"The global CR market is expected to grow by 8-12 per cent year-on-year"

...says **Dr Chetan Tamhankar**, chief operating officer, Siro Clinpharm Pvt Ltd. It was Dr Tamhankar who played an important role in the growth of Siro Clinpharm from a two-member team to a full-fledged transnational clinical research organisation (CRO). With over 15 years of experience, he has made immense contributions to the clinical research industry in India. In this exclusive e-interview with **Saloni Vora**, Dr Tamhankar talks about the current trends in the global as well as Indian CR industry and its future outlook.

Siro Clinpharm's journey since inception...

Siro was established in 1996, when the concept of clinical research (CR) was at a nascent stage in India. The company's early years were invested in learning, setting up systems, processes and training activities. Since our clinical research organisation (CRO) was based in India, we did not have a parent organisation in the US or anywhere in the West to give us readymade SOPs, systems and training.

Despite such a modest beginning, we have come a long way. Today, Siro Clinpharm has an operational presence in several countries including India, Germany, Greece, Estonia, Romania, Czech Republic and Israel. In addition, we encompass countries in Western Europe, Baltic States, Spain, Russia and Sri Lanka. We have also established a sales and marketing organisation in the US.

Recent developments in the CR industry...

As far as India is concerned, 2004 was probably the inflection year when the CR industry started growing rapidly. The trigger point was India's acceptance of full patent protection in 2005, due to which research-based pharma and biotech customers gained confidence. For India, patent concerns were perhaps the last barrier that could prevent the floodgates to clinical trials from opening. Till 2004, India had proved that it could recruit patients and generate credible data that complies with the highest and most stringent international standards of ethics & good clinical practices. But after 2004, several foreign CROs and a few Indian CROs began coming up. Moreover, many big pharma companies began substantially increasing their clinical trials in India.

Current state of the global and Indian CR market ...

According to estimates, the size of the global CR market currently ranges between $ 45-50 billion and is expected to grow by 8-12 per cent year-on-year over the next 10 years or so. Of this, about 40-50 per cent is outsourced to CROs globally. Hence, the CRO outsourcing market size ranges between $ 18-22 billion.

The Indian market is highly fragmented and not many companies share adequate data to arrive at an exact market size. According to estimates, India's CR market was around $ 350 million in 2008, which means that India's contribution is around 0.75 per cent of the global market today. However, this marketshare is small as compared to the potential India has as a country.

Impact of the economic downturn on the CR industry...

We believe that the economic downturn has affected our customers in a negative way. Due to scarce capital /liquidity globally, many small/mid-size pharma and biotech companies have to postpone their CR spending decisions until funds are available. In addition, these companies are focussing on lesser number of candidates.

The rest has been shelved until things improve. The big pharma market has been recently witnessing several mergers and acquisitions (M&As) like the Pfizer-Wyeth merger and Merck-Schering Plough merger.

Pros and cons of the draft rule mandating the registration of CROs...

The recent announcement made by the Drug Controller General of India (DCGI) about the draft rule for Schedule Y-1 mandating the registration of CROs is a positive and important development. It will serve the purpose of being an entry barrier that would ensure that potential 'fly by night' operators are eliminated and only genuine players with robust systems and processes continue to thrive in the country.

On the flip side, genuine players must be shielded from unnecessary bureaucratic hassles. The DCGI office has requested feedback from the industry on the same and we hope some of the concerns expressed by the industry are addressed when the same is finalised.

Ethical issues in the profession...

It is important to recognise that pharmaceutical and clinical development is probably one of the world's most regulated industries. Global regulatory agencies like the USFDA, EMEA and UKMHRA allow a new product to be marketed in their jurisdiction only after they are satisfied that the data submitted is credible and meets GCP standards along with other ethical requirements. Hence, it is futile for any pharma and/or CRO to cut corners and compromise on the quality, as the risk of regulatory rejections weighs far more on their minds than performing unscrupulous work. The way protocols and GCP standards are designed ensures that the 'patient interest' is given paramount importance over scientific benefits. In other words, if the protocol is not designed ethically correct, it cannot be scientifically correct.

Ethics-related challenges faced by the industry...

India faces two major ethical challenges in the execution of clinical trials. The first is regarding the oversight on clinical trials by ethics committees. Since the past 15 years or so, ethics committees in India have improved significantly. Today, most leading hospitals have well-formed ethics committees to review and monitor the conduct of trials. However, there could be some loopholes in the functioning of these committees with respect to their record-keeping and documentation practices for the approval & review process.

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The second challenge is with respect to patient recruitment practices and informed consent process. Before starting a study at an investigator site, a lot of emphasis needs to be laid on patient recruitment practices and informed consent process at the site. The consent process entails the detailed and elaborate process of sharing information by the doctor/ investigator to the patient, the patient's opportunity to consider, ask questions and consult his family & other resources before agreeing or disagreeing to participate in the study. Getting these two aspects right in research methodology and making sure that the science is right in the design of the protocol are the most important ethical challenges today.

Siro Clinpharm's alliance with Advanced Clinical Trial Solutions...

We have recently entered into a partnership with the North American niche expert group Advanced Clinical Trial Solutions to provide patient recruitment and consulting services in North America. Advanced Clinical Trials has a good track record in the execution of oncology trials and this alliance is one of the important steps we have taken towards creating operational presence in America. We are excited to offer this new service to our global customer base.

Challenges faced by the Indian CR industry...

The CR industry faces a multitude of challenges, especially because India is looked upon as a preferred destination for clinical trials.

Access to GCP-trained investigators to support growth: As more and more studies are carried out in India, the investigator base needs to expand to accommodate the demand. Today, some investigator sites in metros are getting saturated, as too many companies are placing their projects there.

Trained manpower: This burgeoning industry will require more staff over the next few years including CR associates (CRAs), data managers, medical monitors, biostatisticians, statistical programmers, medical writers and project managers. Though many training institutes have cropped up in recent years to address CR training needs, a lot of them have limitations due to their inability to provide any hands-on experience. CROs will have to keep investing in the training and development of their employees to overcome this challenge.

Regulatory framework: There has been significant improvement in the regulatory infrastructure in India and the government is taking the right steps to cope with the growing challenges. CROs need to follow up with the government to ensure that it invests in creating the necessary bandwidth in the regulator's office to see to it that they have the necessary experience and scientific expertise to carry out a competent review of applications, assessment of data quality and compliance to GCP on an ongoing basis.

Awareness: The media and general society need to understand CR practices and processes better than what they do currently. For this, the media will play an important role in presenting an unbiased view of the situation. They must refrain from looking at the industry with suspicion and the 'guinea pig syndrome' that many people suffer from must be surmounted.

Future plans for Siro Clinpharm...

We have already expanded to Europe with the acquisition of a mid-size reputed CRO called Omega Mediation. Our current priority is to focus on the completion of the integration of operations of both entities to ensure that we bring synergistic strengths as an international company. We will also look at creating strategic alliances with niche providers in different geographies in next 12-18 months.

Road ahead for the CR industry...

The steady growth of the CR industry is pressurising pharma and biotech companies. Their ability to develop products quickly and with cost-efficiency will drive more work to emerging markets like Central & Eastern Europe, Asia Pacific and Latin America in the near future. India needs to fasten its seat belt in order to cope with this demand. As of now, the country contributes less than 1 per cent to the global clinical trials marketshare, but in future, it would have the opportunity to contribute at least 2-3 per cent. This means that the Indian CR industry would grow almost three or four times in next five years or so and has a bright future.