EffPha

Efficient Pharma Management Corp.

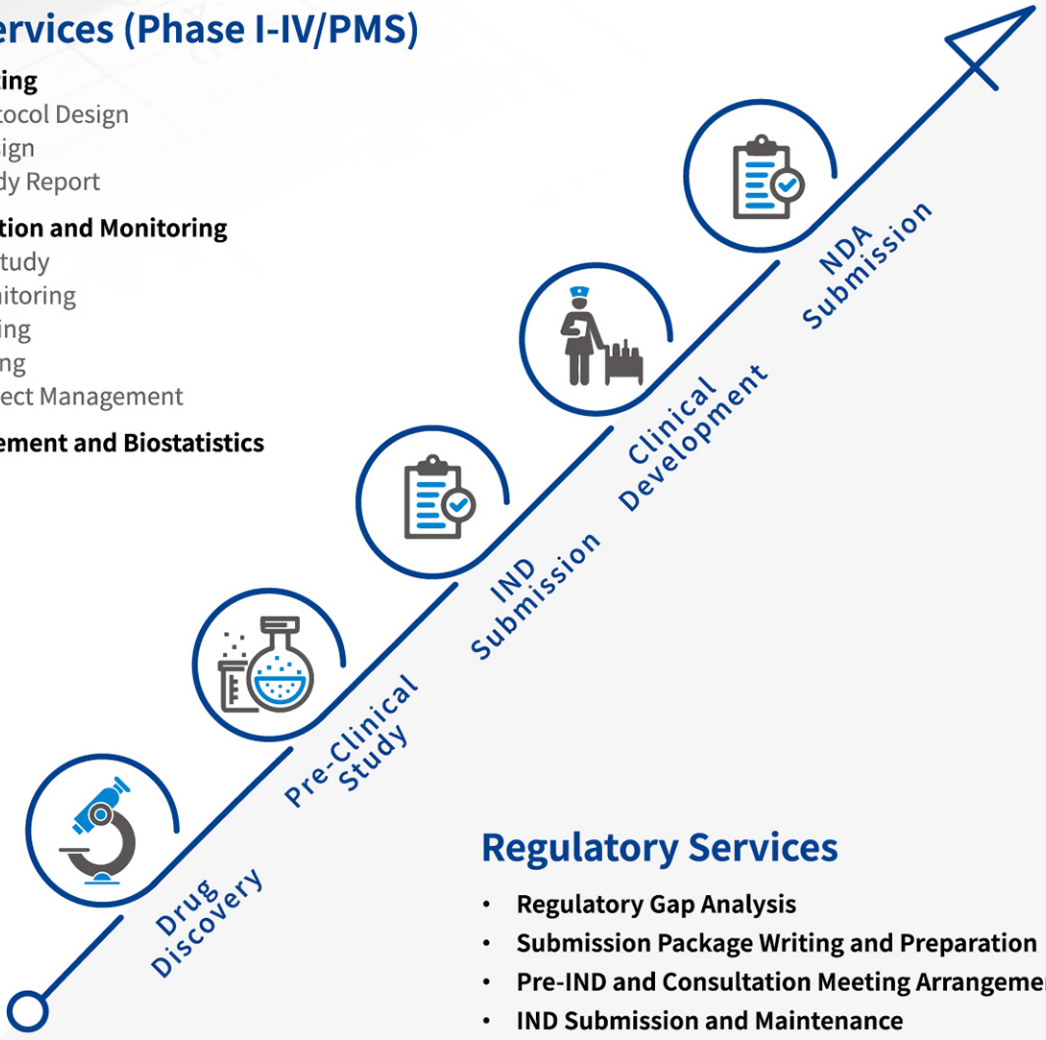
With Extensive **Experience** and **Knowledge**
in Pharmaceutical Product **Development**

Efficient Pharma Management Corp.

