Interview with Young Jack Lee, President, LSK Global PS

13.06.2010

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South Korea has a short history of participating in global clinical trials, but now the country is seeing exponential growth in this area. What has changed in recent years leading to this new trend?

South Korea has been behind in terms of global clinical trials due to unfriendly regulations, but this has changed dramatically in recent years after the introduction of the IND system in 2002. In 2008 there were already about 350 clinical trials in South Korea â?? more than the total in Japan â?? and this is expected to continue growing strongly. Besides its own market, the country is a potential gateway to the nearby giants China and Japan which are now accepting Korean data. In this sense, Korea can develop a very beneficial relationship with its neighbors similar to what Canada has with the United States. There are several characteristics which are shared by countries that have managed to become clinical trial hubs around the world such as Canada, Singapore and Australia. First of all, they are all politically stable and economically developed countries with strong infrastructure. They also have high levels of education and on top of that speak English, which is the common language of international clinical trials. South Korea shares all of these traits as well, except the English factor which is nonetheless constantly improving. We have political stability and a strong economy, having reached an annual per capita income of about $20 000. The country boasts the highest literacy rate in the world and a high quality education system. Moreover, through the years Korea has developed top-notch medical infrastructure and is today at the same level as the leading countries in the world.

How much collaboration is there between Korea and its neighboring countries with regard to clinical trials?

There is a growing awareness among East Asian countries like Japan, Korea and Taiwan about the possibilities and benefits of working closer together in the field of clinical trials. There is genetic homogeneity among our peoples and we therefore have many similar disease patterns. Thanks to geographic proximity, common cultural origins such as Confucianism, and the high levels of education that we share, it is possible to have mutual understanding. There is a lot of space to further grow clinical trials in Asia, which are still a small fraction of what is done in the world, so we need to keep moving forward. Korea still has a very low density of clinical trials relative to its population, but given all of the advantages the country has we can become leaders in Asia first and eventually in the global arena. Although cost is not our main competitive advantage, it is important that Korea is considerably cheaper than the USA and Japan. Our proximity to the huge potential market in China and the fact that the regulatory process over there is very difficult give us other reasons to be optimistic about the future of the clinical trials sector in Korea.

Which are the biggest difficulties you see in the relationship between Asian countries in the field of clinical trials?

There are some particularities among Asian countries that make it challenging to work closer together. For example, the Japanese are very focused on the quality aspect, which is good, but this often leads to conservatism. There is also a need to advance in terms of the regulatory harmonization between countries, and there are already efforts being made in this regard. The language barrier is also an obstacle to further cooperation, despite our shared cultural heritage, but we are using English which is after all the language of global clinical trials.

As for Korea in particular, what is your assessment of the existing potential for clinical trials to continue growing rapidly?

There are five key factors to look at when evaluating the chances of having successful clinical trials in a certain location: the sites, investigators, IRBs, recruitment and compliance. In terms of the sites, Korean hospitals are huge, self-contained and of high quality. Investigators are all university professors on a payroll, so the monetary element is not a problem. Most of them have several years of post-medical training experience in the United States and therefore speak English and are familiar with American medical practices and clinical trials. As for the IRBs, this is one weak area in Korea since there is no active common IRB and the big hospitals tend to have their different requirements. On the other hand, recruitment is very efficient and cost-effective, usually being possible from a hospitalâ??s own pool of patients. Compliance is also a strong point in Korea, as are the compact size and connectivity of the country in communications and transportation which make it easy to navigate. On the regulatory side, there are some problems because the norms have a hard time keeping up with the medical advances and make the system inflexible. Particularly since clinical trials have been growing so rapidly since 2002, there is a lot of stress on the domestic IND review. However, they do a good job in spite of this and certain regulations are currently under review in order to make the process quicker and more efficient. Overall I believe that it is better to have a more open guideline approach than a strict regulatory system. In my view, the main weaknesses of Korea in this area are its short history in clinical trials, outdated regulations and the shortage of the necessary professionals for these activities.

Turning to your company, what was the vision behind the creation of LSK over 9 years ago?

LSK has been in business since 2000, and since 2007 it has been renamed LSK Global PS signaling our path towards growth and global recognition. Like the founders of several global CROs today, I am a statistician. I had worked most of my life in the clinical trials sector, since 1977 when I began with the NIH in the United States. So from the beginning in my career I realized the importance of clinical trials, working a lot in the early phases. Indeed, I have always said that clinical trials require science even more advanced than the IT sector. So when I came back to Korea with all this experience and knowledge, I was very encouraged to create a new company dedicated to clinical trials in the country.

How is LSK Global PS positioned within the competitive CRO market in South Korea today?

This is still a small company, but I believe that we are considered to be the strongest Korean CRO player in terms of our technical expertise. Compared to global companies we do not have the latest technologies, but our brainpower is at the same level and this is the most important. Besides the business aspect, my motivation is to do things right and to carry out quality clinical trials in Korea so that the country in general advances in this field.

What advantages does working with a local CRO offer multinational pharmaceutical companies wishing to do clinical trials in Korea?

The main advantage of being a local CRO is that we know the local system very well and can therefore come up with solutions more effectively and efficiently. There are a number of global CROs with branches now in Korea, but their managers are very junior in terms of their experience level when compared to mine. Whereas they constantly have to pay attention to what their HQ tells them to do, I am autonomous and capable of making quick decisions. LSK Global PS can take a more strategic approach, and we are able to communicate a lot better than a foreign CRO. There is currently a very peculiar situation in terms of the CRO market in South Korea. While in most parts of the world pharmaceutical companies are downsizing and outsourcing more and more, in Korea the multinationals are expanding their size in order to carry out clinical trials directly. This happens because they consider that the global CROs are too expensive and that the local CROs are not ready for the work. So basically there are challenges in terms of size and credibility to overcome, and this is what LSK Global PS is doing today. We have moved to a more spacious location and are now over 70 in the company. Recruiting and training CRAs is one of the most costly and difficult parts of the industry due to the high turnover rate. But we are growing and building a reputation for ourselves.

What are your ambitions for LSK Global PS for the next decade?

I believe that in 10 years, Korea will probably have a CRO market of about $500 million. In such a context, my goal is for LSK Global PS to have a turnover of around $100 million. For this we will have to keep growing in size and credibility to create a virtuous circle for our business.

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