



# Yaohai Bio-Pharma



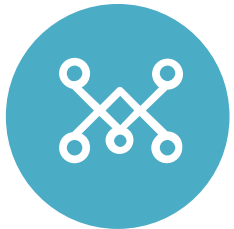
# About Us



- ◆ Founded in 2010, located in **China Medical City** and Beijing **CBP (China Bio-Medicine Park)**
- ◆ The **1<sup>st</sup>** and **Biggest** microbial CRTDMO, end-to-end **solution provider** in Greater 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+ m<sup>2</sup> 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





## Global Biologics CDMO Market

PRESCIENT & STRATEGIC INTELLIGENCE  
Where knowledge inspires strategy



Market Growth Will Accelerate at a CAGR (2021-2030)

**10.3%**

2021  
\$13,173.7 Million

2030  
\$31,839.7 Million

MARKET SIZE



>44% APAC Held the Largest Market Share

GROWTH DRIVERS

- Heavy investment in healthcare infrastructure
- Increasing and aging population.

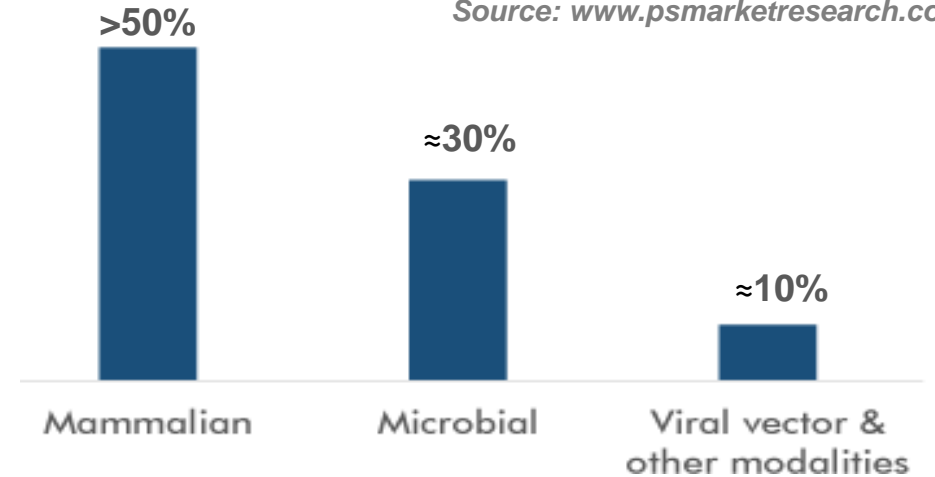
## CDMO Market Growth Rate by Region (2022-2027)

