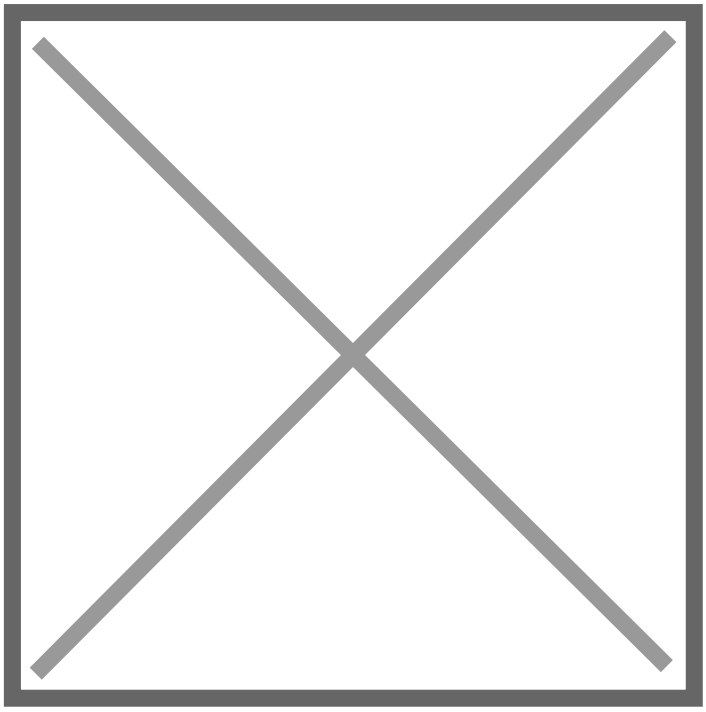
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Small Wonder

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Bhat Biotech

Small Wonder

This is one among the first few Indian diagnostics' companies to receive the ISO 13485: 1996 certificate. It is all set to launch its malaria diagnostic kit shortly and will be coming out with a tumor marker kit in the next 2-3 months.

Bangalore-based Bhat BioTech recently won ISO 13485:1996 certification. This certification assumes significance, as it will facilitate the company to reach out the global markets. "This certificate is a prerequisite for CE marking and FDA approval 501K. If you have the ISO 13485 it becomes very easy to get the CE marking. We are getting it for our pregnancy tests. For entering the European market you should have the CE marking and soon it will become mandatory for all the devices to be sold in the UK and Europe. This is a certification of the quality and the process, it is almost like the WHO GMP norms for the devices but is given for the product and not for the system," informed Dr Shama Bhat, founder and managing director, Bhat Bio-Tech.

Bhat Bio-Tech claims to already have ISO 9001 and WHO GMP certification for all its products. "Without these certifications we could not have gone to countries like the UK and South Africa. Because the first question that they ask is whether the company is ISO certified, then they ask is it GMP certified? These are the major certifications that they are looking at."

Started in 1994 by Dr Shama Bhat, operating in the area of manufacturing of diagnostic kits and recombinant protein reagents, the company has grown its product range to over 60 products in 2004Ã¢â?¬â?•pregnancy, HIV, Hepatitis B and C, urine chemistry diagnostic kits to name a few. The company has considerable oversees presence in nearly 12 countries including South Africa, UK, Nigeria, West Indies, the Caribbean Islands, Peru and Malaysia.

The last few months have been really good for Bhat Bio-tech. It has received a good order from an UK-based company for making pregnancy kits. "I have received a sizable order from South Africa. This is our third order and we will be getting orders from South Africa every other month now. The orders are now picking up," shared Dr Bhat.

Globalization and portfolio extension, the new mantra

Leverage and expand. This has been Bhat's business approach. "When we thought of setting up a company, we wanted to venture into two areas mainlyÃ¢â?¬â?•diagnostics and biopharmaceuticals or recombinant based products. These could be pharmaceutical or industrial products. It took us nearly seven years to start the recombinant-based products. Today, we have four recombinant products (HIV-1-gp 41, HIV-1-p24, HIV-2-gp 36 antigens, and Protein A), which are used for making the diagnostic kits," further elaborated Dr Bhat. At present the strength of the company is 65 including the marketing team and an

R&D team of 12. During the last fiscal year Bhat Bio-Tech posted a turnover of Rs 3.5 crore and this year its turnover is projected at more than Rs 5 crore.

