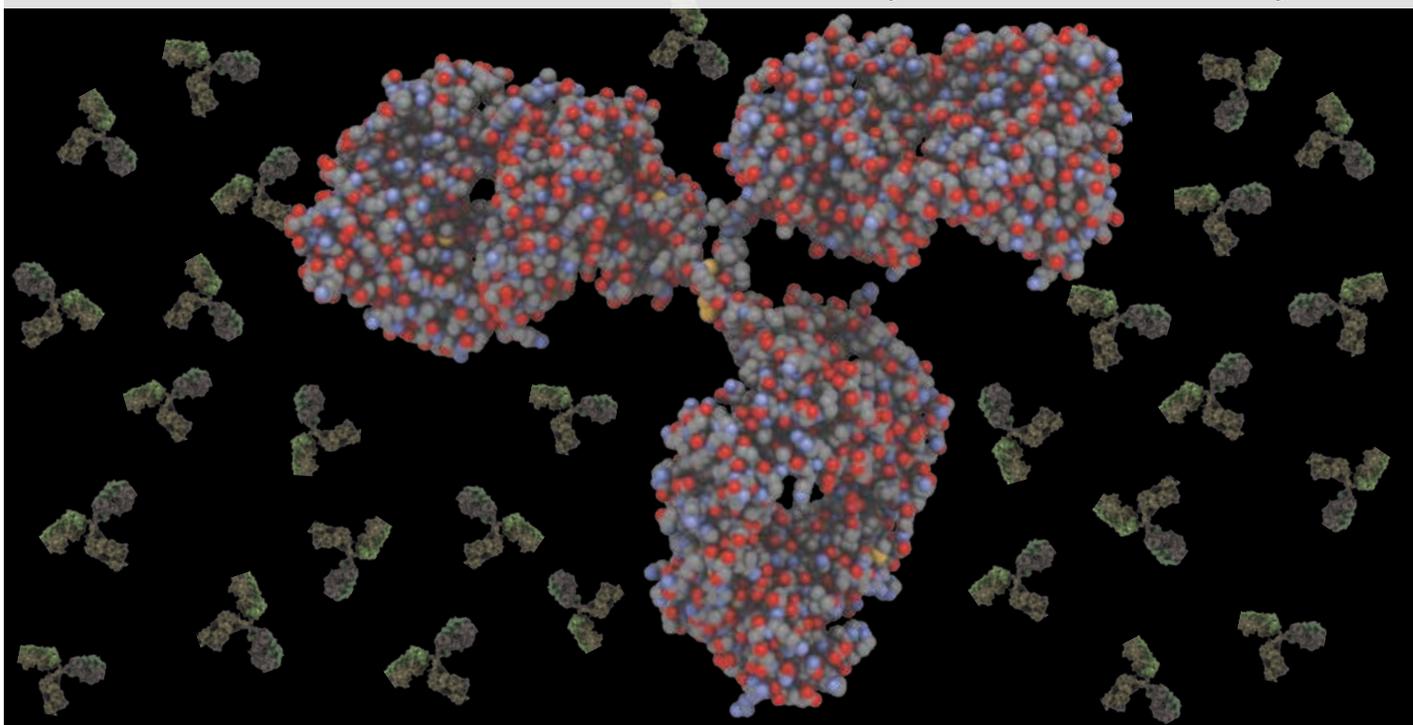


Monoclonal Antibody Discovery



Cutting-edge MAb discovery platforms to deliver high-potency therapeutic antibodies

ILLUSTRATION:
Monoclonal Antibodies

 **药明康德**
WuXi AppTec

Complete MAb discovery services to meet your exacting needs

WuXi AppTec offers three engineering and discovery service platforms for the development of novel high-potency monoclonal antibody therapeutics to best suit your technical, program, and budget requirements.

Our discovery and biology teams comprise over 160 scientists who work within our five main functional groups – research materials generation, hybridoma generation, antibody engineering, high-throughput screening (HTS), and functional assay development – to provide comprehensive discovery and development support.

Antibody Discovery Platforms



WuXi AppTec's Therapeutic Antibody Discovery Services

Research Materials Generation

Assay Development

Antibody Drug Candidate Pool Generation
Hybridoma, Phage Library

High-Throughput Screening

In-Vitro Screen for Drug Leads

In-Vivo Study for Lead Identification

Standard *in-vivo* approach leveraging our advanced hybridoma system

Utilizing unique immunization methodologies, advanced electro cell fusion (ECF) techniques, state-of-the-art equipment, and an AAALAC-accredited animal facility, WuXi AppTec obtains exceptionally high cell-fusion efficiencies (1-10 hybridomas per thousand B cells) and high antibody titers, maximizing our success rate in subsequent analytical tests that include biochemical screening, *in-vitro* cell-based assays and animal studies.

Advantages of highly efficient immunization strategy:

- High antibody titer (up to 1,000,000 ~2,000,000)
- Break immune tolerance (immune response to self-protein)
- Short immunization time (6-8 weeks to achieve immunization peak)
- Less immunogen needed (1 ug immunogen per injection)

In-vivo approach using OMT's OmniRat™/OmniMouse™ platform

WuXi AppTec has partnered with Open Monoclonal Technology (OMT), an innovator in novel transgenic animals for development of human therapeutic antibodies. Together, WuXi AppTec's capabilities and OMT's platform technology enables:

- Generation of patent-free, fully-human antibodies to address all targets, all fields, and all indications.
- Eliminates time-consuming humanization work and need for optimization of lead candidates.
- Can be utilized with our advanced hybridoma system for generating optimal antibody pools for further screening.