Source: Mordor Intelligence



## Global CDMO Market By Cell Line Type \$Million (2021)

Source: www.psmarketresearch.com



# 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**

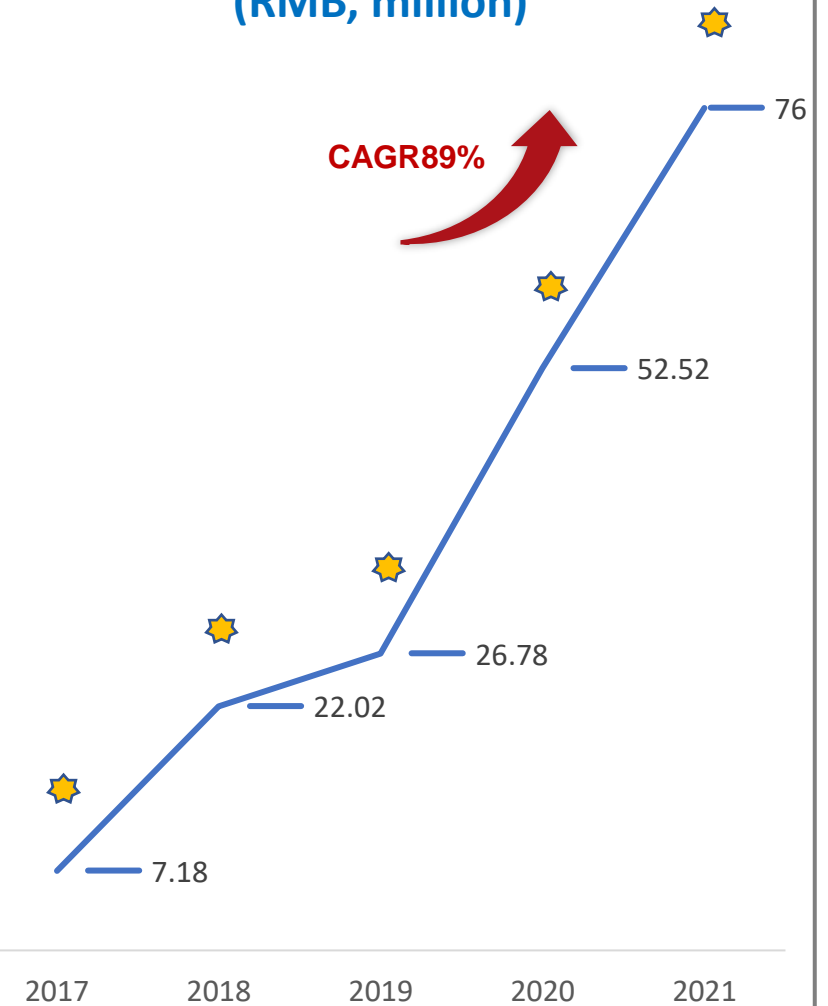


**Microbial Strain Engineering  
MCB/WCB Establishment**

**Contract Manufacturing**

**Process Development & Optimization**

**Revenue of recent 5 years  
(RMB, million)**



# Existing Capabilities



## Building #G27

8, 000 m<sup>2</sup> in operation

DS Line I: **50-500L**; DS Line II: **50-200-1000-2000L**

DP Line I



## Building #G29

10, 000 m<sup>2</sup> in operation

DS Line III: **50-100L**; DS Line IV: **50-500L**,

DS Line V: **50-200-500-2000L**

DP Line II, Quality Control center



## Vaccine Engineering center

1, 000 m<sup>2</sup> in operation

Process Development Center



## Building # G23

3, 000 m<sup>2</sup> in operation

YHNB (IVD), Innovation Center

## Beijing Branch

Nucleic acid drugs and  
Nano-bodies CRO/CDO  
Quality research service  
Medical Beauty materials  
development



