Biocon

Header: Future perfect
Strap: This biotech company goes right back to 1978. Bicon is into everything - from science and technology-driven research to manufacturing. While its associate company Syngene is into drug-based contract research, Clinge, a wholly-owned subsidiary, is a clinical research outsourcing company

Women Entrepreneurs. Where are they? Why don’t we see too many of them. Some blame the fact that women are not courageous or enterprising enough. Others blame the cultural environment. Even while people keep discussing such inanities in the 21st century – one woman way back in 1978 set out to prove them wrong. Meet Kiran Mazumadar Shaw – India’s Biotech Queen. Owner of Biocon - India’s largest biotech company. And she did not inherit Biocon nor did she marry into it. She does not come from an industrial family either. And Biocon is not a soft-skill cosmetic shop kind of business. It has always been a science and technology-driven research and manufacturing company.

Kiran started with a master’s degree in brewing from Australia. However, she chose not to take a safe, predictable career of working in a brewing business in Britain, choosing, instead, to set up a joint venture – Biocon India - with an Irish company. Her study of brewing helped her to get into the research and development activities in fermentation technology. Biocon is engaged in all areas of research in enzyme development. Pharmaceutical research also employs similar methodologies to those used in enzyme development in pursuit of pharmaceutical compounds derived from microbial sources. Plafraactor – a proprietary bioreactor - received US patent recognition in March 2000.

However, Biocon India is not into research alone. It has a strong presence in manufacturing – taking innovations to commercialisation – mainly for export markets. Biocon manufactures a multitude of enzymes. The company’s enzyme clientele spans a diverse and growing spectrum of industry segments – brewing, food and beverages, animal feed, starch processing and textiles, paper and pulp, detergents, leather and healthcare. Biocon India’s most successful commercialisation has been in the area of Statins – a group of cholesterol reducing drugs. Another segment where the company has attained commercial success has been in the area of immunosuppressants. The
company services cardiovascular, anti-inflammatory, gynaecology and hepato-protective segments.

So, why is Biocon India in our list of BPO companies? No doubt it is a successful research and manufacturing company. But it isn’t exactly a ‘business process outsourcing company’.

An associate company – Syngene - carries out drug-based contract research as well as informatics-based software development for the pharmaceutical industry. A wholly owned subsidiary – Clingene – carries out clinical research. Now these are BPO companies.

Clingene – the clinical research outsourcing company - was set up in August 2000 to conduct clinical trials. Conducting clinical trials for foreign companies requires maintaining excellent laboratory standards and pursuing high ethical standards. Clingene has been accredited for world-class laboratory standards by CAP – College of American Pathologists - for meeting global standards. However, more important than laboratory standards is the need to meet the highest ethical standards. Clingene is required to meet standards of good clinical practice of International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Apart from this, there is a need to meet regulatory requirements of the Drugs Controller General of India.

Clingene offers the entire range of services of a clinical research laboratory. This could involve determining bioavailability and bio-equivalence of drug substitute or effectiveness of a new drug. The work could involve patient recruitment, preparing a clinical database, conducting clinical trials and so on. Clingene offers the clinical trial services to Indian as well as international clients. The lower costs and accreditation by CAP attract international pharma companies. Though the business could be as large as US$ 10 billion, government regulations protecting patient interests have prevented proliferation of these services. Clingene is currently a rather small company with just 25 research scientists.

Syngene, on the other hand, offers research services to pharma companies in the area of drug discovery. Syngene was set up in 1994. Drug discovery is often by trial and error basis with some logic directing the effort and trials involving brute force. There are often two aspects in drug trials – the biology aspect and the synthetic chemistry aspect. The biology aspect involves isolating the target in the living organism – bacteria, virus or cell. The synthetic chemistry aspect involves synthesising various chemicals. Once the target has been selected, the synthesised chemical is used for testing the efficacy of its ability to destroy the target. Well, if you thought
biotechnology was mainly about biology – here is a surprise for you. Syngene has almost 175 people in the synthetic chemistry area compared to around 25 engaged in the field of microbiology. But outsourcing research is rather weird. Isn’t it? After all, by definition, it is not predictable. Biocon gets what one may term as predictable research. The blue sky in the air is not outsourceable. However, developing a wish list of molecules and testing them on certain biological ingredients is. Predictable research would involve the kind that feeds more creative research.

Syngene was set up in 1994. However, it has grown slowly due to the hesitation on the perceptions on the ability to deliver and an assurance of quality. Another major fear has been the issue of intellectual property safety and integrity. The other problem that Syngene has had to face is the difficulty in dealing with custom officials and the delays caused at customs.

Kiran Mazumdar Shaw is justifiably proud of the three group companies – Biocon India into research and manufacturing, Syngene into contract research and Clingene into clinical research. However, establishing credibility in the biotech area is an uphill task, she says. Indian companies need to demonstrate intellectual ability and instil confidence in being able to deliver cutting-edge research. There is a need to demonstrate integrity in patent regime.

There are three models of contract research outsourcing. One model works on the time and material basis. This may be chargeable at say US$ 60,000 per annum, per full-time equivalent person. The second is on a milestone basis – payment being released on completion of an agreed milestone. The remuneration in this model can be as much as three times the earlier model. The third model is the sharing of patents and Intellectual Property Rights. Here the payment can be less, but the sharing of patents could possibly result in a massive windfall in case of a successful product.

If the cost of a full-time equivalent person is US$ 60,000, why would any one outsource such a service? Because it would cost almost four times as much to get the work done in a foreign country.

So how does the marketing happen? Though Biocon has a marketing team, the best marketing ambassadors for the Biocon Group are the scientists who move from one pharma company to another or to another biotech company. Also, some of the marketing gets done at prestigious conferences where the best biotech brains get together.

Kiran Mazumdar Shaw is also the President of ABLE (Association of Biotechnology Led Enterprises). She is extremely upbeat about the prospects of the biotech industry. A recent ABLE study indicates that Indian biotech
industry is currently worth Rs 1,830 crore out of which Rs 875 crore account for exports. The employment potential is also huge with current employment being around 6,400, up by 64%. She believes that the opportunity in contract research in biotech could be as large as US$ 2 billion. Though the opportunity in volumes in biotech is lesser than that in the other BPO services, this is a very high-end activity. The margins in biotech make it an extremely attractive business proposition. However, Kiran laments that the investment in biotech companies continues to be inadequate and venture funding is inadequate. Infrastructure is expensive and regulatory regimes are deficient. Despite this, entrepreneurs are setting up new ventures, signifying the intrinsic belief in biotechnology being the business of future.

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<tr>
<th>Company</th>
<th>Start-up Year</th>
<th>Area of Operations</th>
<th>Chairperson</th>
<th>Promoters/Owners</th>
<th>Approximate number of employees</th>
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<td>Clinical Research</td>
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<td>Kiran Mazumdar Shaw</td>
<td>Biocon India</td>
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Approximate Revenues of Clingene and Syngene: Rs. 27 crores (2002-03) and Rs. 17 crores (2001-02)