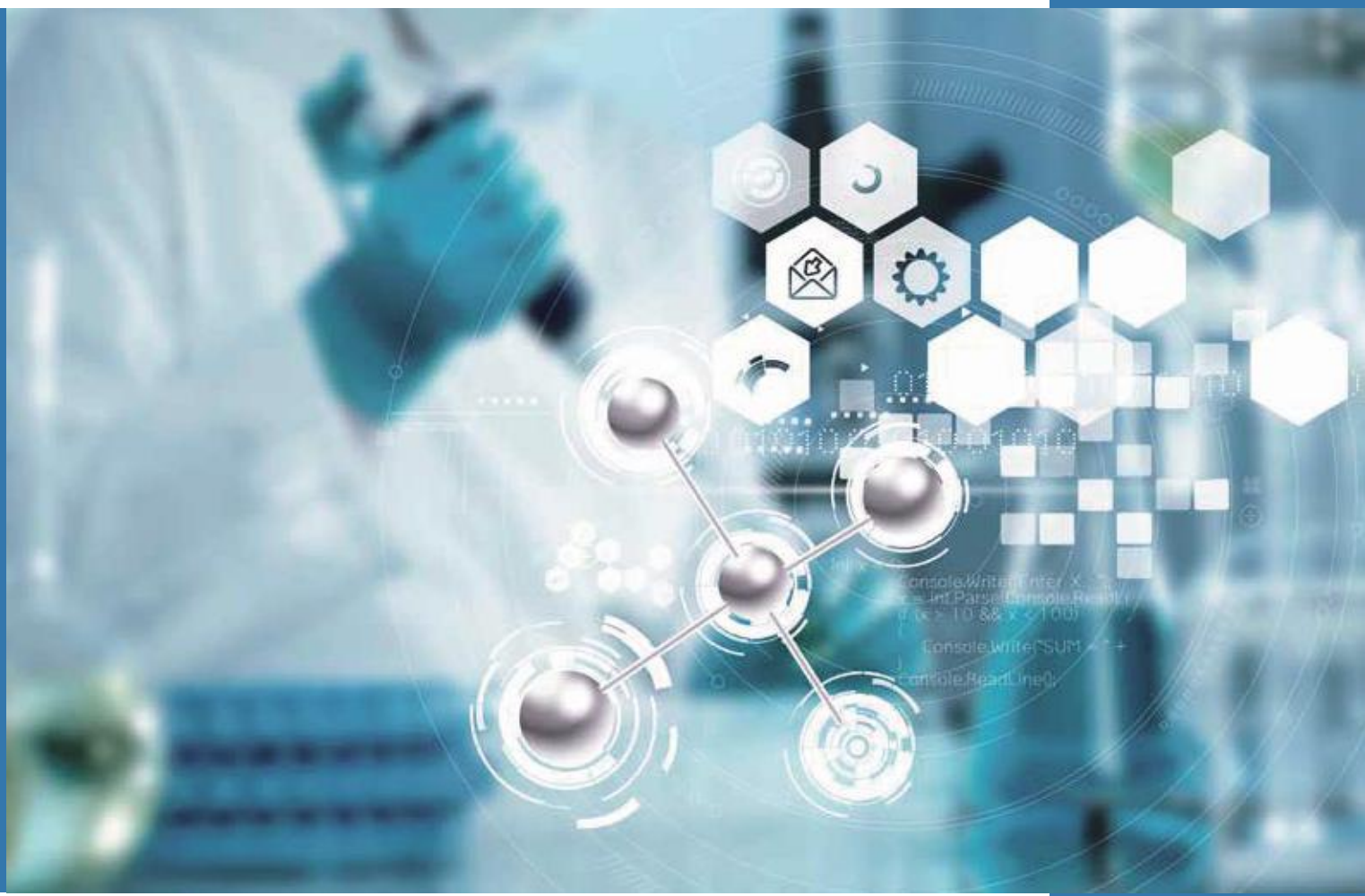
Medicilon

美迪西生物医药



Integrated Preclinical Drug Discovery and Development Services

FOCUS Drug Development & CMC

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

SERVICE SCOPE

Drug Discovery

Chemistry
Biology

Preclinical Research

Pharmacology
Pharmacokinetics
Safety Assessment
Bioanalysis

Drug Development & CMC

Drug Substance
Drug Product

IND Filing

FDA
NMPA
TGA
EMA

Address: 1 Broadway, 9th Fl, Cambridge Innovation Center
Cambridge, MA 02142
Email: marketing@medicilon.com
Website: www.medicilon.com

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

Chemical Analysis Services

- Method development, pre-validation, and transfer
- Compound purity test and related substance analysis
- Content method development (gravimetric analysis, external standard method, quantitative nuclear magnetic resonance, etc.)
- Chiral analysis method development and screening
- Isomer impurity analysis and method development (SFC, HPLC, and GC)
- Purification, preparation (Prep-HPLC), resolution of chiral molecules (SFC or Prep-HPLC) for compounds and impurities
- Structure elucidation by the combination of UV, IR, MS, and NMR spectra
- Compound solubility and stability tests (HPLC)
- In-process control analysis support, standardization of reference standards, analytical procedure validation, study on analytical methods for PGI/residual solvent/elemental impurity, stability study, and other physico-chemical detection analyses (moisture/melting point/optical rotation/ROI/LOD/LC-MS/IR/UV/TGA/DSC, etc.)
- Technology safety assessment and analysis

Address: 1 Broadway, 9th Fl, Cambridge Innovation Center
Cambridge, MA 02142
Email: marketing@medicilon.com
Website: www.medicilon.com

SHANGHAI MEDICILON INC.

Address: 585 Chuanda Road, Shanghai 201299, China Tel: +86 (21) 5859-1500
Email: marketing@medicilon.com Website: www.medicilon.com

Service Hotline

400-780-8018（China） | +86 (21) 5028-2001（global）