**FDA/EMA Industrialization  
Standard**





# 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.



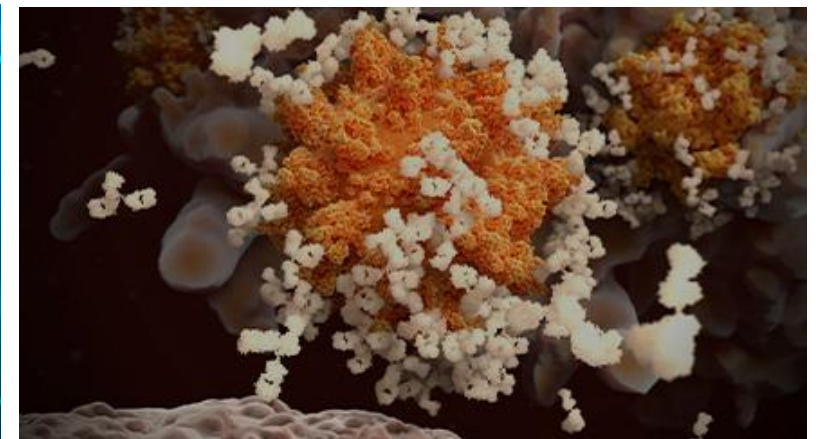
## Recombinant Protein

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



## Nucleic Acid Drug

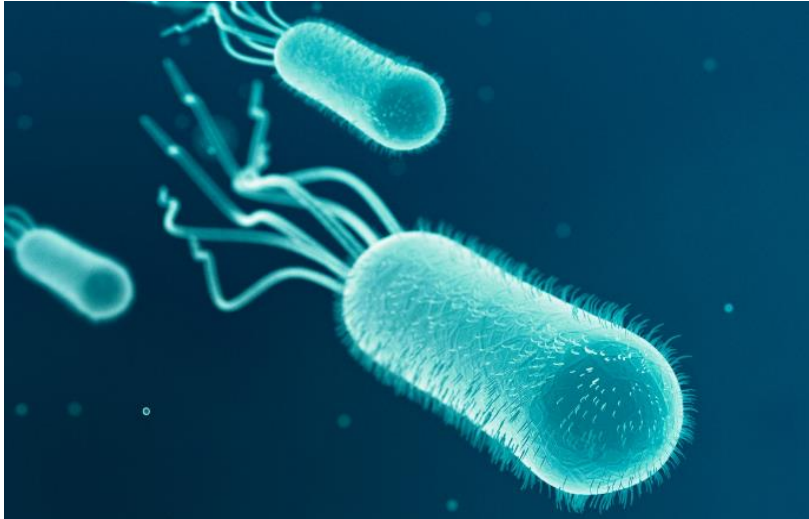
Focusing on the use of plasmid and mRNA, accelerating the progress from R&D to clinical application



## Single Domain Antibody

Global expression platform

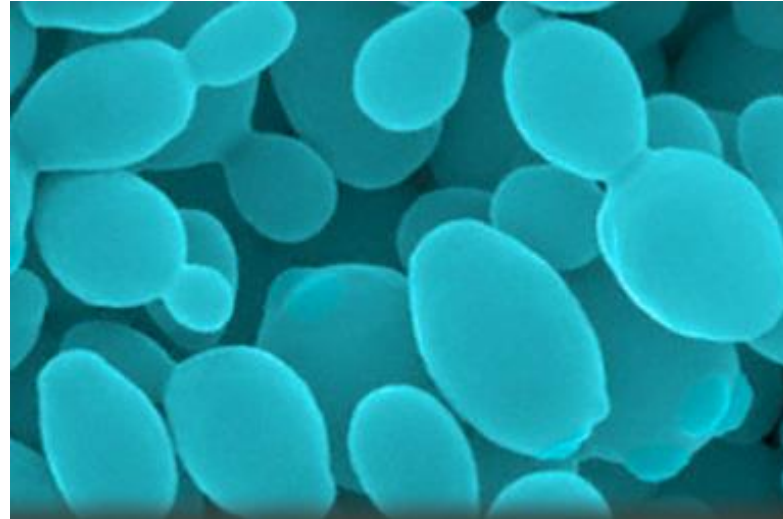




***E. coli***

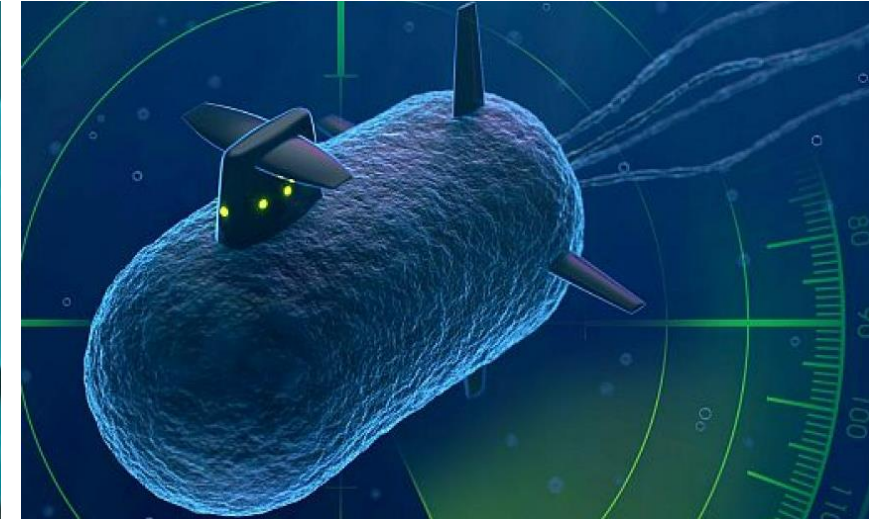
**K-12** strains & derivatives (DH1, DH5 $\alpha$ , RV308, W3110, MG1655, JM109, BW25113...)

