Medicilon

Integrated Preclinical Drug Discovery and Development Services

SHANGHAI MEDICILON INC.

COMPANY PROFILE

From its inception in 2004, Shanghai Medicilon Inc. (STAR Market, stock code: 688202.SH) has been committed to providing comprehensive research and development (R&D) services to biopharmaceutical companies, research institutions, and any organizations working in the preclinical space, with the primary objective of supporting and accelerating pharmaceutical, biopharmaceutical and medical device R&D worldwide.

A Comprehensive CRO for Pre-Clinical Pharmaceutical R&D

- End-to-end services and solutions covering the entire spectrum of preclinical biopharmaceutical R&D. Supporting everything from target discovery, candidate development, preclinical screening and safety through IND submission
- Focus on communication and collaboration with clients in a variety of target indication areas such as neoplasms, neurological diseases, diabetes, inflammation, etc

State-of-the-Art Facilities

- Three R&D centers with over 794,000 ft^2 of lab space in Shanghai, China
- AAALAC accredited animal facilities
- GLP/GMP compliant facilities, instrumentation with FDA and NMPA regulations

High-Performance Teams

- Internationally trained scientists with Ph.D. degree and/or with 10+ years of R&D and management experience
- Timely support and consultations through one-on-one communication

IP Protection

- Strict internal policies and excellent historical track record

DRUG DEVELOPMENT & CMC SERVICES

Services Related to APIs and Formulation

A wide-range of API services for both innovative and generic drugs including process development and optimization, quality studies, scale-up, technology transfer, process validation, and IND registration service.

Over 43,000 ft^2 of formulation laboratory and GMP-compliant facilities can support phase I and phase II clinical trials.

SERVICES

Extensive experience in supporting a wide variety of formulation dosage forms including capsules, tablets, granules, injections, inhalants lyophilized powders, eye drops, ointments, tinctures, etc.

Also supporting formulation process development, quality tests, stability studies, and the evaluation of packaging materials and containers.

Medicilon's Advantages

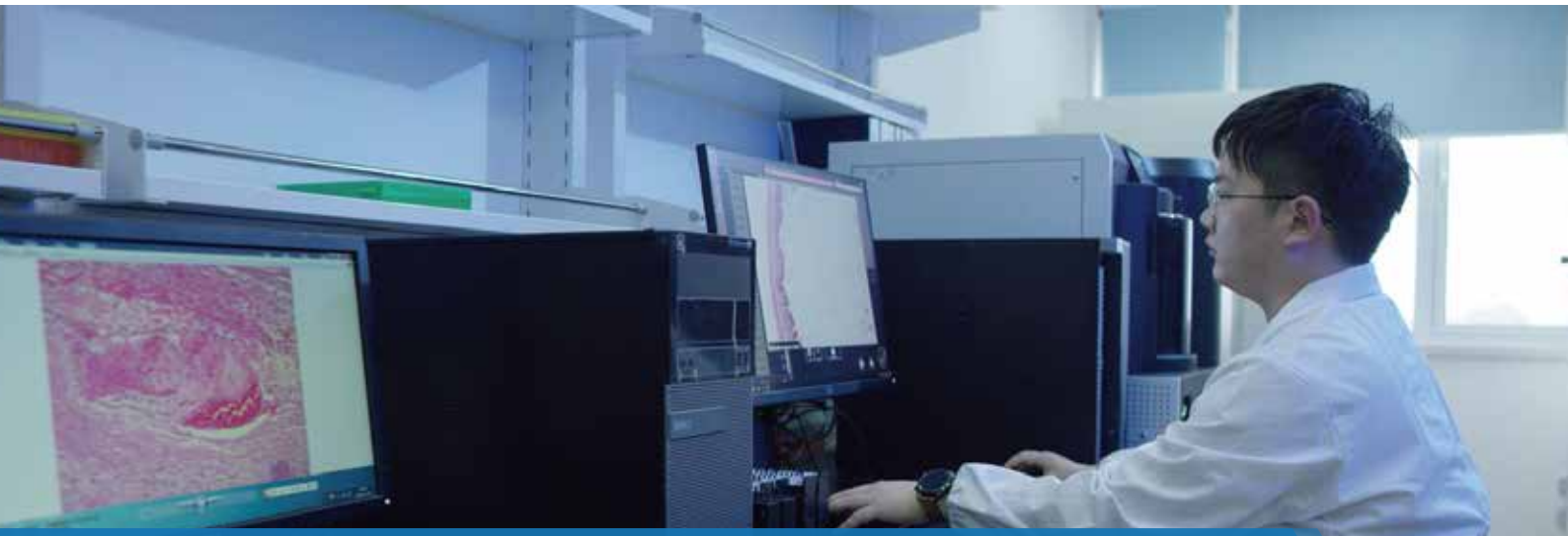
01 Successfully contributed to 100+ IND approvals of APIs for both innovative and generic drugs

