



PROFESSIONAL MICROBIAL EXPRESSION SYSTEM

Recombinant Single-domain Antibody

SINGLE-DOMAIN ANTIBODY CDMO SERVICES

Single-domain Antibody (sdAb) Full Ecological Recombinant Expression CDMO Services Platform

Yaohai Bio-Pharma has a complete one-stop technology platform and CDMO overall solution for single-domain antibodies (sdAbs), which can provide clients with the whole life cycle services from genetically engineered strain construction, establishment of strain bank, lab-scale process development/optimization, pilot process scale-up, IND application and clinical sample preparation, quality specification establishment, analytical method development/verification, quality management system establishment, NDA registration application and commercial production. Life cycle services, supported by the production platform from lab-scale, pilot-scale to large-scale, with a series of services such as process and method development and verification, equipment verification and quality control, and quality research, etc., can meet the cooperation needs of clients from early drug findings, clinical research to marketing at commercial scale.



Single-domain Antibody (sdAb) Service Advantages

Advanced Process Development Concept

- A stable process with high output and yield can be achieved by determining the critical process parameters (CPP) with CQA (critical quality attribute) as the starting point obtained through DoE based on the concept of quality by design (QbD).

Rich Project Experience

- More than 100 projects have been successfully served, covering the preclinical research, clinical phase I, II and III, including several registration projects filed for CN, US FDA and AUS.

Professional Team Guarantee

- Supported by experienced and stable CDMO services team, with rich service and accumulated technical experiences in multiple categories of recombinant protein projects, and focus on process route innovation, quickly resolve process difficulties and reduce the R&D costs
- Professional PM project management team proficiently masters the project management of the whole life cycle of biologics development, can identify and manage the project critical path, identify, control and manage the project risks

Comprehensive Production Capacity Guarantee

- Large-scale preparation services at a scale of 50L-100L, 200L, 500L, 1,000L and 2,000L
- 2 production lines for drug products (vial lyophilized powder/injection, pre-filled cartridge)

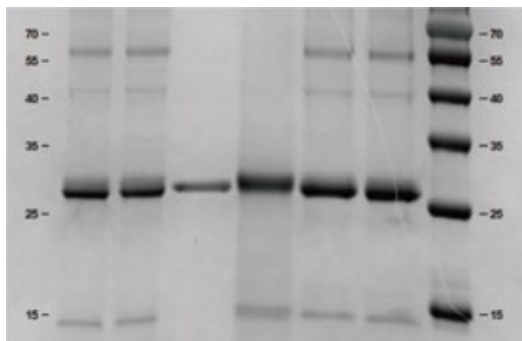
Perfect Quality Management System

- Provide a full range of quality management service, with professional and standardized service guarantee system, and the whole cycle can comply with the requirements of the new edition of the pharmacopoeia and the GMP related guidelines, to continue to deliver products with stable quality for clients

One-stop CDMO Services

- Deliver one-stop service from strain construction to commercial production, covering all stages of preclinical research, clinical phase I, phase II, phase III and biologics production

Service Cases



Objective

Purity $\geq 95\%$; endotoxin $< 50\text{EU/mg protein}$

Developed a two-step chromatography method

Affinity chromatography: affinity using A3, with a purity of up to 94.1%;
Anion exchange chromatography: using 50HQ, with a yield of 73.9%, and a purity of 98.1%

The process target requirements were met after testing the endotoxin.

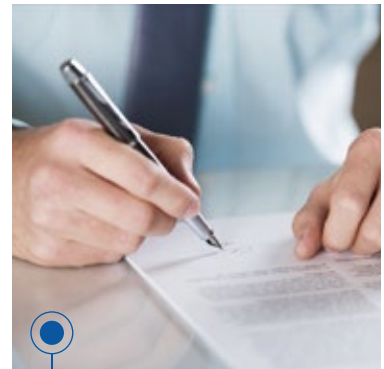
Service Process



PROJECT CONTACT

Project Communication

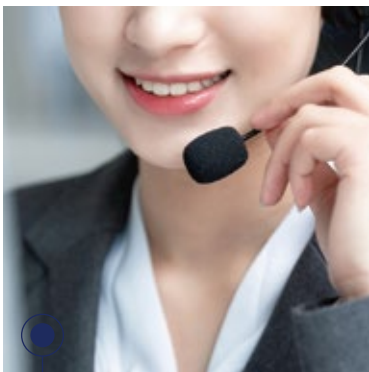
Confidentiality Agreement /
Needs Analysis



READY START UP

Contracting

Gap Analysis /
Quality Agreements



POST-SALE SERVICE

Follow Up Services

Assistance in Official Verification /
Technical Consultation



ACCEPTANCE DELIVERY

Project Delivery

Deliverables Management /
Cost Settlement



EXECUTIVE CONTROL

Project Implementation

GWBS Promotion /
Process Control

SERVE **WITH HEART** & CREATE **THE FUTURE TOGETHER**

CHOOSE YAOHAI BIO-PHARMA

Project Experience

More than 100 projects have been successfully served, covering the preclinical research, and clinical phase I, II and III, including several registration projects filed for China, US FDA and Australia.

Comprehensive Production Line Protection

High quality and diversified fermentation purification services can be provided with the fully automated fermentation systems at a scale of 2-7500 L.

Flexible Cooperation Mode

Offer customized services that cater to the specific requirements of diverse project types, ensuring quality and efficiency in delivering exceptional client satisfaction.

Professional Team

With experienced CRDMO services execution team supported by gradient professionals, the contracting services can be efficiently and collaboratively boosted.

Compliance Service

With professional, standardized and regulated service guarantee system, the whole life cycle complies with the requirements of the new edition of pharmacopoeia, GMP and other related guidelines.

One-stop Service

Provide one-stop service from process development to commercial production.

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