"Government can play a key role in the growth of small biotech units"

How do you foresee the future of the diagnostic sector and what are your plans to cope with the growing competition?

The global diagnostic sector is all set to grow by at least 20-30 percent and in India the growth will be much more as the diagnostics field is relatively new (not more than 10 years old).

Globally, the Chinese products are a major threat. China is dumping the products at such a low rate in the market that it is very difficult to match them. Most of the Chinese companies are based in the US, with their production plants/facilities in China. A few Taiwanese and Korean companies are also there. So the idea is to match their price and of course our quality is any day better than that of the Chinese kits most of time. There is a problem with Chinese quality as they mass-produce and their system is not that good. But I do not know how some of them sell products, which is below our cost.

In India, there are four companies that are real diagnostic kit manufacturing companies and we can compete with them both product and price wise. J Mitra is the market leader in HIV kits and Span diagnostics is the leader in biochemistry and other kits. Tulip manufactures most of the rapid tests. Then there is Bangalore-based Xcyton, which has kits like HIV Elisa and HCV Elisa. Like wise, we are also the major producers of all these kitsÃ¢â?¬â?HIV, Hepatitis B and C, urine chemistry, etc.

How do you source funds for the company?

At present it is internal. We are thinking about venture funds but they are not at all available for the smaller sector. For a small company, it is very difficult especially if you are looking at Rs 1-2 crore. Nobody is interested in investing that kind of money. They are looking at Rs 4 crore or more. And we did not want to borrow too much as that would strain our capability in case we are not able to sell the products within the stipulated time.

Initially, we received some government support, we got a term loan from KSIIDC and then we got a subsidy of Rs 30 lakh from the Karnataka government. Now we are in the process of registering as an R&D company with the central government so that we can try for funds through programs like Technology Development Board (TDB).

But one thing common for getting funds is that you should be a sizable company. For a small company it is very difficult.

Bhat Bio-Tech is now venturing into contract research. This is an extension to its ongoing contract manufacturing in diagnostics. This year, it has added up another 6,000 sft area to its facility and also modernized the manufacturing area with class 10,000 clean room. Dr Shama Bhat believes that contract research and manufacturing is a good model for growth for a small and growing company like his.

Another example of leveraging its strengths is introduction of biotech teaching kits and training programs. This initiative is aimed to address the lack of quality teaching kits (except those supplied by Bangalore Genei) in colleges imparting biotech education. Dr Bhat felt that training programs are a must, as most of the colleges do not have good facilities for training. Since the company had all the equipment in place and very good trained personnel, it started giving training in basic and industrial biotechnology, which is not possible to impart otherwise in colleges. The company charges a nominal fee for the courses to cover for the costs and other incidental expenses. "I get nearly five enquiries every day by mail, through phone or in person from students for industrial training. So we thought why don't we start a regular program from which people can benefit. It is the need of the hour. There are very few biotech companies that are doing this kind of work," added Dr Bhat.

Future plans

Bhat Bio-Tech is not doing any kind of core research work but is doing more of development. In the future, it is bringing out several other diagnostic kits like that for malaria, which is ready, except for some evaluation tests and licensing. The other products in the pipeline include the TB kits and tumor markers for cancer marker kits and then western blot kits. Next, the company wants to make the PCR-based kits for all the infectious diseases like HIV and HVC. It already has the know-how and the basic technology and only has to modify it a bit to suit particular diseases. "We are a growing company and want to bring out at least 5-6 products every year. And once you establish yourself in the market then automatically contract

manufacturing comes in," opined Bhat. Besides making diagnostic kits, the company also plans to start manufacturing generic biopharmaceutical products (like insulin and growth factors) in the next six to eight months.

Rolly Dureha