Interview: Albert Liou, Vice Chairman, Asia-Pacific Region, PAREXEL

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Many of your counterparts have spoken about the unique operational and strategic challenges China poses to their organizations. How does PAREXEL adapt itself to compete in China, and how does it work differently here than elsewhere in the world?

First off, we know that within another two to three years China will be the worldâ??s second largest pharmaceutical market. Because of that, demand for clinical research and trials, which will be necessary to get drug approvals and conduct studies in China, will be higher, in terms of both volume and quality requirements. For some time now PAREXEL has prepared for this change in a number of ways, and have been a leader among the global CROs in terms of investing in the quality and quantity of the people, IT, leadership, and training that will drive success. We have also expanded geographically, and implemented a comprehensive strategy across four established affiliates in Shanghai, Beijing, Guangzhou, and Chengdu, and just recently, we opened another in the Northeast, in Shenyang. Each of these cities has its own importance within the clinical research environment. Beijing is important due to regulatory affairs, because it is close to the SFDA. Shanghai, where PAREXELâ??s regional headquarters are located, is a very international city. The newest affiliate in Shenyang will take advantage of the Japanese language capability within that region and leverage the potential for this to serve as an offshoring office for the Japanese market. In Chengdu and Guangzhou, PAREXEL definitely wants to expand relationships with hospitals and investigators in the Western and Southern parts of the country.

In terms of IT investments, weâ??re bringing proprietary informatics systems, which provide electronic data capture capability and clinical trial management system, as well as patient recruitment and randomization technologies. We will be able to provide a full web based eClinical suite,

PAREXEL has located all our functions in China â?? not just a partial team. This means that we have regulatory consultants, phase II-III clinical development management team, peri-approval experts, data management, statistics, project management, and the rest, all in China. For any local or multinational company (MNC) which wants to conduct clinical studies here, we can provide a fully functional, complete service and not only provide the clinical studies but operational and strategic consultancy for China. As we grow strategically, China is a very important focus within PAREXEL, and our strategy for China has been very clearly defined.

Weâ??ve met with local CROs who are very enthusiastic about healthcare reform, citing the billions injected into new drug development during the 11th FYP and the more than 300 new

IND filings that resulted â?? but how would you evaluate the supporting infrastructure that needs to come around this huge influx of funds?

This is an important point, to recognize that drug development is not merely a matter of cash, but of infrastructure which includes human talent and experience that is equally if not more important. Compared to five or 10 years ago, there have been great improvements, but there is still a long way to go.

The fact is that the government can support the industry through investment. Indeed, the local CROs and domestic innovation-based companies and VCs are well supported from an investment perspective in this sector. However, infrastructure still lags. The number one area in need of improvement is regulatory timelines. Five years ago, we talked about IND taking 6-10 months, but recently this figure has more than doubled, and is a significant handicap to innovation.

Another point concerns hospital quality. The number of hospitals prepared to conduct clinical trials has improved significantly compared to 10 years ago, but the volume of hospitals with real experience in GCP and participating in clinical trials remains limited, as do the numbers of PIs and other professionals who can design protocols for drug development, not just for academic purposes. When we talk about regulatory affairs, hospitals, and quality, and the people who can design protocols for new drug development, itâ??s important to note that formerly majority of the protocols were designed from outside of China â?? mostly by Western countries with greater experience.

When we see the 12th Five Year Plan and the goal to create at least 20 new drugs, the current lack of infrastructure casts doubt around whether it will be achieved.

Speaking to your point about IND approval times, we saw an interesting presentation yesterday at the BIO China conference, where Peng Wang, Simcereâ??s CSO, said that although the average IND approval times were around 14 months, the last three successful IND applications had been approved at 12, 10, and 10 months respectively. What low-hanging fruit would you recommend the government pick in order to reduce these times even further?

