Medicilon

Integrated Preclinical Drug Discovery and Development Services

FOCUS IND Filing

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

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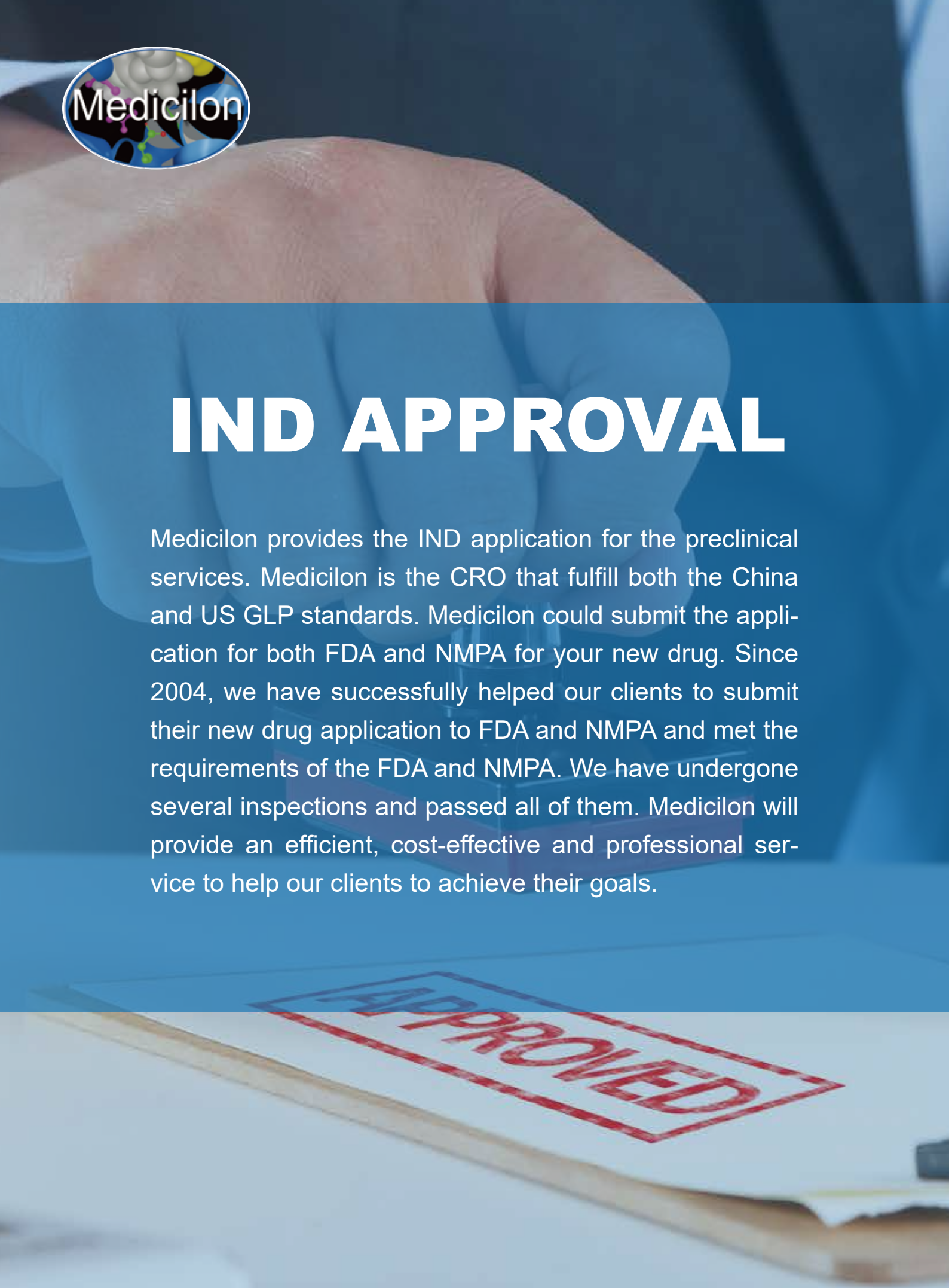
IND APPROVAL

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.



Medicinal Development Service Timelines for Small Molecules

Lead Discovery	Lead Optimization	Candidate Selection	Preclinical research and IND submission
4-6 months	5-8 months	3-5 months	12-18 months

Clinical Trial Registration Assistance

Medicilon assists global clients with the IND and ANDA applications to the FDA and NMPA

- Submission of IND/ANDA applications to FDA and NMPA on behalf of the clients
- Assist with IND registration package preparation in the format of SEND and eCTD
- Project management
- Compile, assess, and review technical documents for IND and ANDA submissions
- Multilevel of reviewing process to ensure the accuracy and compliance before filing
- A dedicated, experienced project manager maintains frequent communications with the FDA/NMPA agency throughout the application progress till the final approval is granted

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