

## Intellectual Property and Outsourcing in China: Minimizing risk whilst maximizing return on investment

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### Description

The pharma outsourcing industry in China has experienced over 35% year on year growth in the past few years. Increasingly, the sophisticated service offer of multinational CROs/CMOs is being challenged by improving Chinese players importing Western expertise, experience and business models to this fast growth market. However, there are still wide variations in service quality and capability from domestic outsourcing providers and many pharma and biotechs in Western markets are still reluctant to transfer parts of the drug development process to China.

Their concerns largely stem from issues around intellectual property rights (IPR), copyright infringements and counterfeiting. At both a corporate and governmental level, this weakness has been recognized and several key changes have been made to Chinese patent law, while service providers have also sought to improve their IPR protection processes and service standards. Nonetheless, key differences in secure IPR protection standards and service capability remain among domestic players.

'Intellectual Property and Outsourcing in China' is a new report published by Business Insights that explores the expanding pharma outsourcing market in China to discover how large pharma, small-sized pharma and biotech can most effectively utilize the country's service offerings and capabilities. It examines the latest outsourcing trends and service provisions across all stages of the drug discovery process and profiles the leading domestic CRO/CMOs. This report provides an in-depth investigation of the changing IPR protection landscape in China and analyses the strategies which can minimize infringement risks. Case studies are used to illustrate the success of recent CRO/CMO partnerships with Western companies and key criteria for selecting suitable service providers are also identified.

Some key findings from this report...

- China is the world's most attractive destination for Pharma outsourcing based on an analysis of patient pools, cost efficiency, regulatory conditions, available expertise and infrastructure.
- There were 694,153 patent applications in China in 2007, a CAGR of 22.5% on the number of applications in 2003 (308,487). At this rate, China will be the world's largest patent-filing jurisdiction by 2012.
- China's service capabilities are strong, with full-scale medicinal chemistry services currently available from 26 CROs. Services include structure-based rational drug design, structure-activityrelationship (SAR)-based activity/potency optimization, and the optimization of pharmacological properties for lead compounds.
- In the next 3 to 5 years, the service capabilities of many China-based service providers will develop quickly and change the IP risk profile. Currently, the domestic industry is highly proficient in large-scale manufacturing but relatively weak in preclinical and clinical drug development, and as providers' capabilities increase the need for verification of effective IP protection protocols will intensify.
- The market will experience high growth of around 35% year on year to 2011. During this period, the industry will likely see investment in targeting, identification and validation capabilities.

Top reasons to order your copy today

- Understand how large pharma, small-sized pharma and biotech companies can benefit from the Chinese pharma market with this report's analysis of the number of companies involved, levels of industry maturity, and existing/projected service offering capabilities.
- Assess the the risk factors associated with outsourcing decisions and measure the suitability of China-based CROs and CMOs with this report's examination of each class of service provider and the key criteria for selecting the most appropriate company, including IPR protection protocols, service quality/capability, cost and geographic location.
- Understand how the IPR protection environment in China is evolving by evaluating the latest regulatory developments and patent application trends for domestic and multinational companies, in addition to this report's market forecasts for outsourcing industry growth to 2015.
- Identify how IPR protection varies across each stage of the R&D process and use case studies of partnerships between Chinese CROs/CMOs and Western companies to measure the success of recent endeavours.

Key issues examined in this report...

- Variable service offerings. Many Chinese pharma companies that have API manufacturing skills only offer their services on a seasonal basis. They are not professional CMO providers, as their service offerings are largely dependent upon spare production capacity levels.
- Inflated service claims. Although many CROs/CMOs claim a broad service scope to attract business, their actual service skills are limited to only a couple of areas. Specifically, scientific staff often lacks sufficient experience, training and deliverability guidelines.
- Inconsistent IPR protection system. IPR protection is no longer a serious issue amongst top-tier service providers but may still be weak in lower tier domestic companies and those operating in rural areas.
- IPR infringement cases and counterfeit drugs: Drug counterfeiting is still a real problem and most IPR infringement cases are related to trademark/copyright violations. However, there have been no reported cases of infringement of a western pharma or biotech's IPR by a Chinese company during their outsourcing collaborations.

Your questions answered...

- How does China compare to other outsourcing destinations?
- What services are offered by the CRO and CMO industry in China?
- What are the advantages of outsourcing different stages of the R&D process by large/small-sized pharma and biotech companies?
- What are the government's development priorities for the industry?
- How has medical infrastructure supported region-specific growth in outsourcing and will this trend continue?
- What is the strongest sector of China's pharma outsourcing industry in terms of both number of companies and strength of their services?
- Who are the major Chinese players in contract research and in which areas do they specialize?
- Which multinational companies have projects outsourced to China?
- What actions are the government taking to strengthen IPR protection?

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