Interview with Albert Liou, General Manager Asia Pacific, Parexel Apex International Korea

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Over the last several years we have seen a shift in clinical research from traditional healthcare markets to Asia. How do you see this trend evolving in the coming years?

Right now Asia provides an excellent clinical research environment compared to ten years ago. I see Asian clinical trial activity dramatically increasing for many reasons. The number one reason is that the regulatory environment has substantially improved. The ICH has been widely accepted by most Asian countries, and has made global clinical studies feasible in Asia. Secondly, several hospitals and medical infrastructures are excellent. The investigators and other scientists at these facilities are very experienced and have top-notch talent. Asia still has a great number of patients with unmet medical care needs. There are huge populations in Asia with similar disease patterns as Western populations waiting for new, innovative drugs. There are also some diseases, such as HPV and hepatoma, which have a unique profile here in Asia. These unique disease profiles provide many opportunities for local companies.

Japan is already the second largest pharmaceutical market, with China following close behind at number 8. Within the next 2-3 years, China will become number 5. Korea is currently ranked number 13, and Taiwan's market is swiftly growing.

Asia's regulatory improvement; the excellent infrastructures; the experience and talent of the investigators and scientists; Asia's ability to provide faster patient recruitment; and the potential of the pharmaceutical market in Asia are the main reasons why a large portion of outsourced development is shifting to Asia.

We are seeing global studies in Phase II and III starting to include 20-50% of their patients from Asia. Asia is becoming very dynamic in terms of clinical research and especially in clinical trials. I think this trend will continue for at least the next five years.

South Korea is a relative latecomer to the clinical trial industry, but it is now growing very strongly. How do you see Korea as compared to other major clinical research hubs in Asia including Japan, Singapore, Taiwan, and the upcoming China?

We first became involved in Korea about ten years ago, in 2000. We were one of the very first foreign CRO's to go to the country. Over the past ten years, I have seen a gradual improvement in the environment. However, even now, CRO's choose Singapore as their first expansion point in Asia. Prior to the acquisition by PAREXEL in 2007, APEX had a very different strategy. We started in Northern Asia, namely Taiwan and Korea. Ten years ago, multinational companies needed to get marketing approval before they were allowed to conduct clinical trials in Korea.

The regulatory reform in 2002 had dramatic effects, allowing global trials (Phase I,II, and III) to be run in Korea. Even 7-8 years ago, all documents had to be translated to Korean, which sometimes took up to 3 months. This was a huge drawback, but the guidelines were changed, and now only few documents need to be translated. Most importantly, the Korea FDA shortened the IND timeline to 30 working days. Over the last ten years I've seen huge support from the government and medical community in Korea.

Korea also has many great medical centers and highly trained staff. In addition to the regulatory changes, the investigators are much more knowledgeable and experienced than before. The Korean market has a population of 47 million, which is quite large. So the strengths here are the same as before, favorable regulatory reform, great research centers, and investigators and patients who are among the top in Asia when it comes to global study recruitment and compliance. The medical doctor associations are also a great forum for sharing knowledge and improving the quality of trials here in Korea.

When you started your company, Apex, you were one of the first foreign CRO's to come to Korea in the clinical trials market. How was this early experience in terms of building trust and setting up a new line of business?

At the beginning it was rather difficult. We started by networking with local supporters. We knew of the potential in Korea and believed we could become the best CRO operating in Korea and Asia at large. Korea and Taiwan are strategically important countries. Singapore and Hong Kong are important too, with good infrastructure, investigators, and prevalent English. But overall, companies are coming here due to patient recruitment and compliance, as well as high quality research. We saw that if we want to be the best Asian CRO, we would have to focus on the Korean market. I was thinking long term, and at that time global CRO's had a passive Asian

development approach; meaning that if a client asked them for a trial in Hong Kong or Singapore, then they would try to provide it, but they didn't try to promote Asia. We were a small CRO and we needed to get into a niche specialty. We planned on getting hands on experience in local clinical operations and regulatory know-how, and aggressively establishing our local networks with hospitals and investigators.

The boom here didn't start till 4 or 5 years ago. Our strategy was always preparing for this long-term spike in growth. In the beginning it was difficult. There wasn't much of a CRO market here and we had to do a lot of educational work and handholding for the community. Our efforts have greatly paid off and have been reflected in our clients' recognition. Currently we have about 60 clinical research experts in Korea, and I believe we're one of the largest CRO's in the country in terms of size, quality, and services offered.

As the Korean CRO market has developed and grown in recent years it has also become much more competitive, with numerous new players establishing a presence here. Which are PAREXEL's key distinguishing factors in this context?

I think the Korean CRO market can be divided into two segments; local CRO and global CRO. The local CRO's focus is primarily on local development and in a few cases, regional. Compared to these local CRO's, PAREXEL is much stronger in terms of quality and ability to conduct clinical trials regionally and globally. With its acquisition of APEX, PAREXEL incorporates the strengths of our building efforts throughout the Asia/Pacific region. For instance, in our first few years at Apex in Korea we dug in local roots and made relationships with hospitals, regulatory agents, and clients. Now those investments have paid off. Since other global CRO's are few and have come late to the country, our early entry into the market has given us huge advantages. I think we have a much better feel for the local environment and are more mature in terms of manpower and infrastructure, especially when it comes to conducting global or regional e-clinical trials. We have a very strong regulatory and clinical operations team.

