment

- Strain engineering & construction
- GMP secondary strain library (MCB+WCB) establishment

Process Development & Optimization

- **Fermentation process** development & optimization
- **Purification process** development & optimization
- **Preparation process** development & optimization
- Related product preparation

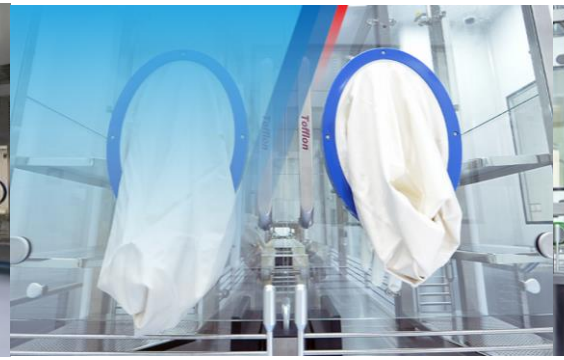
GMP Compliance Scale-up Production

- **Fermentation** scale-up & production
- **Purification** scale-up & production
- **Preparation** production
- Preparation of standards

Method Development & Quality Control

- **Quality standards** research
- **Method** development & validation
- Sample commissioned testing
- **Stability & compatibility research**

Fill-Finish Services


Workshop	Equipment	Dosage Form	Specification Range	Maximum Output
1500m² Aseptic preparation workshop in accordance with GMP requirements for Any Modalities (biologics, vaccines…)	Filling speed: 2ml vial 160~300 vials/min, 10ml vial 140~200 vials/min Lyophilization capacity: 2ml 37800 vials (4200 * 9 layers) 10ml 20043 vials (2227 * 9 layers)	Pre-filled injectables Lyophilized powder injections Eye drops Oral solutions Inhalation formulations	**1-25mL**	Annual production: **10 million** injection (vials) **5 million** lyophilized powder for injection (vials)

Equipment For Process Development


1


2


3

4

5

6

1 –Sartorius BIOSTAT C full-automatic Bioreactor-30L

2 –Quadruple fermentation system made by Bioengineering AG -7L

3 – GE AKTA System

4 –BIO RAD Gel Imaging System

5 – qPCR made by ThermoFisher

6 –SCIEX capillary electrophoresis;

Equipment For DS Production

Fermentation system 2000 L

Disc centrifuge

High pressure homogenizer

Automatic buffer Configuration/storage system

Explosion Proof Facilities/ High-potency Suite

High pressure chromatography

Sterility Isolator

Hollow fiber system

Equipment For QC

HPLC
Thermo (U3000/Vanquish)

HPLC
Agilent 1260

Molecular
Devices iD3

GC
Agilent 8890

qPCR
ABI QuantStudio5

mRNA Service Platform

Yaohabio 耀海生物

Pre-clinical → IND → Phase I → BLA → Commercialization

Early Research

- Sequence Design & Optimization
- Plasmid construction and seed libraries
- mRNA synthesis and quality control
- Formulation Studies
- In vitro activity studies

NanoStar Pharmaceuticals

Proprietary LNP

Process Development

- Plasmid linearization process
- mRNA processes (transcription system optimization, mRNA purification, Scale up)
- LNP process (encapsulation, scale up)
- Process validation, characterization

Analysis method development

- Method Development/Validation (stock solutions, formulations, process control samples, impurities)
- CQA Tests (identification, integrity, purity, stability)
- Stability Pre-evaluation Studies, Stability Studies

GMP Service

- Raw Material Control Release
- Drug Substance/formulation Registration Batch Manufacturing
- Technology Transfer
- Quality Assurance/Release Testing
- Registration Services

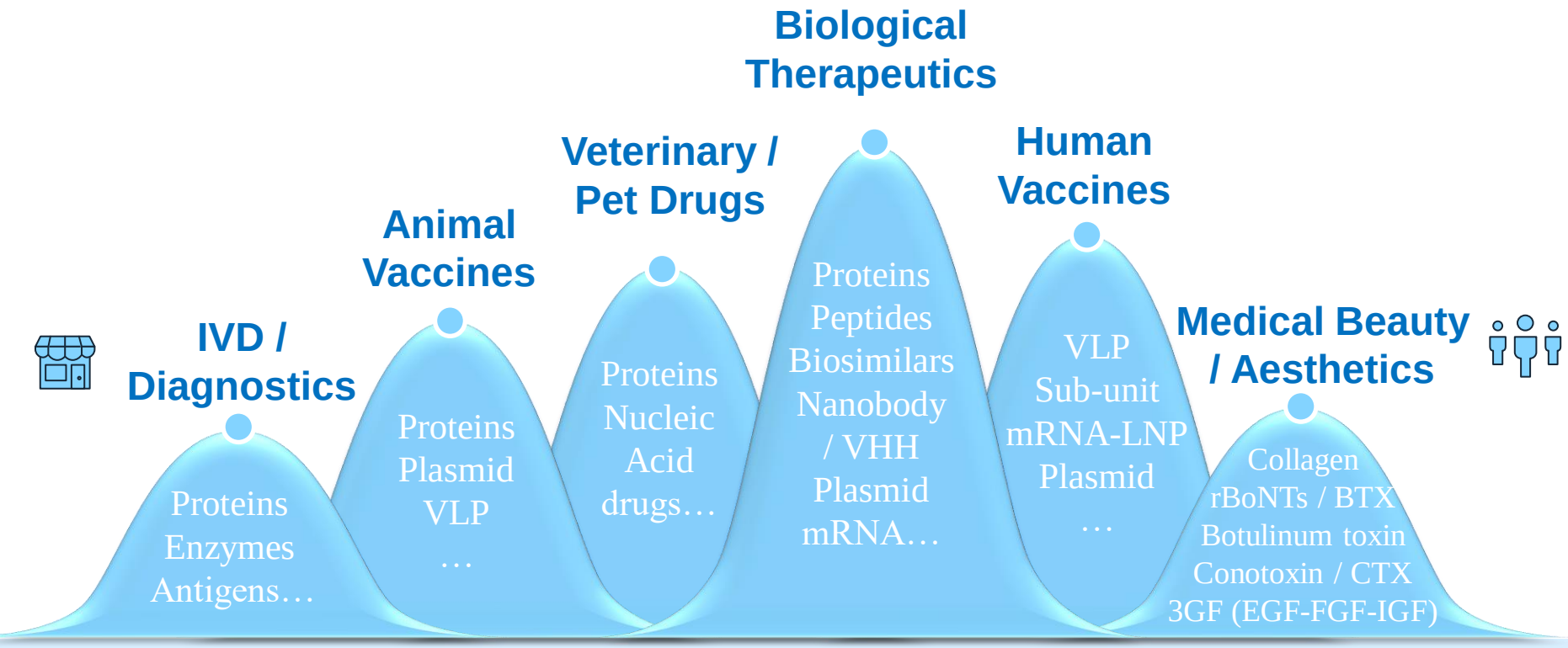
UBC

LI LAB UBC PHARM SCI

Strategic Partners

From Concept to Vaccines One-stop CRDMO

Strategic Services Focus



- Extend service chain
- Form CRO/CDMO integration
- Promote the comprehensive competitive advantage of technology and scale
- Based on the microbiology expression and cultivation
- Raw material and CDMO service integration
- Give full play to the comprehensive advantages of talent and microbial track

Website: https://www.yaohai-bio.com.cn/

Email: BD@yaohaibio.cn

Sincere Service for a Shared Future