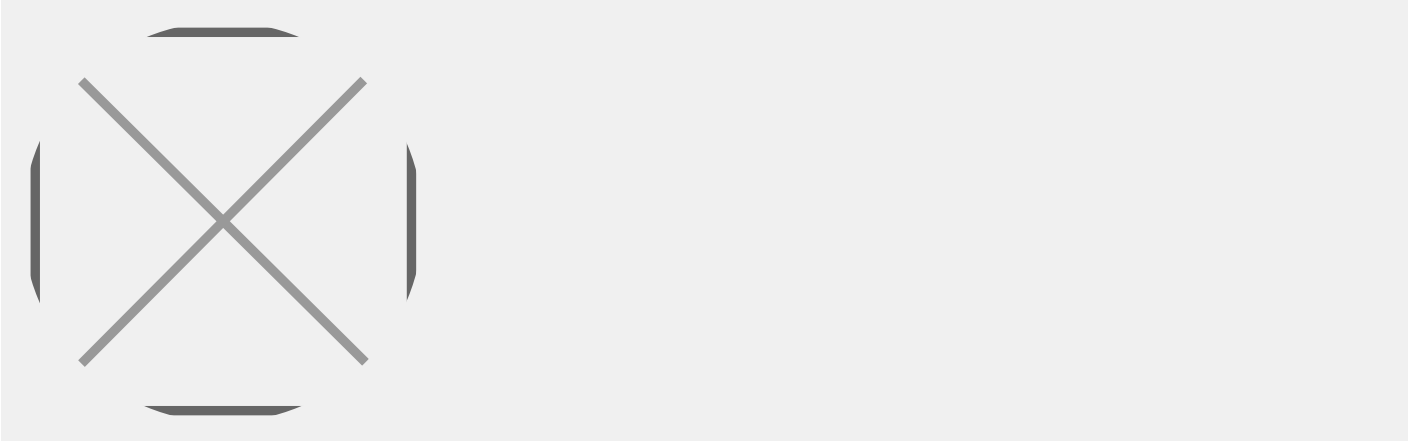
Interview: Albert Lou, Vice Chairman, Parexel



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PAREXEL has been in Asia Pacific (APAC) since the company entered Japan in 1995. It chose Taiwan as its regional base of operations with the 2007 acquisition of APEX, a company you founded in 1999. Today, does Taiwan continue to make sense as PAREXEL's APAC headquarters?

We believe that it does. Many multinational clinical research organizations (CROs) have chosen Singapore, China, Japan or Australia to base their APAC operations, but PAREXEL has taken a different route.

The first reason we chose Taiwan is because of available talent. In this country, many members of my generation were educated in the US or Europe and have worked in the West for a number of years before returning home. In fact, in the 1980s, more students enrolled in US graduate programs came from Taiwan than any other foreign country. Taiwan's president and vice president, our cabinet ministers and our prime minister are all US PhD holders. This means that here, companies have access to English-speaking, highly educated and internationally minded talent. In addition, that talent also comes at a more reasonable cost in Taiwan when compared to others in the region.

Taiwan's geographic location also makes it an ideal place for international corporations to establish their headquarters in the APAC region. As the hub that connects Europe, the United States, Japan and emerging Asian markets, Taiwan is crucial in terms of its high economic and strategic value. Taiwan is a great stepping-stone to China. With the signing of the Economic Cooperation Framework Agreement (ECFA) between the two countries, trade barriers have decreased

significantly and will continue to do so. Our previous administration had a rather antagonistic relationship with Chinese leaders, but our current government is more business-minded. They want a win-win, and ECFA is a result of that mentality.

Taiwan also has a great relationship with Japan. Japanese culture is heavily ingrained in our country, and many Japanese companies are more comfortable going to China through Taiwan. In fact, when I was still managing operations, our colleagues in Japan reported to me in Taiwan. This was quite unusual for a global CRO.

Talent and two-way access to the second- and third-largest pharmaceutical markets in the world—China and Japan—are Taiwan's greatest strengths. And we're close to Korea as well.

Carl Firth, CEO of the Singapore-based virtual drug development startup ASLAN, told Focus Reports, "Without a doubt, people are looking to leverage Taiwan data in China. The Economic Cooperation Framework Agreement (ECFA) signed in 2010 created a framework that could support that clinical collaboration in the future. However, China has had those agreements with Hong Kong in the past as well, and the mere existence of an agreement doesn't mean leveraging it is straightforward." Would you agree with this statement?

I wouldn't compare Hong Kong to Taiwan. While what Mr. Firth said is certainly true, the fact is that Taiwan has over 130 internationally-certified good clinical practice (GCP) hospitals qualified to conduct Phase I-III studies, while Hong Kong has perhaps five; Taiwan has 23 million people to Hong Kong's seven million. Hong Kong's numbers are simply less impactful.

Taiwan also has a burgeoning biotech industry that is looking for a market like China. This means that our government, which wants to help this industry succeed, will actively promote clinical trial cooperation with China as a strategic priority. This may not be the case for Hong Kong authorities. On the flip side of that coin, Taiwan is positioning itself as a hub for multinational companies to conduct research, while Hong Kong has limited strength in this area, because even as a small market, its costs are comparable to the US—more than double what Taiwan offers.

What concrete results have you seen from ECFA, and how feasible is full protocol harmonization and mutual data recognition in the future?