In China, if the government makes a commitment to do something, they will do it. The question is: What are the incentives and motivation for the Chinese government to do so? Most people sometimes have doubts or questions about whether policies are heavily related to international trade barriers or to protect domestic pharmaceutical companies. But the fact is that if drugs demonstrate a clear target for life-threatening diseases, and diseases that are more prevalent to the Chinese patients, they will be prioritized to faster approval. For others, it may be different. Of course, if more drugs originate in China and developed here, the motivation to simplify the processes and approve would be higher. Fortunately, there are more and more overseas returnees coming back to China and conducting R&D with their expert knowledge, and after we have more innovative compounds developed here, there is more incentive for the government support further improvement in processing and timeline. Itâ??s a fact that now â?? and when I say this I mean in practice, not in regulation â?? almost all foreign imported biologic products do end up conducting all phase I, II, and III studies in China, which further delays drug approval. Thatâ??s something the industry is worried about. It used to be that if you had conducted a global phase III study, which includes required number of Chinese patients and PK study, it would qualify for Chinese market approval. But right now in practice, itâ??s different for biologic products. Japan used to be in a similar situation; they have now changed. Unfortunately, China has headed in the opposite direction, and for many this is a cause for concern.

When we met with Ling Zhen from Quintiles, he spoke of the importance of market segmentation, of being able to serve the up and coming locals or SME biotech companies from the US and Europe, and had even established a specialty local operation in this regard. What is PAREXELâ??s strategy in this regard?

PAREXEL has a strategic approach for the kinds of clients you mention. For many companies, global scale is redundant when they are looking only to conduct studies in China. In that case, what use is a PM in Australia, data management in India, regulatory consultant in Taiwan, and monitoring in China? This kind of infrastructure is simply unsuitable for a smaller biotech which may choose PAREXEL to work towards marketing a single drug in China. Therefore, PAREXELâ??s approach is to establish a dedicated China team, with all the training, project management, and operational execution in China. The operation is completely China-focused. All the resources are in China, but the quality is the same global gold standard, and we audit everything the same. That means weâ??re going to take out the redundancies and make things simple, which streamlines processes and resources. We have regulatory expertise, project management expertise, and operational and local hospital expertise, but based on this streamlined work we can achieve great efficiencies and transfer this benefit our clients directly â?? without a single compromise on quality.

What is your view on the medium-term development of Chinaâ??s CRO sector?

In the last two or three years we have seen, and over the next five years we can expect to see, a change in the fundamental structure of the market. The CRO market will be global, and the bigger CROs can expect to capture 75-80% market share. I also expect the CRO market to see more demand for strategic partnership models â?? not just for the large pharmaceutical companies but also from small and mid-sized biopharmaceutical companies. Some CROs may choose a geographical niche â?? for instance, excellence in the Chinese market â?? and will be chosen on a case by case basis. It will not be easy for smaller CROs which choose to not to specialize and I expect many of these will not survive. . Some of the niche CROs may flourish by specializing in regulatory, consultancy, early phase trials, or central labs, though few of those will be able to survive and be profitable. For the China market, PAREXELâ??s approach is to create unique business units to tackle each kind of unique client challenge. That means that although we are a global CRO, to satisfy the requirements you mention, such as the local pharmaceutical and some foreign biotech with limited resources we are able to tailor our service models to support them.

If you see some big changes in the CRO market in the next five years, what is your ambition for PAREXEL in Asia over that time? How will PAREXEL evolve along with the market; where do you want to bring the company, and how will you bring it there?

I expect PAREXEL to continue to grow and evolve in Asia Pacific. For some time, PAREXEL has been considered a leading CRO in Asia, and our global footprint, proprietary technologies and the expert talent that we can attract are important differentiators for us. . We know that our Asia operations are keys to the future, and that the Asian market including Japan, India, Korea, and China will become even more important. In the last 10 years, few CROs have been successful in the region, but PAREXEL will continue our strategy, which means emphasizing not only the scale and number of our offices, but also the leadership team which will come from this area. PAREXEL will continue our growth not only in terms of size, and locations, but particularly in regulatory and operational expertise in all clinical phases, and relationships and eClinical capabilities. Asia is already an important growth region within PAREXEL, and I expect to see this trend continue, and continue in a significant way.

As a final message, what do readers need to know about PAREXEL in China?

Following the acquisition of APEX PAREXEL has had a presence in China for 12 years. In 2007 PAREXEL acquired APEX â?? a company I founded â?? which enabled significant growth for PAREXEL in China. We were the first MNC CRO in China, which means our clients benefit from a long history and a long relationship with hospitals, the SFDA regulatory bodies, and have allowed us the opportunity to participate as strategic consultants for the industry. That relationship will continue. Our expertise, experience, infrastructure, technology, relationships, and know-how â?? thatâ??s our strength. PAREXEL will continue to bring our clientsâ?? products to China, and continue to bring Chinese drugs to the global market. China is an important strategic location for our clients and business.

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