Boon or Bane

With the cost of manufacturing on the rise, it seems as if outsourcing has become an appealing choice for pharmaceutical and biotech organisations, with an increased interest in emerging markets such as India and China proving popular

Aiswariya Chidambaram at Frost & Sullivan

Outsourcing has increasingly become a strategic move for most pharmaceutical and biotech companies rather than a mere cost-cutting tool. With manufacturing costs contributing to a major chunk of expenditure, pharmaceutical and biotech companies consider leveraging the services of contract manufacturing organisations (CMOs), which are equipped with the required expertise, technology and tools, as a viable option to save costs and time. Currently, the US and Europe account for nearly 75 per cent revenue share of the global pharmaceutical and biotech contract manufacturing markets; however fast growth is anticipated from the large number of emerging CMOs in Asian countries – such as India, China and Singapore – which can effectively compete on cost. While outsourcing manufacturing to CMOs in emerging markets is on an increasing curve, forging strategic partnerships with such CMOs is likely to be a sought-after strategy by the pharmaceutical majors, as it helps them gain easy access to the emerging markets. However, as quality and timely delivery are the major concerns, a cost advantage alone does not propel clients to opt for CMOs in emerging markets.

The results of a recent end-user analysis conducted by Frost and Sullivan, based on the key competitive factors involved in the selection of a CMO by pharmaceutical and biotech companies for contract manufacturing services, can be seen in Table 1 on page 38.

Emerging Trends

The key trends which are expected to have an impact on the global pharmaceutical and biotech contract manufacturing markets are:

Patent Expiry of Blockbuster Drugs and Biologics

With several patented and first-generation biotech drugs nearing the end of their life cycles, companies prefer outsourcing their manufacturing and other developmental activities, retaining

Table 1: Pharmaceutical and biotech contract manufacturing markets: key competitive factors in the selection of a CMO (global study), 2012

Factor	Rating
Quality	9.6
Technical expertise	8.1
Reputation/credibility	6.6
Capacity	7.0
Cost	8.8
Approved facilities/regulatory support	7.3
Timely delivery/speed	9.0
Communication	6.0
Personal relationship	7.0
Location	6.3

Note: The factors were rated on a scale of 1-10 with 1 = lowest importance and 10 = highest importance, based on the end user's input.

Source: Frost & Sullivan analysis

only the marketing rights. The plants present poor utilisation rates of 20-30 per cent, making it highly unprofitable for companies.

Increased Industry Consolidation

Big Pharma companies are constantly on the lookout to expand their business into the biotech sector and gain access to the highly fragmented emerging markets. This is expected to foster industry consolidation in the form of mergers, acquisitions and strategic partnerships, and result in large-scale contract deals between big pharma companies and CMOs that possess the required expertise and reliable presence within local markets.

Expansion of Manufacturing Capacities

As independent generic firms consider biosimilars to be a more definitive and commercially attractive segment than commodity generics, the demand for additional biomanufacturing capacity is expected to be high in the long-term. As the global biopharmaceutical industry is characterised by greater outsourcing of mammalian cell culture activities, a significant expansion of capacity is expected in this sector, as opposed to the microbial cell culture systems.

Novel Drug Delivery Mechanisms

As a large number of new products that are based on innovative technologies across diverse therapeutic segments are likely to be launched over the next five years, small and mid-sized innovator pharmaceutical and biotech companies are expected to leverage the expertise and resources of CMOs. Currently, nearly 35 per cent of the drugs in development worldwide represent biologics, and in Europe, more than 1,000 biological drugs are in the pipeline. The track record of biopharmaceutical approvals in recent times has also been noteworthy.

Increasing Adherence

Although traditionally CMOs have focused on manufacturing services as their core business segment, the changing needs of clients and the emerging concept of 'virtual pharma' has led to an increase in realisation of the importance of value-added services, which include: process development and optimisation; marketing support; sales and distribution; logistics; and packaging. This provides a 'one-stop-shop' option for customers where they can exploit the resources and expertise of the CMOs to reap maximum benefits while they concentrate on their core capabilities and R&D activities.

Emerging Markets

Cost-efficiency, which includes benefits such as improvement in overall cost structure, significant cost-savings, manpower cost-savings, and reduction in asset base and capital expenditure, is the major driver for suppliers to outsource manufacturing to CMOs