EffPha provides drug development services for pharmaceutical companies. Our services focus on information integration for the submission package preparation, strategic planning, and efficient management of the clinical study to accelerate your drug development to approval. With extensive regulatory experience and multi-cultural familiarity, EffPha serves as your regional hub in Asia, and bridges the gaps between Asian and global pharmaceutical industries to widen your market reach.

Clinical Services (Phase I-IV/PMS)

- **Medical Writing**
  - Clinical Protocol Design
  - ICF/CRF Design
  - Clinical Study Report
- **Study Execution and Monitoring**
  - Feasibility Study
  - Clinical Monitoring
  - Study Auditing
  - SAE Reporting
  - Clinical Project Management
- **Data Management and Biostatistics**



Regulatory Services

- **Regulatory Gap Analysis**
- **Submission Package Writing and Preparation**
- **Pre-IND and Consultation Meeting Arrangement**
- **IND Submission and Maintenance**
- **NDA Submission (NDA, BLA, ANDA)**
- **eCTD Compilation and Publishing**
- **Product Registration**

Our Services

EffPha's integrated services efficiently bring your product to global market

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REGULATORY SERVICES

- Regulatory GAP Analysis
- Taiwan FDA/CDE Consulting Meeting
- US FDA Pre-IND Meeting
- Technical Writing/ Compilation (ICH/CTD)
- IND Submission/ Maintenance
- Bridging Study Evaluation Application
- Designation for Expedited Review
- PMF Application
- NDA Submission (NDA, BLA, ANDA)
- Post-approval Changes Application

CLINICAL SERVICES

- Clinical Study Planning
  - Site and PI Selection
  - IRB Document Preparation and Submission
  - Clinical Site Initiation
- Clinical Study Management and Monitoring (Phase I-IV)
  - PI Meeting
  - Study Planning and Preparation
  - Study Execution and Monitoring
- Medical Monitoring
- Data Management
- Biostatistics

NON-CLINICAL STUDY MANAGEMENT

- CRO Recommendation
- Protocol Review
- Study Management
- Study Report Review

SCIENTIFIC EVALUATION & SUPPORT

- Clinical Synopsis and Protocol Design
- Medical Writing
  - Investigator's Brochure (IB)
  - Informed Consent Form (ICF)
  - Case Report Form (CRF)
  - Clinical Study Report (CSR)
- Strategic Consultation
- Technical Consultation

OUR STRENGTHS

EXPERIENCE & KNOWLEDGE / QUALITY & EFFICIENCY

Expertise We gathered experts with **20+** years of drug development experience

Facilitate We facilitate and accelerate our client's drug development process

Fast-growing We have completed more than **200** projects since founded in 2009

Precision We provided advice and knowledge that achieved **100%** regulatory approval rate

High-Quality We follow GxP requirements and make sure the quality is satisfactory

Adaptability We are familiar with both local and global regulatory standards, and are able to adapt to the fast-changing environment

