

# **Link China Solutions**

One Stop Solutions to Link UK and China Business

## Introduction

Link China Pharma Solutions (LCPS) is a dedicated specialist service provider to promote research, technology cooperation or licensing and business collaboration between China and UK life science research institutes, biotech and chemical pharmaceutical companies to maximize the value of research and business alliances, gain the competitive advantages in the global market.

LCPS bring in-depth industry experience and global market knowledge to support UK small, medium and large biotech and medtech pharmaceutical and life science companies to build the collaboration with Chinese partners and provide a full suite of services across each phase of the outsourcing lifecycle from strategy alignment, partnership selection, collaborative partnering, outsourcing transaction in drug discovery and development, clinical trial, contract manufacturing, China market entry and development so that our clients can minimize the cost, gain the competitive advantage in the global market and place themselves well ahead to access one of the biggest pharmaceutical market in the world.

LCPS will help UK and European companies save money and time by evaluating potential China partners, monitoring and implementing China outsourcing project with due diligence check, strong hands on project management practice, in-depth local life science/pharmaceutical industry knowledge and strong local government and industry connections. LCPS work with the highest level of Chinese technology partners and largest EU standard Chinese pharmaceutical manufactories. We will help our clients monitor strictly for the Chinese partners according to the SOPs, technical standards and regulations provided by our customers.

LCPS fully respect customers' intellectual properties and work closely with IPR law firm both in UK and China to ensure absolute confidentiality of any exchanged information, perform regular progress and compliance check to maintain high standard.

We aim to provide the "high standard, reliable, ethical, efficiency and effective" services to build a strong alliance with our clients and business partners to work together for the common good and better health for all in the world!



# Why China?

The main advantages and major opportunities for pharmaceutical industry CRO and CMO in China.

#### Growth in China Pharma Market

Due to the rising cost of procuring leading developer, scientists and sophisticated technology, and tight governmental regulatory requirement, drug development in the US and EU is becoming increasingly expensive and time consuming and also the pharmaceutical companies are facing the pricing pressure in healthcare markets and quest for improved margins and growth for the revenue constraints. China has emerged as an increasingly attractive option for companies aiming not only to reduce prohibitive investments in time and finance, but also as a growth power house as the wider global economic balance shifting towards the direction of China's favor, and the rapid growing importance of end-markets in China matched with an influx of western-trained scientists and pharmaceutical expertise make China the most favored value chain destination for future growth and development across the whole pharmaceutical and health care industry. Chinese sales of Western-style pharmaceuticals were estimated to value \$13.1bn in 2006, achieving year-on-year growth of 30%, the China pharma market is expected to be worth £27 billion and China will become the world's fifth leading consumer of pharmaceuticals by 2010, 2nd or 3rd by 2020. Significant numbers of global pharma companies have announced plans to expand their R&D operations in China over the past two years. These include AstraZeneca, GlaxoSmithKline, Pfizer, Novo Nordisk and Wyeth.

## Growing China scientific base and R&D capability

Increasingly pharma and biotech companies have to set their strategic sights on a future world where China is not just a great market potential and manufacturing powerhouse for global pharma industry, but also the growing R&D capability of drug discovering and the cost advantage of the R&D in China can save the research costs by up to 60% and drug developers can expect typical savings of 30% of the total cost in the west.

Chinese government institutes have some proven skills in core biology. Vendors are capable of



offering services in protein expression, stem cell research and genomics. Johnson & Johnson has been outsourcing basic biology work to Chinese vendors. China has a large pool of skilled scientists. There are about 128 universities and colleges of medicine and pharmaceutics, complemented by 53 tertiary vocational technical colleges. There are about 666 institutes dedicated to science and technology. In total, as of 2007, there were over 1.6 million science and engineering graduates (including undergraduate, masters and PhD students) and about 7.7 million enrollments for doctoral and masters study programmes. There are 20 labs with good laboratory practice(GLP) certification; new regulations should boost that number.

# Why China?

## Growth in China high standard pharma manufacturing capability

The growing number of Chinese CMOs obtained US Food and Drug Administration (FDA) approval for their operations and completed good manufacturing practice (GMP) certification. Some CMOs operating in China have obtained approval from the FDA or COS gaining credibility for their quality standards. At the end of 2005, more than 5,000 Chinese drug manufacturers had obtained their Chinese GMP certificates 16. With an increased commitment to international standards, China CMOs are securing more outsourcing orders from big pharmaceutical companies. The commitment to Western standards is also being reflected in the modernization of plants, and moves to innovate through the development of technologies, such as PAT are necessary to ensure facilities are ready to meet future manufacturing needs.

The region has a large pool of educated and appropriately qualified talent with the ability to run manufacturing plants equaling western complexity and quality.

The significant cost advantage of CMO in China from 30% up to 60% of the cost in the Europe or US. China's attractiveness for API manufacturing has convinced companies like AstraZeneca to step up outsourcing investment. David Brennan, chief executive, said all "active pharmaceutical ingredients" (API) would be produced externally within a decade as part of his strategy of "maximizing the efficiency of our supply chain while maintaining the highest possible standards of quality and security of supply." The firm has set up a dedicated sourcing center in Shanghai.

## **Pre-clinical Development**

The growing capabilities in pre-clinical trials in a wide variety of species and capabilities residing with government-sponsored institutes and privately owned companies. It is approximately 20 labs with good laboratory practice (GLP) certification; new regulations should boost this number.