**B** strains (BL21, BL21(DE3), BL21(DE3) pLysS, BL21(DE3) Rosetta...)



**Yeast**

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



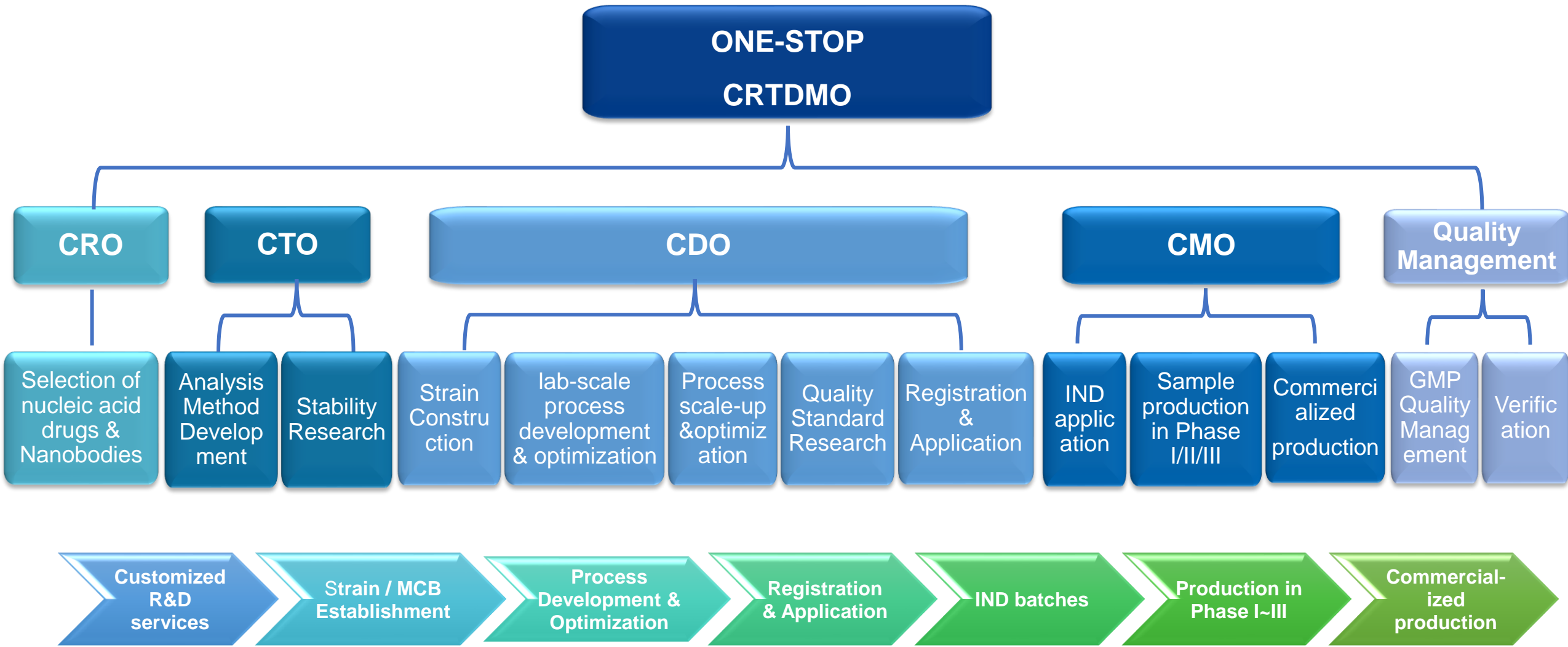
**Tailor constructed Strains**

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





# Cooperated Projects

US-China  
application

7

EU-China  
application