EffPha

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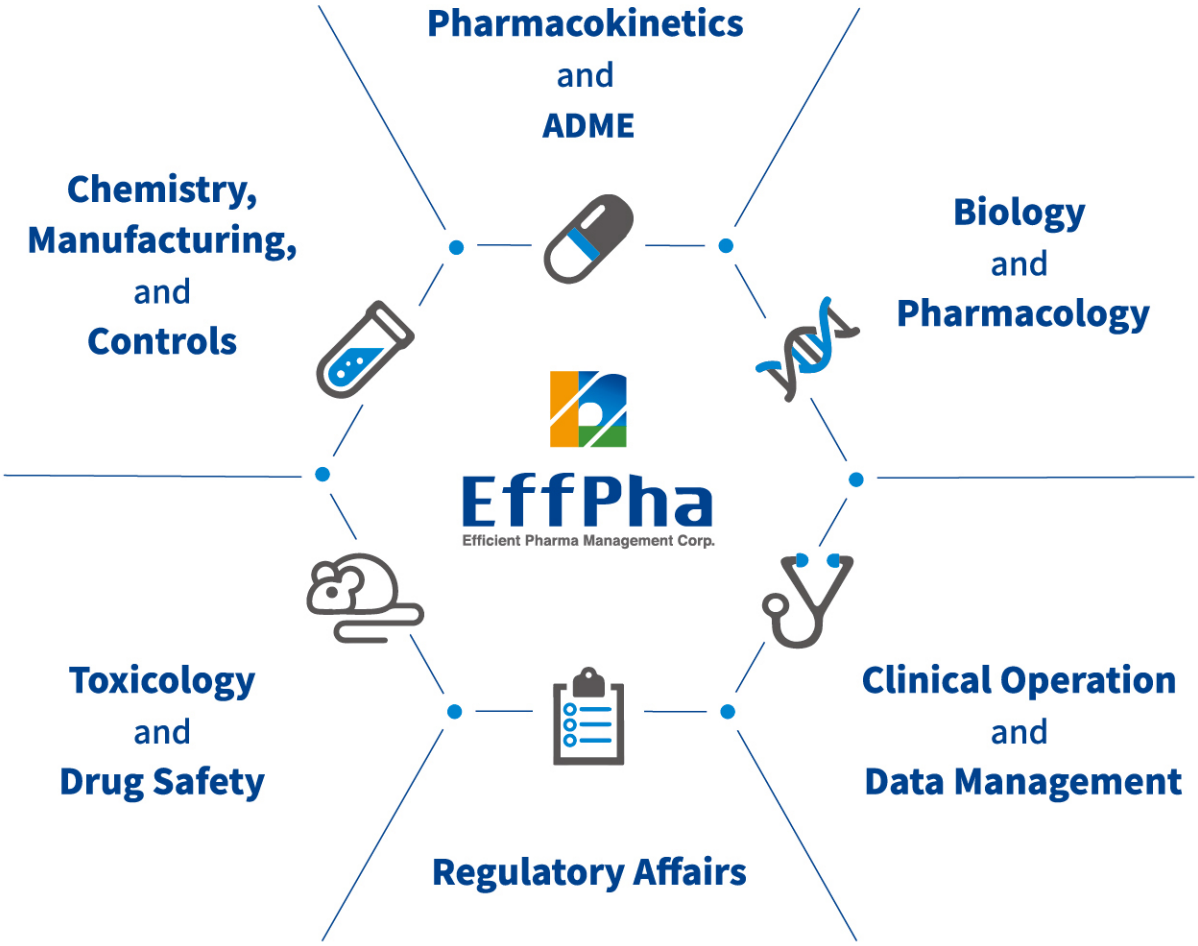
Efficient Pharma Management Team

Experienced and integrated team is an important part of the long-term success of EffPha.