## Clinical Trials and Large Patient Pool in China

High-quality SFDA-approved hospitals exist

Several multinationals conducting global trials at Chinese sites

Low-cost and efficient enrollment compared with the United States and Europe

Trial approval times will improve in the future

China has large populations of patients who are able to participate in studies. Many such patients are 'treatment naïve', and therefore, fulfill the needs of many trials. Another key advantage of conducting trials in some Asian territories is that many hospitals or doctors are serving large numbers of patients. So companies can recruit more quickly from a smaller number of sites. By June 2008, China had 428 clinical trials registered on the website as under way and a cumulative total of 870 completed or ongoing trials compared with 737 in India.

## **Our Services**

Link China Pharma Solutions also provides a full suite of services across each phase of the outsourcing lifecycle from strategy alignment, partnership selection, collaborative partnering, outsourcing transaction in drug discovery and development, clinical trial, contract manufacturing, China market entry and development so that our clients can minimize the cost, gain the competitive advantage in the global market and place themselves well ahead to access one of the biggest pharmaceutical market in the world.

Link China Pharma Solutions has carefully selected and formed strategic partnership with some of the best CRO and CMO companies in China to offer a broad range of services in the fields of Genomics, Proteomics & Antibody, Chemicals, Formulation, Non-clinical Research and Diagnostic & Vaccine for pharmaceutical development, drug discovery and research.

## Our CRO outsourcing services are specialised in:

#### **Chemicals:**

Small Molecular Synthesis Leads Discovery and Optimization Target Validation High Throughput Drug Screening

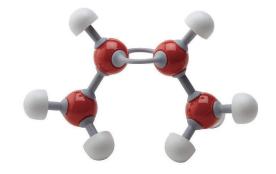
Diagnostic & Vaccine:
Pathogen Isolation and Culture
PCR Primer Design
Rabbit Polyclonal Antibody Preparation
RT-PCR Diagnosis Kit Development
Immuno-Detection Kit Development
New Vaccine Development

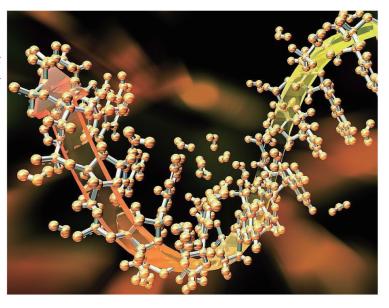


Sustain Release Formulation Development Controlled Release Formulation Development Immediate Release Formulation Development

#### **Genomics:**

DNA Sequencing and Genotyping Gene Cloning, Synthesis and Mutagenesis Gene Vector Construction and Large Scale Manufacture In vivo Gene Delivery





## **Our Services**

Non-clinical/ drug evaluation:
Dose-Ranging study
Efficacy Evaluation in Animal Models
Animal-Based Drug Screening
In vivo PK/PD/TK
Safety pharmacology studies
Non-GLP/GLP Toxicity Evaluation



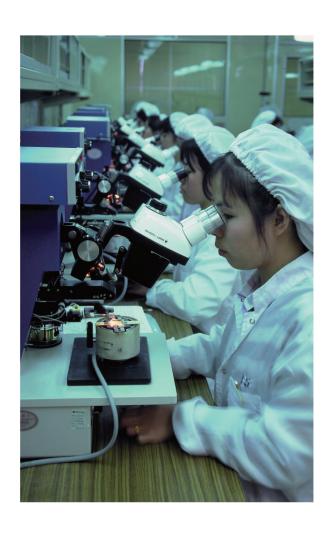
## Our Drug Discovery and Research outsourcing services can provide:

Organic Synthesis and Parallel Synthesis
Intermediates
Templates
Libraries
Reference compounds
Metabolites
Chiral synthesis

Medicinal Chemistry:
Hit-to-lead
SAR development
Lead optimization
CADD
Biological testing
ADME
PK/PD profiling

Discovery Biology:
In vitro biology
In vivo pharmacology
Facilities of animal
Molecular diagnosis
GMP-complied microbiology

Drug Metabolism and Pharmacokinetics(DMPK)
In vitro assays
Bioanalysis
Drug metabolism
Pharmacokinetics



## **Our Services**

#### Our clinical research services include:

Clinical Trial Essential Documents
Preparation (Protocol, CRF etc)
Clinical Trial Initiation (Selection of
Qualified Investigators and Sites,
Investigator Meeting, IRB/IEC
Sub-mission, Study Site Agreement
etc)
Clinical Trial Manitoring

Clinical Trial Monitoring
Clinical Project Management
Clinical Trial Auditing
Medical Reporting Writing
Function Genomics & Drug Discovery



With a genome-based drug target validation platform, it is possible to systematically study human gene functions and to discover and develop proprietary genome-based drugs.

#### **Virtual Drug Development**

Efficient "concept-to-market" strategies for product introduction, a new model for development of early stage drug candidates. Virtual drug development, in which intellectual property takes precedence over physical assets, allows scientists within develop novel concepts on small-scale platforms, or sometimes simply on paper alone. For investors, outsourcing facilitates them to take their concepts to market without large investments in human and physical capital, thus results in capital efficiencies and rapid scale-up to commercial product.

#### **Contract Manufacturing**

Contract manufacturing from kilos to tens of tons of APIs and regulated intermediates, Bulk ingredients, Drug delivery, formulation, Fill & finish, packaging, Supply chain, logistics etc.

#### Regulatory Registration and Market Entry Consulting

With specialised expertise in the field of drug regulatory registration and market entry strategies consulting, advise and help pharmaceutical companies launch generic and newly patented drugs into Chinese and European markets according to Chinese national and European drug regulatory requirements.

## **Contact Us**

LCPS located in Cambourne business park in Cambridge, only 40 minutes train and 1 hour drive from London.It's easy access to standstead and heathrow airport.

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