02 Integrated solutions covering the entire drug discovery and development spectrum including technology development, scale-up, manufacturing, and registration

03 In-house pilot-scale agent workshop and 2 cGMP API production lines fulfilling the IND approval requirements of the FDA

04 Rapid and continuous expansion in industrial capacity and capability

05 Active engagement and collaboration with other research institutions on innovation



PRE-CLINICAL SAFETY ASSESSMENT GLP & NON-GLP

Medicilon's state-of-the-art facilities are fully AAALAC-accredited. With state-of-the-art platforms and experienced scientists, Medicilon ensures that drug efficacy and safety assessments are conducted in the most professional manner while meeting the global regulatory standard. From stand-alone preclinical studies to comprehensive IND-enabling packages, Medicilon provides flexible service options to assist biopharmaceutical clients efficiently reach their development millstones.

In Vivo Toxicology

- General toxicology
- Safety pharmacology
- Development and reproductive toxicology
- Genetic toxicology
- Inhalation toxicology
- Immunotoxicology
- Carcinogenicity study
- Local toxicity study (hemolysis, allergy, and irritation tests)

Histopathology

- H&E staining
- Immunohistochemistry (IHC)
- Tissue cross reaction (TCR)

Clinical Pathology

- Hematological analysis
- Urinalysis
- Clinical biochemical analysis
- Hemagglutination analysis
- Lymphocyte typing

PHARMACOKINETICS

Medicilon's PK/PD department has 19+ years of experience in preclinical pharmaceutical safety assessment. Our experienced scientists and dedicated study directors provide expert guidance as well as oversight of the overall project to ensure quality and KPI's are met on time and budget. From high throughput screening to a full-scale New Drug Application (NDA), Medicilon's flexible and highly competitive solutions can be tailored to meet each sponsor's needs.

In Vitro ADME

Medicilon's *in vitro* ADME services range from high throughput screening to IND enabling support. Our objective is to provide competitive, flexible, and customized solutions meeting each individual sponsor's requirements at different stages of the drug R&D pipeline.

- Lipophilicity, solubility tests
- Caco-2 permeability
- Transporters: substrate and inhibition studies
- hERG test

Distribution

- Protein binding: plasma, tissue, and microsomes
- Red blood cell partition

Metabolism

- Metabolic stability: microsomes, S9, and hepatocyte
- Matric stability: plasma, tissue, and buffer
- *In vitro* metabolite profiling and identification

DDI

- Cytochrome P450 (CYP) inhibition (IC_{50} and TDI)
- CYP induction
- Enzyme phenotyping: phase I and phase II enzymes (recombinant enzyme and chemical inhibition)

In Vivo DMPK

Service Overview

Pharmacokinetics screening service

Pharmacokinetics/Toxicokinetic for IND submission

- Formulation screening
- Multi-period crossover bioequivalent
- Tumor-bearing mouse PK/PD
- Tissue distribution (biodistribution, BBB permeability studies)
- Mass balance
- ^{125}I, ^{14}C, ^{3}H labeled isotope drug metabolism research
- Drug-drug interactions
- Metabolite identification and profiling
- Excretion studies

Modality

Small and large molecular therapeutic products of almost all modalities

Biologically Relevant Animal Species

Rodents, rabbit, canines, swine, non-human primates (Cynomolgus and Rhesus monkey)

Surgical Techniques

Venous cannulation, biliary cannulation, infusion pump, implantation, and continuous trace blood collection

Dose Strategies

Single, multiple, and cassette dosing

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IND APPROVAL

Medicilon provides the IND application for the preclinical services. Medicilon is the CRO that fulfill both the China and US GLP standards. Medicilon could submit the application for both FDA and NMPA for your new drug. Since 2004, we have successfully helped our clients to submit their new drug application to FDA and NMPA and met the requirements of the FDA and NMPA. We have undergone several inspections and passed all of them. Medicilon will provide an efficient, cost-effective and professional service to help our clients to achieve their goals.

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