Interview with Dr. Chetan Tamhankar, Chief Executive Officer, SIRO Clinpharm Pvt Ltd

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SIRO Clinpharm Pvt Ltd

Undeniably, the landscape for CROs has dramatically changed compared to when you started in the 1990s. The idea of having India as a clinical research destination was not mature yet at that time. Has India reached that desired level of maturity today?

India has indeed matured compared to when we started. Way back in 1996, when we initiated clinical research to GCP standards, we figured that, although access to patients was not a problem, adequate training of GCP investigators and local ethics committees were lacking in many places. In fact, I recall working personally with some of the doctors and hospital administrations to provide them with the necessary guidelines and help shape up the ethics committees. This scenario has changed dramatically today.

Another transition we have seen over the last years is that clinical research has transcended limits of metropolis Indian cities such as Mumbai, Delhi and Bangalore to mid-size cities like Indore, Hyderabad, Chandigarh etc. This expansion was crucial to achieve scale in Indiaâ??s domestic market. To support this, we have implemented a so-called â??Centre of Excellence Programâ?•, that is run by a dedicated team from within our medical services department. Every month, the team identifies new doctors and investigators in tier 2 and 3 cities.

The access to manpower has also improved in terms of clinical research associates, project managers, data managers, statisticians, medical writers and so on. In particular in the last 3 or 4 years, we have seen a dramatic increase in this kind of skill sets. The industry has faced challenging years with staff turnover on the rise. However, this trend has now gradually stabilized.

There have been several welcome changes in Indian regulatory environment over last few years such as issuance of Indian GCP guidelines, new schedule Y implementation and recent requirement of CRO registration. These changes will certainly add credibility to Clinical Research in India. However in recent months, the predictability of regulatory approval has declined which is a cause of concern for Industry in India.

While CRO activity has increased in India over the years, the number of trials conducted, relative to the population, is still less than for example Taiwan or Australia. Apart from regulatory issues, what may have been holding India back?

While the quality and regulatory compliance has improved dramatically over the last few years, India has slowly started to lose the cost arbitrage it had about 10 years ago. Furthermore, big pharma has been postponing some clinical trials in view of the high levels of recent M&A activity.

At the smaller biotech level, the recession sucked most of the money out of the system. As a consequence, instead of focusing on 3 or 4 molecules, this number fell back to 1 or 2. The stakes for having successful trials therefore ominously increased for such companies, which in turn made such players less price-sensitive. As a result, many smaller Western players preferred to retain their clinical trials in the West at a higher cost, simply because they would be able to better control the process.

Nevertheless, having India as a clinical outsourcing destination is still a popular train of thought. What do you see as the main growth drivers for SIRO Clinpharm in the coming years?

Considering the aforementioned limitations, we at SIRO Clinpharm realized a few years back that remaining an â??India onlyâ?• company would result in a glass ceiling for our growth.

In 2008, we therefore acquired Omega Mediation, a mid-sized European CRO based out of Germany. This takeover gave us a footprint in Europe in Germany, Estonia, Romania, Czech Republic, Greece and a number of other Central- and Eastern European countries. Over last 6 months, we have also expanded our reach in other Western-European countries such as France, Spain and the UK, as well as Russia. This strategy de-risks SIRO Clinpharm, as it reduces the companyâ??s dependency on the Indian market.

Because of Indian regulatory restrictions in global trials, SIRO is allowed to recruit only limited percentage of patients from India. The other patients thus have to be recruited from other countries, which is why a wider international presence helps us get more clinical trials approved.

Another factor SIRO Clinpharm has been playing out is its Indian heritage. Since the company was established in an emerging market 15 years ago, it makes sense to leverage this as strength to position the company as an emerging markets specialist today. This is also why we opened our office in Malaysia last month, while we further plan to expand to the Philippines, Thailand and a number of countries in South East Asia later this year. We aim to build on the fact that we have a strong footprint in regulated markets such as Germany and France, while we aim to get most of the additional patients from the emerging markets. The twin advantage of this strategy is the cost and speed of getting the desired number of patients recruited.

Other Indian players also emerged at the same time, resulting in a very fragmented market. What distinguishes SIRO Clinpharm from the others, who may have the same ambitions to become emerging markets specialist?

A first plus is definitely our early-mover advantage. Having moved into these markets so early, we clearly have an advantage in terms of the experience we have managed to build up. While there are many CROs in the Indian market today, few started as early as SIRO Clinpharm. This has allowed us to go beyond India, which is still rather rare for most of the other players. This is particularly important today as most of the studies have become global.

