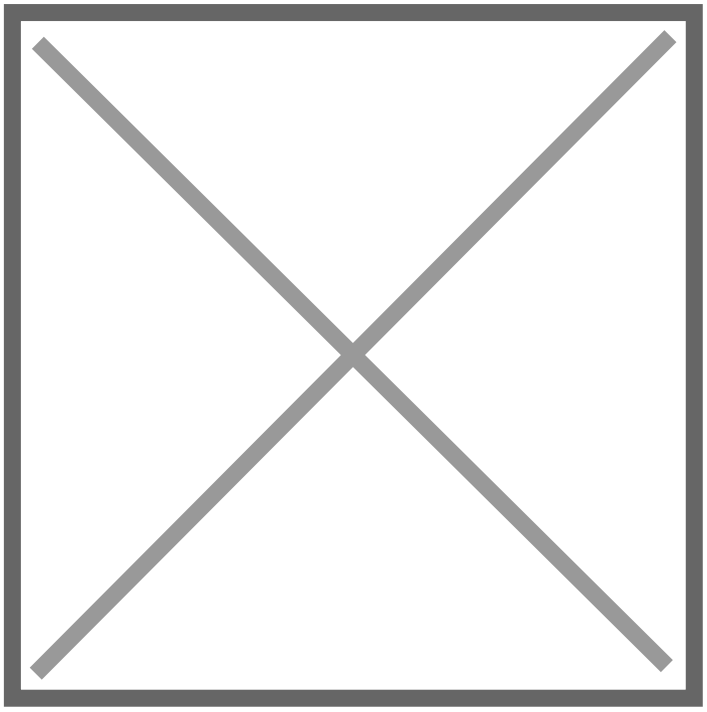
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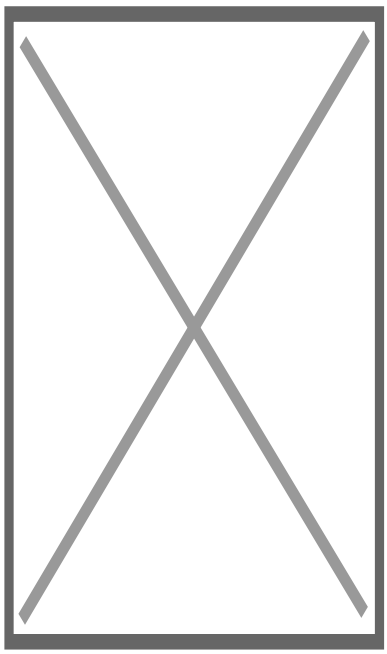
Asian CMOs in demand

07 April 2009 | News



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Asia never had it so good. Multinational pharma companies are de-risking their R&D manufacturing by outsourcing it to Asian contract research and manufacturing companies—in turn effecting substantial cost savings and keeping their faith in Asian capabilities



The global pharmaceutical industry has been facing many challenges in the form of increasing competition from generics, rising cost of new product development, declining research and development (R&D) productivity, shrinking average patent life, and mounting governmental pressure to reduce drug prices. Given the backdrop of such a competitive landscape, the decisive factors for growth and sustainability are faster new drug development and cost containment with “contract manufacturing” emerging as a strategic option offering several advantages.

Firstly, outsourcing provides pharmaceutical companies the opportunity to avail flexibility, quicker time- to-market, and lower scale-up costs. Thus, companies are able to meet growing demand for new drugs and focus on their core competencies. Secondly, outsourcing enables companies to reduce excess capacity in their manufacturing networks and restructure supply chains. Finally, value-added outsourcing services meet the increased demand for specialized manufacturing capabilities in key technical niches and increased demand for back-up sources of supply.

The global contract manufacturing market was about $38 billion in 2007 as per ValueNotes & Know Genix estimates and is expected to grow at CAGR of eight percent by 2010 to touch $49 billion. Global market for pharmaceutical contract manufacturing is estimated at $20.4 billion for 2008, notes Global Industry Analysts. The US is the single largest market for pharmaceutical contract manufacturing with revenues projected to be $12.8 billion in 2012. In terms of revenues, although North America and Europe are the largest markets, Asia with its immense manufacturing capacity is projected to exhibit robust growth. Exhibiting a CAGR of nearly 16 percent, Asia Pacific is expected to emerge as the fastest growing region in the global pharmaceutical contract manufacturing market. Injectables represent the fastest growing product segment, and are forecast to record revenues of $10.6 billion by 2015. Solid Dosage Forms, the largest segment, is vibrant with a projected market value of $12.3 billion for 2010.