1

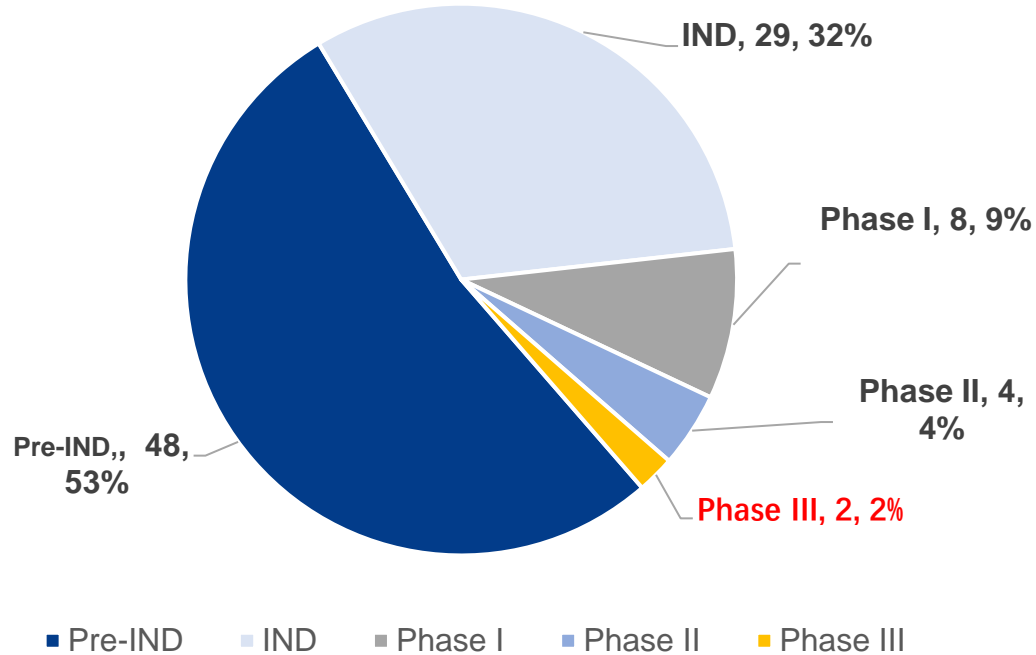
AUS-China  
application

2

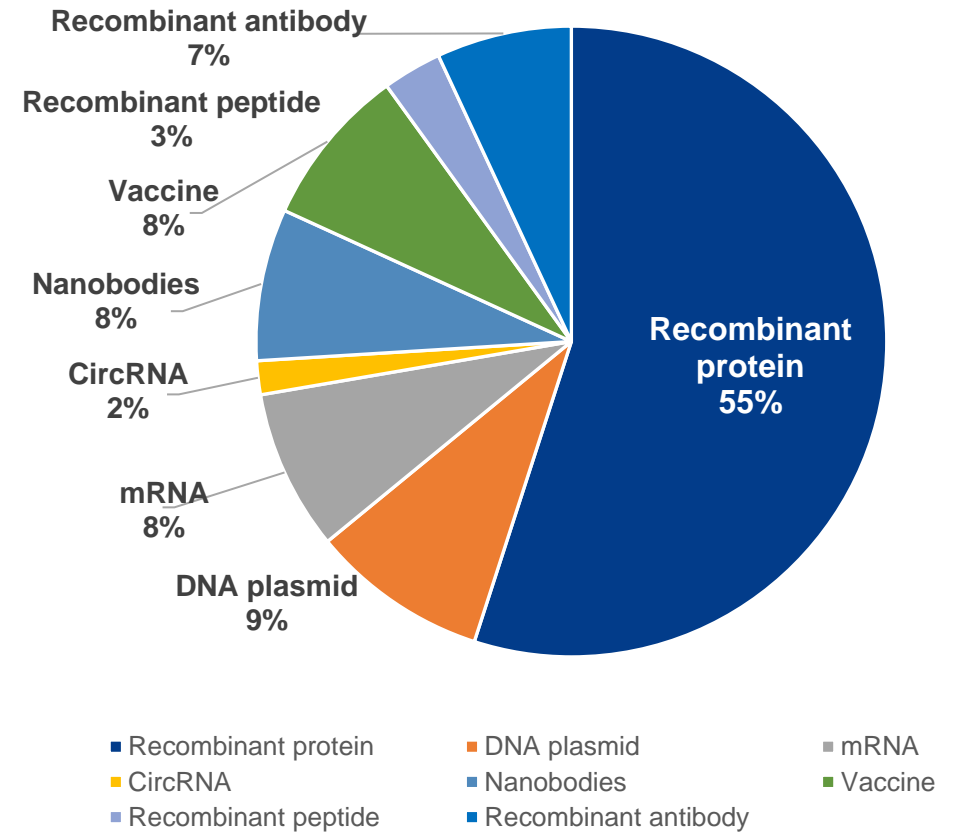
CAN-China  
application

1

Based on project phase



Based on project type



# Stand-alone 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



1500m<sup>2</sup> 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)