SIRO Clinpharm also has strong capabilities in FTE/FSP in India. This is not classical clinical research with regards to patient recruitment, investigators and so on, but it is an area where we have approximately 100 people from large pharma that sit in our offices. They handle all the medical writing, the biostatistics programming and the data management processes. They have access to their servers back in Europe and function as an extension of their offering in data management, medical writing etc. The advantage of this strength is that it is easily scalable. I do not see why we cannot increase the 100 people we have today, to 500 people by 2014. This is another growth area for us.

Having state of the art infrastructure and technology is clearly a must in the industry today. Can you elaborate on the added value of the On Trak Program you launched recently?

A couple of years ago, SIRO Clinpharm invested in the Oracle Life Sciences platform, which has a data management application. It also has an application for project management, where it is a possible to upload reports, track patients, and perform site management and so on. Clients can have access to this system if desired, which basically gives them real-time access to ongoing information on their project. At the same time, financial performance can also be tracked through the same application. All in all, the system brings in a significant amount of efficiency.

At a cooperation level, we have seen SIRO Clinpharm building several partnerships, with examples of VCRO in Taiwan and DreamCIS in South Korea. How have these partners helped you to expand the business?

It is a two-way approach. When clients approach us with the demand to recruit patients in several countries, we subcontract part of it to our partners in places where we do not operate ourselves. These partnerships allow for expanded access to our customers. This of course works vice versa.

Why these two companies in particular?

We went through a process where we scanned the markets first, looking for more mature CROs. We understood that these two players had what we were looking for.

Yet, because our clients inevitably also require patients in Western markets, we retain our footprint there too. Getting patients from both emerging and developed markets is our value proposition.

The pharma industry has very high attrition rates. How do you see the people factor today?

This industry went through a really difficult time in that sense. Around 2007-2008, people were shifting jobs for 5 to 10% salary increases, while those with only limited experience aspired for supervisory roles. In the last couple of years, this trend has slowed down, although it has not yet reached the level of the more mature markets.

The industry will continue to grow in India, and demand for clinical trials and positions related to the sectors will continue to be significant in the coming years. The aforementioned FTE/FSP is one example of a growth area as such. Functions such as medical writing will give higher value propositions than other business services. In fact, SIRO Clinpharm will set up a medical writing training institute, which will open its doors in just a few months from now. We will have 2 to 3 batches of graduates per year that will cater to our medical writing needs.

What can you further bring to the table to increase the loyalty of your staff?

SIRO Clinpharm has several initiatives in place to do so, of which the salary compensation is of course just a small part. Other initiatives include the opportunities to work on international projects, while there are various other softer factors that also play an important role.

In fact, over the last few years we have seen that having the SIRO stamp is being valued very highly in the Indian market. This is something we are very proud of.

In turn, what are you proud of, of what has been achieved in these 15 years?

When you start off with such business, you are everything: from janitor to CEO, and I personally have done all the business functions (apart from programming). I have seen this company growing, both domestically and internationally, which has been a very exciting journey. The past few years

were challenging, as the CRO industry also suffered from the recession. Nevertheless, we believe that 2011 will be better than what we saw in 2008-2009.

Back in 1996, would you have thought that the company would grow to such extent?

We were very optimistic in those times, but it took until 2004 for the real growth to kick in. Until then, growth mainly came from increasing word-of-mouth publicity and repeated work from the same customers. From 2002 onwards, we started looking at potential partners to drive work to India. In that year, we established a strategic alliance with Covance, which had been looking for a mature Indian CRO. While the agreement gave us some growth perspectives in the first 2 years, the amount of work was not exactly what we were expecting to achieve. One reason for this was the fact that the pharma and biotech industries were not actively asking for Indian patients yet. This changed in 2005, when India signed up for patent protection.

It still seems that the story has only just started, with rumours of SIRO going for its IPO. What is on the top of your agenda for the coming years?

I have three points on the strategy radar. First -consolidate existing business. Second â?? expand into emerging markets further. Third and last â?? expand the operational capability in North America. Now is the time to evolve from an international CRO into a global CRO. Year-on-year, we are planning to grow by 30%.

Do you have a final message for our readers?

Over the last 15 years, India has delivered significantly on the opportunity of clinical research. At SIRO Clinpharm alone, we have gone through at least 3 US or European regulatory inspections. This reflects the fact that India has delivered on the quality that is required. Although there are still some uncertainties today, the inherent India story has not lost. We are therefore very optimistic about India, as well as many other emerging markets in Asia.

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