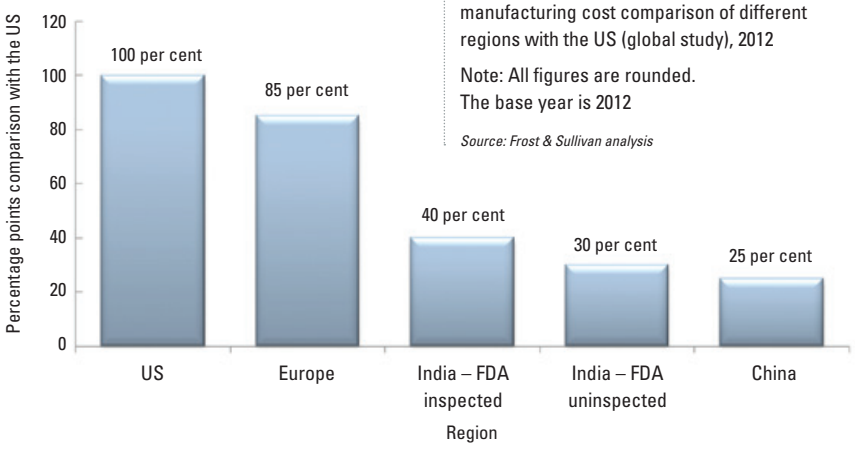

Figure 1: Pharmaceutical contract manufacturing market: percentage points manufacturing cost comparison of different regions with the US (global study), 2012

Note: All figures are rounded.
The base year is 2012

Source: Frost & Sullivan analysis

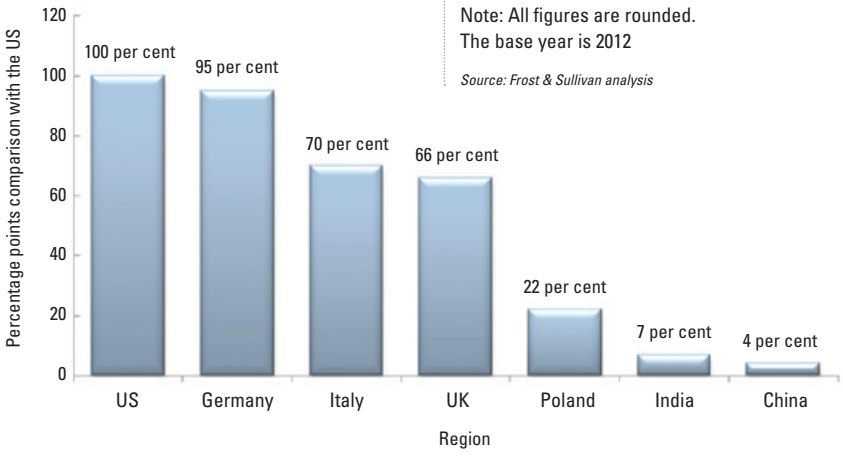

Figure 2: Pharmaceutical contract manufacturing market: percentage points labour cost comparison of different regions with the US (global study), 2012

Note: All figures are rounded.
The base year is 2012

Source: Frost & Sullivan analysis

Table 2: Pharmaceutical contract manufacturing market: key strategic tie-ups between Indian and multinational pharmaceutical companies (global study)

Indian company	Contract Research and Manufacturing Services (CRAMS) partner	Products
Lupin Labs	DMS (US)	API for Cephalosporins
	Fujisawa (Japan)	Cefixime
	Apotex (Canada)	Cefuroxime, Axetil and Lisinopril
Nicholas Piramal	Advanced Medical Optics (US)	APIs, formulations and eye products
	Allegran (US)	Bulk drugs and formulations
	AstraZeneca (Sweden)	Intermediates and APIs
	Pfizer (US)	APIs and formulations for veterinary products
Wockhardt	Ivax (US)	Anti-ulcer
Dishman Pharma	Solvay Pharma (Belgium)	APIs and formulations
	GlaxoSmithKline (UK)	Intermediates and APIs
	AstraZeneca (Sweden)	Nexium
	Merck (Germany)	Losartan
Orchid Chemicals	Apotex (Canada)	Cephalosporin and other injectables
	Bexel (US)	Drug discovery research in metabolic disease
Sun Pharma	Eli Lilly (US)	Cardiovascular products, anti-infective drugs and insulin
Kopran	Synpac Pharma (US)	Penicillin
Cadila Healthcare	Altana Pharma (Germany)	Intermediates and APIs
	Boehringer Ingelheim (Germany)	Gastrointestinal and cardiovascular products
	Mayne (Australia)	Joint venture for producing patent drugs
Biocon	Bristol Myers Squibb	Contract research for bulk drugs
	Pfizer (US)	Contract research for bulk drugs
	AstraZeneca (Sweden)	Contract research for bulk drugs
Shasun Chemicals	Eli Lilly (US)	APIs
	GlaxoSmithKline (UK)	APIs
	Reliant Pharma (US)	APIs
	Alpharma (US)	Generics and APIs
	GlaxoSmithKline (UK)	APIs for Ranitidine, Nizatidine and Cyclosorine
Ipca Labs	Merck (Germany)	Bulk drugs
	Tillomed (UK)	Atenelol
Bharath Biotech	Wyeth (US)	Vaccine and bio-therapeutics
	Eli Lilly (US)	New chemical entities, cardiovascular, central nervous system, diabetology and oncology
	Novartis (US)	Intermediates and APIs
Matrix	GlaxoSmithKline (UK)	APIs
Divis Laboratories	Merck, Abbot and GlaxoSmithKline	Custom Chemical Synthesis