The European and North American pharmaceutical contract manufacturing sector has been categorized into three tiers. Tier 1 companies offer end-to-end services ranging from clinical trials to commercial manufacturing, logistics, packaging, and marketing assistance. Tier 2 companies provide services ranging from early stage project development to commercial level manufacturing. Tier 3 companies are conventional manufacturing companies, which address the needs of the generic drugs industry. However, contract manufacturing in Europe is dominated by generic drug variants, while in North America branded versions are preferred. In Asia, numerous local players operate in the market. Key global market participants include Althea

Technologies, Catalent Pharma Solutions, Dishman Pharmaceuticals and Chemicals, DSM Pharmaceuticals, HAUPT Pharma AG, Jubilant Organosys, Kemwell, Nipro Corp, NextPharma, Patheon, and Penn Pharmaceutical Services.

The Asian contract manufacturing organizations (CMOs) account for an ever-expanding share of global pharmaceutical manufacturing and is expected to account for around $3.3 billion of the total projected $23 billion CMO market by 2010. A growing number of CMOs have obtained US Food and Drug Administration (FDA) approval for their operations and completed good manufacturing practice (GMP) certification. Asian countries provide a significant cost advantage with manufacturing savings of upto 50-80 percent of the cost that would be incurred, if the manufacturing is undertaken in western territories.

The governments in the region are encouraging local companies to shift to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S)—two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive cooperation in the field of GMP. In South East Asia, Malaysia and Singapore have joined this PIC/S, which currently has 33 participating authorities including WHO, Unicef, EMEA and EDQM. Thailand and Philippines are soon expected to join this scheme. This will boost the volume of manufacturing activities to the region.

Frost & Sullivan says the region will continue to hold its lure with low production costs, increasing reliant manpower, incentives from the local governments to lure CMOs, implementing IP laws to assure companies of the viability of producing/outsourcing to their countries and expanding healthcare markets in the growing economies. These factors are supporting the Asian CMOs to secure more outsourcing orders from big pharmaceutical companies. In India, for example, there are close to 100 FDA-approved pharmaceutical facilities—the largest number in any country outside the US. Chinese company Zhejiang Huahai Pharmaceutical became the first company to get FDA approval in 2007 and is expected to start exporting its finished drug to the US by 2012. Opening of USFDA office in China in November 2008 is testimony that more companies in China are looking for the US approval and exporting their drugs to the western markets. All these make the region an attractive destination for pharmaceutical contract manufacturing.

PricewaterhouseCoopers notes that Asian countries provide a significant cost advantage for pharmaceutical manufacturing. The overall costs of drug manufacturing in India, for example, are up to 50 percent cheaper than in western territories. Cost savings on this scale present a compelling reason for manufacturing outsourcing to Asian CMOs. However, cost savings are nothing compared to the need to ensure quality and safety. The reports of deaths linked to contaminated heparin in the US sourced from China highlight the critical issue of quality. The general trend, however, is of ever-increasing quality of work from Asian territories. To overcome these safety and quality issues the governments in region are taking measures to provide quality healthcare to the public.

Besides regulatory system in place, the region has a large pool of educated and appropriately qualified talent with the ability to run manufacturing plants matching western complexity and quality. Several CMOs operating out of Asia have obtained approval from the FDA gaining credibility for their quality standards. China completed Chinese Good Manufacturing Practice (GMP) certification as far back as July 2004 on all the drug manufacturers in the territory. At the end of 2005, more than 5,000 Chinese drug manufacturers had obtained their Chinese GMP certificates. There is an ongoing effort in China to increase inspections on already certified manufacturing sites, in response to evidence that some of the certified manufacturers have not consistently adhered to GMPs in the past.

With an increased commitment to international standards, Asian 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, to ensure facilities are ready to meet future manufacturing needs.

PricewaterhouseCoopers (PwC) also notes that China and India, followed by Korea and Taiwan, are now providing an atmosphere for the pharmaceutical industry where benefits such as the pool of educated and qualified scientists, intellectual property law reform and market growth are outweighing factors that had previously inhibited development, principally uncertain regulatory frameworks and enforcement. It also noted that Singapore is best suited for complex and technology intensive manufacturing. Among the hotspot territories, it has access to the best technology and funding for outsourcing high-technology intensive products. Apart from this, Singapore also has extremely well regulated IP protection and enforcement regime, and is considered one of the best among all Asian territories in terms of regulatory compliance. Along with Australia, Singapore has consistently topped the rankings as the top Asian territory for IP protection and enforcement. Singapore is able to attract companies like Lonza besides being home to local companies like A-Bio and Beacon Pharmaceuticals.