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PS, Korea's largest local contract research organization (CRO) gives his insights on the evolution of the clinical research environment over the past four years, the need to foster local CROs if the government is to truly embrace innovation, and the cultural differences in clinical research between East and West.

What have been the main developments for LSK Global PS over the last four years?

We have managed to double in size over the last four years, now exceeding over 300 members of staff across various units operating autonomously. Our services have also expanded into pharmacovigilance. Sometimes there are issues with one section of the business growing at a faster pace than others, but it has been my job to ensure that we maintain some consistency. We still remain a very quality orientated business. This is our greatest asset. We follow regulations by the book, never cut corners, nor compromise on quality. If you do this, eventually you will develop a reputation. Indeed, every CRO talks about quality or about ethics, but these often amount to empty words. After all, no one will say they are low quality or unethical. Thus, it takes time for partners to realize that we truly mean what we say. LSK Global PS has managed to establish this reputation for high-quality work which has helped elevate us to be the leading CRO in Korea.

We are still running 190 projects at this time, making us the largest local CRO in Korea. The majority of our work is now based in Korea, through the local affiliates of multinational companies, local Korean pharmaceutical companies, or small biotech ventures. In the past, we worked with a number of multinational CROs, but this has declined as more and more have opened up their own affiliates in the Korean market. Most global CROs now have an affiliate in Korea, increasing the competition for global studies. In fact, we have not been involved in a project involving multinational CROs for the past two years. We still participate in a number of global projects, but they come directly from sponsors in the US or Japan.

When we work with global CROs, the scope of our work is rather limited, focusing on tasks such as site management and patient recruitment: other areas of the project such as data management tend to be conducted outside of Korea. Conversely, when serving a local company, we cover the entire scope of activities including data and statistics, safety management, and pharmacovigilance. Today our work is considerably broader than it was previously. LSK Global PS also has Korean sponsors conducting trials outside of Korea. For example, we undertake the data management, CSR, and pharmacovigilance for their overseas studies.

How was the presence of multinational CROs crowding out the local market?

The dynamics of the marketing career have substantially changed. The market situation is now very fluid. In the past, local CROs did not have to compete with multinational CROs for local projects, which were generally awarded to Korean CROs. However, this is no longer the case. We now compete with the affiliates of multinational companies receiving a growing proportion of the local studies by local sponsors.

Local Korean companies have preconceptions about working with global CROs, viewing them with some vague expectation. However, there is no difference for sponsors between global and local CROs. There is no difference in terms of quality; in fact, our quality can often be superior as we are based locally, so can better monitor conditions and make decisions closer to the study, in contrast to a global company where the major decisions are made abroad, such as in the United States. LSK Global PS has firsthand experience of this. There was a local company who awarded a local study contract to a multinational CRO. Over time they realized the difficulties in working with them. As a result, they had to divide the contract, and part of it was awarded to us. Henceforth, I am very confident that the market will readjust over the next few years and local business will return to local CROs.

What is the role of CROs in the government's innovation drive to embrace the 4th industrial revolution?

The biotech industry is growing rapidly in Korea. Often Biotech ventures now have one or two products in their pipeline, but sometimes lack the necessary capital for development. In these circumstances, we are able to assist them by investing in and guiding the clinical studies. Sometimes we will also make an in-kind investment. This is a win-win as they receive the assistance of a high-quality CRO and we become a member of the project. Moreover, this provides LSK Global PS with a vested interest, incentivizing even more diligent work.

The CRO is a depository of know how. We are the knowledgebase. Since LSK Global PS began operations we have conducted over 1000 clinical trials as of early of this year. There is no company in Korea that has comparable experience. We have also conducted studies in the US, Europe, Japan and Korea as well as Taiwan, China and other Asia-Pacific countries. Experience is knowledge in clinical trials.

Unfortunately, the Korean government does not understand the importance of local clinical research organizations. They also fail to comprehend that when global clinical research organizations are conducting trials in Korea, knowledge and know-how is lost. We need to cultivate and keep that knowledge within Korea. Companies like Samsung Bioepis and Celltrion use global CROs, so these Korean based multinationals are not transferring that know-how back to the local market. The Korean government must come up with a solution to this if it is to truly embrace the fourth Industrial Revolution and build a biotech hub locally.

How does the culture around clinical research differ in Korea compared with your experience in the USA?

Both Japan and Korea both have very significant drug industries; they are the only Asian countries whose pharma companies can compete on the global stage. However, both of these are underserved by global CROs. This is because of a very important cultural difference. Korean drug companies are run mainly by pharmacists or biochemists whereas US research is dominated by medical doctors. While the medical doctor is best suited to determine the treatment, the pharmacist has a better knowledge of the drug. Thus, clinical trials are driven by drug experts in Asia and by treatment experts in the West.

In traditional Chinese medicine, a systemic and holistic view is taken, treating the symptoms rather than the source of a disease. This is still how Asian medicine has been driven. In contrast, western medicine is experiment-based, focusing on clinical trials for instance. When the medicines are discussed with partners in the United States, it revolves around the mechanism. In eastern medicine, there is considered to be multiple mechanisms. This is because you're not treating one source of disease, but instead multiple different sources.

Nowadays modern medicine is dominated by western medicine. This is hard to adapt to for those with an eastern mindset. Koreans and Japanese are very active in modern medicine drug development, but this traditional mindset still makes the concept of clinical trials very awkward for them.

Western CROs are accustomed to being dictated to by the sponsors, who are believed to hold the knowledge. In Asia, the CRO is supposed to know best. This creates a conflict. When I receive an RFP from the United States, it is meticulously detailed. In contrast, Korean and Japanese companies will provide just rough ideas. Then throughout the process, the sponsor will begin asking questions. Our competitive advantage is that, given my 30 years' experience of working in the United States where I was engaged in a number of significant drug development projects, we are able to adapt to both approaches

What are your ambitions for the next 3 to 5 years for our LSK Global PS?

The combined revenues of local clinical research organizations have remained constant in the past few years. In contrast, the revenues of local affiliates are rising very rapidly. Korean projects abroad are also increasing exponentially. Hence, I am looking at the potential of tapping into this market.

I am also targeting overseas projects originating from Japan. There is a cap for our growth in Korea due to the size of the local pharmaceutical market. Because other markets such as the Japanese market are so huge, even if there are small changes and fluctuations, we will still be able to benefit as a business.

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