# Equipments For Process Development



- 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;



# Equipments 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



# Equipments For QC



HPLC  
Thermo (U3000/Vanquish)



HPLC  
Agilent 1260



Molecular  
Devices iD3



GC  
Agilent 8890



qPCR  
ABI QuantStudio5





# mRNA Service Platform

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



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



Strategic Partners

# From Concept to Vaccines One-stop CRDMO



**Prophylactic**  
**Veterinary**  
DNA Vaccines  
Subunit Vaccines  
Polysaccharides  
Vaccines (Bacterial Capsule)  
Biologic Vaccine Adjuvants

**Therapeutic**  
**Human**  
RNA Vaccines  
VLP Vaccines  
Protein/Peptide-based  
Vaccines  
Live-attenuated Vaccines

## Yao hai Bio-Pharma

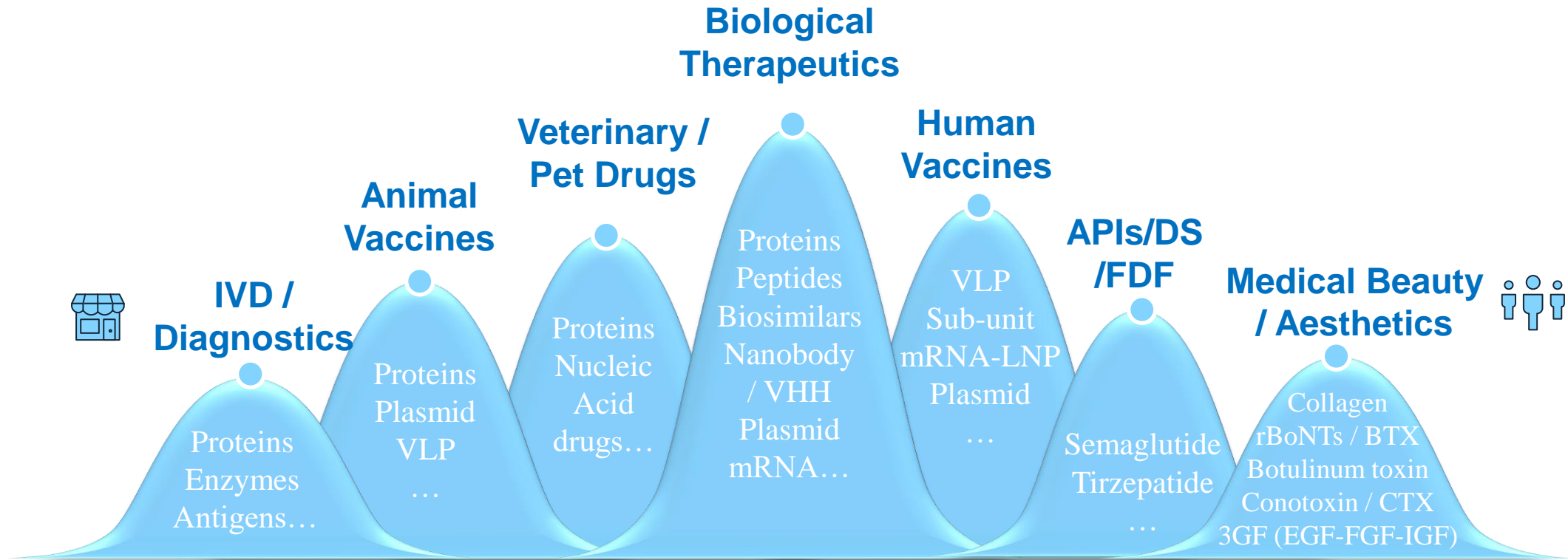
**From Concept to Vaccines One-stop CRDMO**

Toxoid Vaccines      Heterologous Vaccines  
Conjugate Vaccines

Infectious Diseases: Viral Infections, Bacterial Infections, Parasitic Infections  
Tumors, Autoimmune Diseases



# Strategic Services Focus



- Interferon alfa-2b / IFN- $\alpha$ 2b
- Interleukin 2 / IL-2
- Growth Hormone / GH / Somatotropin / Somatotropic Hormone / STH

- 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



Jason Soung

Head of International Business Development



***Microbial Biologics CRDMO***

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