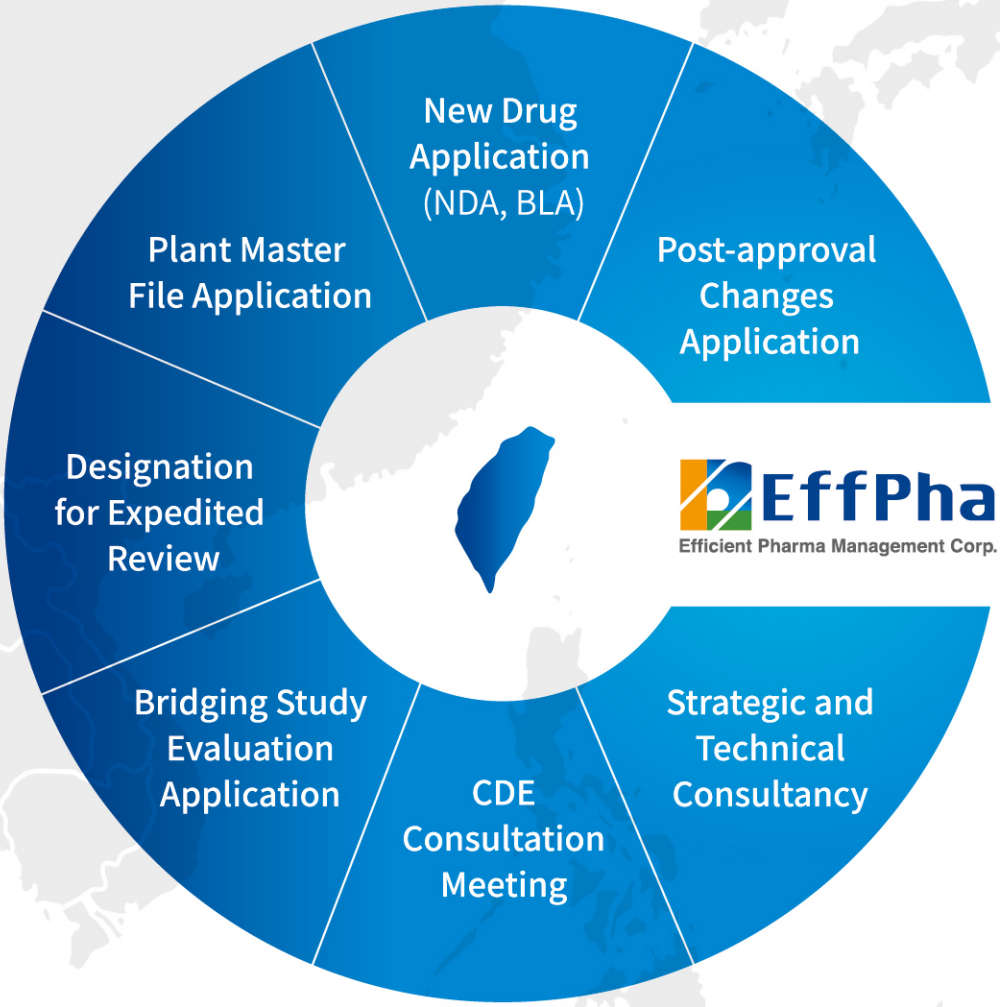


Our Scientific Team

Our scientific directors have more than 20 years of experience working in the core team of leading pharmaceutical companies and have participated in the development of a variety of novel drug products with various formulations and indications. With our extensive experience and knowledge, EffPha is able to support our clients with the most efficient product development service by minimizing the risk and accelerating the drug development process to approval.

Many International Pharma Companies Choose Taiwan as a Gateway to the Asia Pharmaceutical Market. How about Your Company?

Over the past three years, EffPha has built on many successful experiences by submitting a considerable amount of new drug applications and post-approval changes which all obtained regulatory approvals for our foreign clients.



How Can You Miss Taiwan in Your Asia Pharmaceutical Market?

EffPha develops regulatory strategies for your product, and offers a full range of services from non-clinical development, new drug registration, to post-market activities.