As far as concrete results from ECFA, we're not there yet, but we see some promising preliminary steps.

Under a Greater China paradigm, companies will generally conduct Phase I and Phase II trials in Taiwan, where IP legal protection is safer, the approval process (the clinical trial authorization) is faster and takes two to three months in Taiwan, versus 12 to 24 months in China). Furthermore, there is a wealth of great hospitals, researchers and patient protection system. Ideally, Chinese authorities will accept this data and Phase III trials will take place in Taiwan and China, with an eye toward simultaneous new drug application (NDA) filings if the trials go well.

This, of course, is the ultimate goal of harmonization efforts: that any new drug will be simultaneously approved in Taiwan and China.

Right now, as the program runs its course, only local companies have the opportunity to leverage this model. At each stage of the development process—be it Phase I all the way up to the NDA—there can be a hiccup, and stakeholders from both sides will have to find a solution. But with time, if the model works, international companies will benefit by getting involved as well.

To what extent does that interest extend to making Taiwan more attractive for foreign companies looking to conduct multi-center trials?

Taiwan has put considerable effort into this area. We've looked to ensure our regulatory environment meets international standards. Agencies like the Center for Drug Evaluation (CDE) and Taiwan FDA (TFDA) make international collaboration a priority, and our GCP protocols meet or exceed global requirements.

We know that having a strong regulatory system and well-developed clinical research environment are the main prerequisites. Without them, there is no way for local companies conducting early and mid-phase trials in Taiwan to use that data for a Phase III study abroad. There would also be no way to attract multinational companies to conduct research here. I attended a meeting 13 years ago, where a group of Taiwanese leaders were discussing how they could position Taiwan for global competition in drug development. The outcome of the meeting was that first and foremost, a world-class regulatory system and high-standard clinical research infrastructure must be in place. Taiwan has had a GCP framework since 1997, and I have seen that with time, we have continuously strengthened it.

How does Taiwan's clinical research environment compare to South Korea's?

I have to admit that South Korea is ahead of Taiwan in certain areas. The Korea National Enterprise for Clinical Trials (KoNECT) has been quite successful in promoting Korean clinical environment internationally. Korea positions itself not only as a regional hub in Asia, but also as one of the

important global hubs for clinical research.

Five years ago, Korean officials asked PAREXEL, as a leading international CRO, to produce a white paper outlining suggestions for how the market could achieve this positioning. I headed the project, which sought to describe where Korea was then, where it needed to be and how to get there. Working with colleagues from our APAC and global headquarters, we spent nearly a year interviewing relevant stakeholders. At the project's end, a Who's Who of leaders from industry and government attended a conference that examined how Korea could get ahead. Major funding was allocated—one billion USD over ten years.

There is no questioning that Korea has international ambitions, and that it will pursue them aggressively. I saw that back in 2000, when I set up my first office there. The questions I was asked—how does Taiwan do bridging studies? How does Singapore work with the US FDA?—demonstrated a clear goal to be the best. I have to admire what the Koreans have done.

And so today, Taiwan is a good window to China, but Korea is a window to the world. Is that right?

I agree. Taiwan is perhaps too focused on the Chinese market rather than global markets and that kind of reliance can be dangerous. China offers a great market in close proximity, but our relationship is complicated and has at times been contentious. If the situation sours again, Taiwan will be in a bad position.

What Taiwan does have, as we've noted, is a healthy indigenous biotech industry. According to Taiwan's Biotechnology & Pharmaceutical Industries Promotion Office (BPIPO), Taiwan Inc. currently has 17 compounds in Phase I of development, 73 compounds in Phase II and III, and 6 compounds at the new drug application (NDA) stage. What is your view of the maturity of the drug development ecosystem in this country?

Firstly, what Taiwan has achieved in a short time period is impressive. Those statistics speak for themselves.

But with that said, for A-Z drug development, we still find gaps. In terms of pure clinical trial quality, Taiwan can rightly be in the same conversation as the US and Europe. This is indicative of a larger theme, as Taiwan has great capabilities in each step along the development chain, but linkages are not as strong as they could be.

Academically and therapeutically, Taiwan is capable in certain areas, including liver disease, for example. But in terms of drug development from discovery to market, we are several years behind the West. We need leadership that can unite the links in the chain. We need, as well, our first success stories to serve as motivation and as development models, and we anticipate our first stories to come shortly. Sometimes, a company reaches an advanced stage but the fuel runs out. This shouldn't be a problem for Taiwan because now our capital market is really rallying behind our biotech players.

A common theme you've mentioned in the past is the fact that PAREXEL was an early mover in Asia among multinational CROs. With the increasing Asian presence we now see from many of your largest counterparts in the industry, what sets this organization apart today?

Firstly, PAREXEL has a long history in APAC. We have a head start, but more than that, we have continually invested here. We are nearly 4,000 strong in APAC—over 25 percent of our total global workforce of nearly 15,000 and which is equal to the resources we have deployed in the US or Europe. We have continually invested in our leadership team, regulatory team and medical team. We have continually invested in eClinical capabilities and consulting. We are the only full-service CRO in Asia.

We are capable of taking local companies to the global stage. We can help our international clients navigate Asia. We can walk in the water because we know where the stones are hidden. We know the regulatory and clinical systems in APAC extremely well. Here, we are natives.

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