In-vitro lead generation and screening utilizing phage display libraries

Our antibody engineering group provides high-quality therapeutic antibodies via advanced library design/synthesis phage display technologies. Capabilities include:

- Existing naïve, immune, and synthetic human phage display libraries
- Custom library construction
Library size: $10^8 \sim 10^{10}$ | Positive rate: >95% | Diversity: >85%
- Supporting antibody engineering & development services
Affinity Maturation | Liquid phase panning
Site-specific mutation and glycosylation modification

In-Vivo Biology / Therapeutic MAb Lead Identification

WuXi AppTec has validated over 91 patient cell line-derived subcutaneous tumor xenograph models for *in-vivo* studies, and our *in-vivo* biology teams support studies for therapeutic MAb lead identification for these disease states:

- Oncology
- Immunology and Inflammation
- Cardiovascular and Metabolic Diseases (CMD)
- Infectious Diseases
- CNS/Pain Diseases

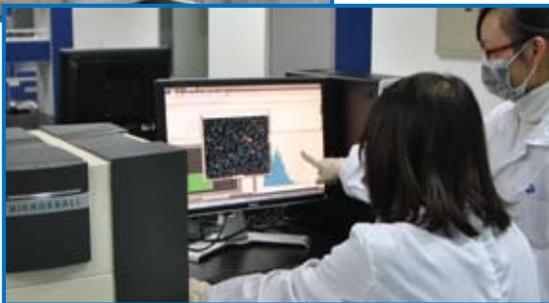
Integrated Support Services

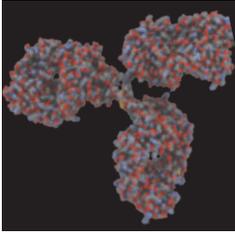
- Humanization of existing mouse monoclonal antibody
- Affinity maturation of monoclonal antibodies
- Single-domain antibody discovery and generation via immunized Llama
- Recombinant protein and antigen production
- Monoclonal antibody production (1-500mg)
- Cell line generation with high expression of membrane protein targets
- Large-scale ELISA screening
- High-resolution FACS analysis
- High-throughput FACS screening
- FACS-based affinity determination for antibody against membrane protein
- SPR-based antibody full kinetic affinity (Kd) analysis
- SPR-based high throughput antibody Koff determination and affinity ranking
- Epitope binning studies
- Epitope mapping
- Antibody isotyping
- Sequencing of antibody from hybridoma
- Phage library construction
- Phage library panning
- ADCC assay
- CDC assay
- Cell mineralization assay
- Cell lipid accumulation assay
- Cell proliferation assay
- Antibody functional block assay for ligand-receptor binding
- Apoptosis assay
- Cytokine stimulation assay
- Signal transduction phosphorylation assay

High-Capacity Antibody Screening and Characterization

Our experienced team provides high-throughput MAb screening by ELISA, FACS and other image-based binding methodologies (e.g., Mirroball), as well as antibody biochemical characterization to ensure the identification of antibody drug candidates with high potency and to find those suitable for functional assays and animal studies.

- ▶ Throughput via ELISA or Mirroball/FACS
 - Primary Screen: 10,000 – 50,000 samples per assay
 - Secondary Screen: 1,000 – 3,000 samples per assay
 - Characterization: 100 -300 samples per assay
- ▶ Biochemical characterization
 - Antibody isotyping
 - Antibody affinity ranking (whole IgG, scFv or Fab format Koff ranking)
 - Epitope binning
 - SPR-based affinity measurement
 - Cell surface protein affinity estimation by FACS
- ▶ *In-vitro* functional characterization
 - Cell migration/invasion
 - Angiogenesis
 - Cell signaling
 - Antibody function
 - Proliferation
 - T-cell and B-cell activation
 - Gene expression
 - Total of more than 50 established assays





Monoclonal Antibody (MAb) Discovery

WuXi AppTec's comprehensive R&D platform provides unsurpassed technical expertise coupled with global regulatory experience. Our personnel, facilities and laboratories are equipped to provide the full range of discovery and development services, including monoclonal antibody engineering, discovery, research materials generation, cell line engineering and construction, analytical product characterization, bioprocess development, and preclinical and clinical manufacturing services.

PROGRAM FEATURES

- Capabilities to develop fully human MAbs using OMT's transgenic OmniRat™ and OmniMouse™ technologies.
- Human MAb phage display technology platforms.
- Custom phage display library generation.
- World-class advanced hybridoma technology platforms for therapeutic MAb discovery.
- Exceptionally high cell fusion rates (1-10 fusions/1,000 B-cells) for creation of hybridomas.
- High-throughput analysis of MAb pools (up to 50,000 samples / assay).
- Wide array of in-vitro and in-vivo antibody screening and characterization assays.
- AAALAC-accredited animal facility.
- Proven target-to-lead capabilities.
- Reliable, cost-effective solutions, with global access to the world's fastest growing healthcare markets.
- Highly trained discovery team with senior leadership that includes Ph.D.s and M.D.s with 20+ years' experience in developing antibody therapeutics.
- Full range of services from discovery to commercialization.
- State-of-the-art laboratory and manufacturing facilities (GMP and non-GMP).

Contact WuXi AppTec for MAb discovery services:

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