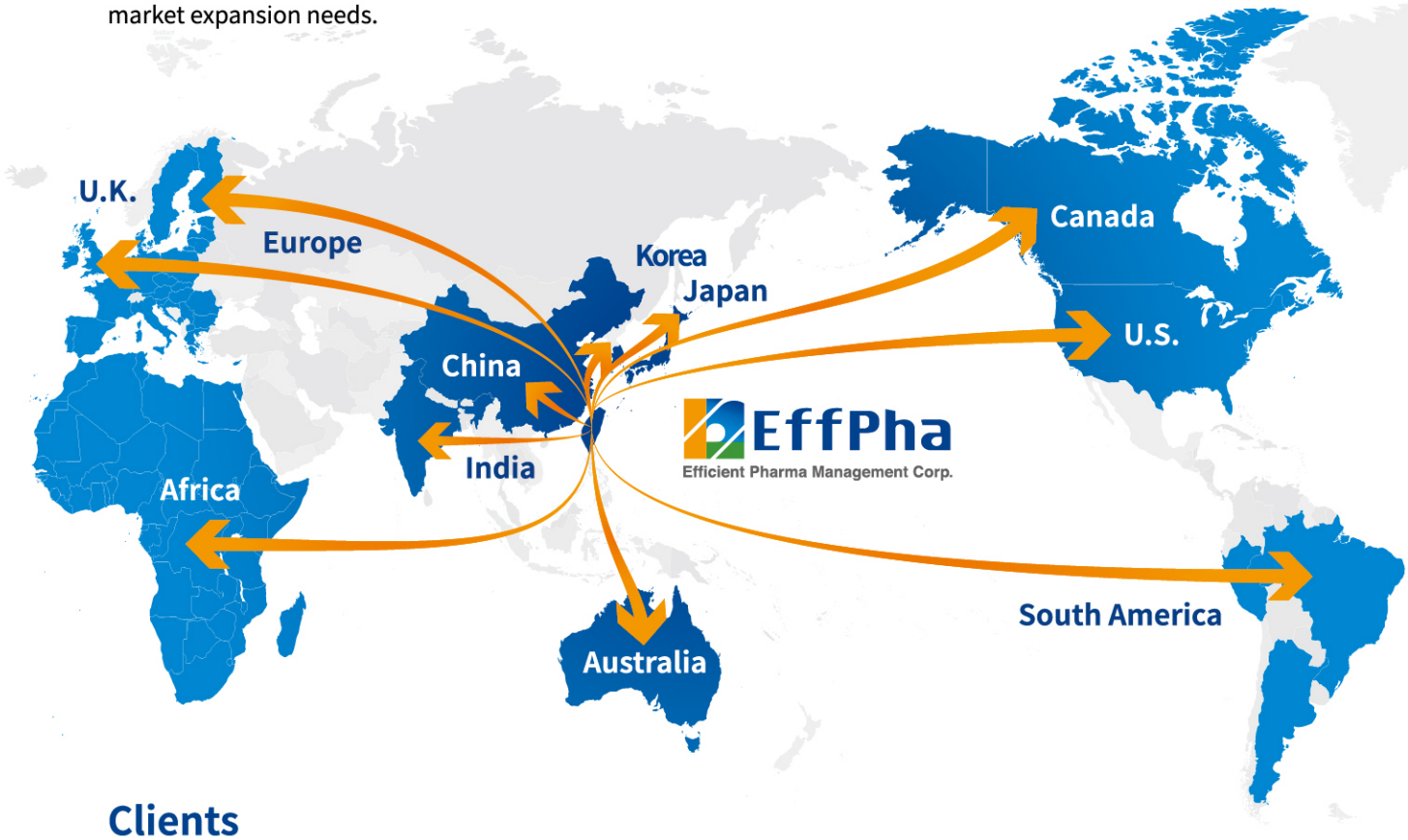
Our teams have a strong understanding of the regulatory environment in Taiwan, and have experiences with domestic and foreign new drug registration and various regulatory or approval pathways in Taiwan.

Regardless of Where You Are in Your Development Process, EffPha is Your Trusted Partner. We Provide Efficient and Cost-effective Solutions to Satisfy Your Needs.

Global Presence & Experience

Global Reach

We assist clients to apply for drug approval for Taiwan and US markets. We also work with partners globally to conduct clinical study and product registration to meet your market expansion needs.



Clients

With EffPha's high quality service, efficient responding and communication to requests, we have successfully gained trust of a variety of global clients.

TAIWAN
- Pharmaceutical Company
- Biotech Company
- Government Funded Research Center

CANADA/ US
- Pharmaceutical Company
- Biotech Company
- Venture Investment Firm

JAPAN/ KOREA
- Pharmaceutical Company
- Biotech Company
- Venture Investment Firm

CHINA
- Pharmaceutical Company
- Global Contract Research Outsourcing Provider

INDIA
- Generic Pharmaceutical Company

UNITED KINGDOM
- Clinical Management Company

We Are Your Valuable Partner for Drug Development

We provide efficient project management in coordinating different functional vendors. With fast problem solving ability, spontaneous interaction and communication, EffPha is your partner to help you manage your product development and ensure your studies are performed intelligently and correctly to meet global regulatory requirements.

If you would like to learn more about our services,
please contact us at services@effpha.com

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