Source: Frost & Sullivan analysis

in the emerging markets. Low-cost destinations such as India and China provide cost savings of approximately 60 per cent compared to western countries. The cost arbitrage results primarily from labour and manpower costs, which is almost seven to eight times less than in the US and Europe. Countries like India not only have a large pool of qualified and experienced manpower with strong chemistry skills, but also lead the world with 119 Food and Drug Administration (FDA) inspected facilities, thereby ensuring product quality.

Traditionally, however, emerging Asian markets have been looked upon as favoured destinations for manufacturing of bulk drugs, where active pharmaceutical ingredients (APIs) and intermediates – particularly APIs for generic drugs – represent nearly 80-85 per cent volume share of total outsourcing by international pharmaceutical companies. Outsourced manufacturing of advanced bulk drugs for niche therapeutic areas, APIs for new chemical entities, biotech-based APIs and formulations to emerging markets, currently represent a relatively small segment and are expected to gain momentum in the future. The primary reason for this could be the limited technical knowledge of pharmaceutical companies and CMOs in emerging markets, as compared with those in more developed regions, with regard to manufacturing of technically challenging formulations such as sterile products, controlled-release products, combination drugs, biosimilars, and specialty pharmaceuticals. To date, very few Indian companies have focused on the manufacturing of complex technology-based products, which include Dr. Reddy's and Biocon for biosimilars; Sun Pharma and Lupin for injectables; Cadila, Dr. Reddy's and Troika for transdermals, and so forth. Besides, multinational corporations fear the breach of proprietary information and reverse engineering of patent protected molecules to produce generic equivalents, when outsourced to less regulated markets.

Strategic Alliances

The immense untapped potential of the emerging markets have made them attractive targets for multinationals to enter into strategic partnerships with. Outsourcers, who are mostly global companies, require understanding of the regulatory scenario of a particular country in terms of policy, law, regulations, implementation, and most importantly, dealing with regulatory agencies. As CMOs also perform the important task of dealing with regulatory agencies besides manufacturing, penetration into the emerging markets becomes easier for global companies by acquiring or forming strategic partnerships with CMOs in emerging markets. It is alarming to note that generic drugs exported from India account for nearly 15 per cent of the generics in the US, and with drugs worth $67.5 billion losing patent protection in the US, it is expected that Indian companies will capture at least 30 per cent of the replacement equivalent generics by 2017. Therefore, it is interesting to note that big pharma companies and global generic pharmaceutical companies show greater preference towards generic companies offering contract manufacturing services, as opposed to exclusive CMOs in emerging countries. The primary reason for this is that these companies not only possess expertise across different therapeutic segments, but they also have well-established distribution and marketing arms in their respective domestic markets, which in turn makes it easy for multinationals to gain access to less regulated markets. Table 2 shows a list of key contract research and manufacturing deals between Indian and multinational pharmaceutical companies.

Table 3: Pharmaceutical and biotech contract manufacturing market: strategic recommendations for the success of CMOs (global study), 2012

Approach	Actions	Strategy
Reacting to change	• Develop drugs for key indications • Customise according to customer needs and preferences • Comply with new government policies	• React and respond as needed • Defend and protect company's position in the market
Anticipating change	• Analyse prospects for market globalisation • Research customer needs, preferences and expectations • Monitor new technological developments to predict the future • Foresee capacity requirements	• Plan ahead for future changes • Invest in R&D • Instill competitive capabilities • Improve the product line • Strengthen distribution
Leading the change	• Pioneer new and better technologies • Introduce innovative products that open new market opportunities and spur creation of whole new industries • Seek to set industry standards	• Seize the offensive • Be the agent of industry change • Influence rules of the game • Force rivals to follow

Source: Frost & Sullivan analysis

Conclusion

Outlined in Table 3 are a number of strategic recommendations for the success of CMOs. Despite the vying attention of global participants towards the emerging economies, it is crucial that CMOs in emerging markets conduct extensive research on customer needs, preferences and expectations, and align their services in conjunction with global trends.

About the author

Aiswariya Chidambaram is a Senior Research Analyst with the Healthcare Practice of Frost & Sullivan. She has authored, syndicated and customised market research reports on key therapeutic and service areas for both the European and global pharma and biotech markets. She has also contributed several insightful articles to reputed journals, magazines and newsletters in Europe, and has awarded healthcare companies demonstrating excellence in specific market/product segments and technologies. Aiswariya holds a BTech in Biotechnology from Anna University.
Email: aishwariyac@frost.com