Our ten years of experience means that we know the industry leaders and we can find the right hospital with the right type of patients for a given study. It really does make a big difference to be able to give clients predictable timelines, have relationships with doctors, know the culture, and understand the local business customs. Thus, operations-wise, experience-wise, and manpower-wise, we have advantages over other global CRO's here in Korea.

After several years of very strong growth of the CRO market it Korea, what are your expectations of the situation in 2009?

The CRO market should have even stronger growth in Korea than in recent years. This is because the global biopharmaceutical industry is becoming very cautious in terms of how it spends its money, and it is more concerned with the value of each dollar. I believe that this will drive more

clinical trials to Asia and specifically to South Korea. Here we have the quality, the best value in terms of timeline, patient recruitment and quality of data. Korea really does produce the best product per dollar spent.

In 2007 Japan started allowing foreign data in Phase II and Phase III trials. This will really encourage domestic Japanese biopharmaceutical companies to look outside Japan for clinical trials. At the beginning, their approach has been rather risk averse. For the most part, they are only looking at similar Asian markets such as Singapore, Taiwan, Hong Kong and Korea. Of those countries, Korea and Taiwan are the preferences. PAREXEL is well positioned to help Japanese companies with these Asian studies.

Many in Korea's CRO sector are speaking of the country becoming a gateway to the Chinese market. Do you believe this is truly feasible?

I would say yes and no. Korea is trying to become this kind of entry point. But as everyone knows, China has its own agenda and issues. For the industry, currently, the biggest challenge is regulatory approval time in China, which can take 6-12 months.. This makes other Asian countries much more attractive. I don't see this changing in the near future – within two years. I don't think the government has any motivation to change this practice.

While it is Korea's strategy to become a bridge to China, in reality they need to figure out a concrete way to achieve this goal, and they need partnership with the Chinese government. For the Chinese government, only one thing comes first – Chinese business. They look to protect their domestic companies and healthcare system above all else. In this regard, it is somewhat risky for Korea to pin their goals on another party's actions. I would like to see this happen, but in reality, it is something of a challenge.

2007 was a big year when the company you founded, Apex, became a part of PAREXEL. To what extent has this broadened and enhanced the capabilities of your operations in Asia?

Apex had been working closely with PAREXEL for 4 years before we were acquired. Since 2003 PAREXEL and APEX had an alliance, and we conducted more than 50 global studies together. A position emerged where we had a very natural relationship in part because we had very complimentary strengths. PAREXEL had very large-scale operations in Japan, Europe, the US and Australia. We at Apex were very strong in Korea, China, Hong Kong, Taiwan, Singapore, and other parts of Asia.

By the time of the merger, we had already adopted a lot of PAREXEL's training and SOP because we saw them as very effective. Thus from an SOP and project collaboration point of view, we were already very integrated.

After the acquisition, the company provided many combined regional and global clinical development capabilities including medical, regulatory, marketing, and quality assurance expertise, and also a comprehensive suite of eClinical technology solutions. These technologies include IVRS/IWRS, EDC, clinical trial management systems, and medical imaging. Many of our Korean biotech clients use our regulatory consulting service in the US and Europe. That provides the local biotech and pharmaceuticals with a great vehicle to reach out to global markets. I think this is an incredibly valuable service that we bring to our Asian clients. The first locally domestic Korean drug to enter the US was an antibiotic and the regulatory portion was fully supported by PAREXEL. Thus, PAREXEL was heavily involved with the first Korean drug to get US FDA approval. I think we also have a big role to play in helping global biotech and pharma in bringing in their products to Asian markets.

It takes a very entrepreneurial spirit to create and build up a successful multinational company as you did with Apex. Now in a different stage of your career, what motivates you most in your corporate position within PAREXEL?

Asia plays a huge role in PAREXEL's overall focus, from internal structures to a direct CRO presence. The company has a leading presence worldwide, and has locations throughout the Americas, Europe, the Middle East, South Africa, and the Asia/Pacific region. PAREXEL has 15 offices in 11 Asia/Pacific countries, including Australia, China, India, Indonesia, Japan, Malaysia, the Philippines, Singapore, South Korea, Taiwan, and Thailand. As a global company we are focused on how we can utilize the strengths of each region. We are looking to continue significant investment in Asia as the business in the region is very dynamic.

My team is looking to carry out our vision in Asia. PAREXEL shares the same vision that I had for Apex before we were acquired. In many ways, business and expertise are shifting to Asia, making my job very interesting. It has also been exciting for me to go from being an entrepreneur to becoming a corporate executive; there are new challenges and many things to learn. So for these reasons, I very much enjoy my role managing PAREXEL's Asia/Pacific regional operations.

What is your final message to the readers of Pharmaceutical Executive?

We have implemented cutting edge technology, such as IVRS/IWRS, EDC, clinical imaging, and clinical trial management systems, giving us a huge advantage in Asia. This technology will provide efficiency and unmatched competitive advantages in the region.

Expansion in Asia has allowed PAREXEL to truly become a global company. This global footprint forms a bridge between Asia and the West in the biopharmaceutical industry. It has made both the introduction of biopharmaceutical products from Asian companies to Western regions and Western companies to local regions more feasible. Additionally, PAREXEL's assistance to our clients in Asia and throughout the world contributes to getting safe and effective new treatments to patients on a

global basis.

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