

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



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With

7,000 employees in 25 locations across 12 countries in the region, PAREXEL now has more than a third of its global staff in Asia Pacific (APAC). Albert Liou, Vice Chairman, Asia Pacific, PAREXEL, discusses the biotech momentum that has been boosting the attractiveness of the region in terms of new drug development activities. He also provides insights into the company's unique contribution to the R&D-driven ecosystem in Taiwan, where the global clinical research organization (CRO) also has its regional headquarters.

As Vice Chairman, Asia Pacific for PAREXEL, what would you highlight as the most impactful trends occurring in the region when it comes to drug development?

Asia Pacific is at the tipping point of an innovation revolution, which has already started to materialize. In the past, this region was widely considered a fast-recruitment, low-cost CRO market, where the volume-based approach prevailed. However, in many APAC countries, this time is now definitively over.

The number of R&D-driven biotech companies emerging from Taiwan, South Korea, Singapore, Hong Kong, and China has been soaring over the past few years. In the meantime, many historical, well-established pharmaceutical companies are leveraging the important resources generated by their generics businesses to bolster new drug development activities, whether as the result of a

fundamental strategic shift in these companies' R&D strategies or through the establishment of research-oriented subsidiaries.

This innovation drive has been nurtured by the increasing number of *returnees*, who – after having studied among the most prestigious universities and worked for some of the most advanced biopharmaceutical companies globally – return to Asia and leverage easily-accessible private equity or government-backed funding to launch their own biotech companies. These industry experts and scientists have honed a remarkable technology and market expertise in the EU and U.S., which naturally contributes to accelerating the development of their companies.

Where does Taiwan stand in the regional context that is marked by heightened ambitions in the biotech field?

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Taiwan holds a particularly vibrant stock market for small- and medium-sized biotech companies. Whether they are already generating revenues or not, accessing substantial funding is no longer an issue for an increasing number of Taiwan-based biotechs.

In the meantime, Taiwanese regulators have worked to ensure that the country's regulations are now aligned with the most stringent international standards. Taiwan has had a Good Clinical Practice (GCP) framework since 1997, and I have seen that, with time, the country has continuously strengthened its regulations to ensure protocols now meet or exceed global requirements. Thanks to this strong regulatory system and well-developed clinical research environment, local companies can now conduct early and mid-phase trials in Taiwan and use this data for a Phase III study in the U.S. or in the EU. For agencies like the Center for Drug Evaluation and Taiwan Food and Drug Administration, international collaboration is now a priority. This remarkable openness also contributes to propelling our local industry onto the global stage.

Additionally, Taiwan's medical and clinical capacities are absolutely world-class, as the country holds an impressive number of Key Opinion Leaders in a large number of medical specialties, ranging from liver cancer to hepatitis B and hepatocellular carcinoma. Moreover, Taiwan boasts more than 130 nationally certified GCP hospitals qualified to conduct international standard Phase I-III studies.

Although Taiwan has an abundance of financial resources, a high-quality clinical network, and a robust regulatory environment, the country still lags behind the West when it comes to A-Z drug development. From the design of Phase I trials to the integration of market approval and

reimbursement requirements in key markets, we still find significant gaps among the value chain that only strategic partnerships with international industry experts can bridge. This is exactly where PAREXEL steps in as a global CRO with the capacity to conduct international, multi-center studies.

In Taiwan, one of our most valuable differentiators is our strong commitment to further enhancing the country's R&D ecosystem by operating as a knowledge and expertise center. We are the market leader in Taiwan and also stand as the largest CRO in the country. Taiwan is our APAC regional hub, and we have approximately 500 employees in the country. We amplify this with our global reach, helping Taiwanese companies develop their new drugs globally.

In this regard, Taiwan's Minister of Economic Affairs, Minister Lee, highlighted during our recent interview that *"the generalization of new R&D pipeline approaches, notably based on a broader use of CROs, CRAs and other drug development partners, has strengthened the competitiveness of Taiwan's pharmaceutical and biopharmaceutical companies."*

PAREXEL has been playing this role for more than 35 years, bolstering the development of emerging companies in countries such as the U.S., Europe, Japan, and South Korea. Through these partnerships, we have accumulated an unrivalled level of expertise that meets the various needs of companies.

In Taiwan, this expertise is even more critical: despite the biotech boom that the country has experienced over the past decade, the country still lacks a biotech champion to drive the overall ecosystem. For example, no emerging company has had a true new chemical entity approved in the U.S.

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In Taiwan, there is still a strong need for technology and expertise related to the entire drug development lifecycle. The needs for protocol design in an Early Phase trial are very different than the expertise clients seek for late-stage trials. At every stage of the drug development journey, we know what clients need and have the necessary expertise.

We are bringing our expertise where it is critically needed to bolster Taiwan's R&D ecosystem. For example, traditionally, we formed strategic alliances with hospital sites. But now, in addition, we work with Si2C (Taiwan Supra Integration and Incubation Center). Si2C aims at "Branding Taiwan Biotech" to build-up Taiwan biomedical ecosystem, securing talents for biomedical technology,

connection of the value chain and identification of potential projects. They establish seed funding to support early stage academia R&D or startup companies linking investments in later stages of product commercialization and support the government in establishing a new, one-stop shop biotechnology parks model.

By collaborating with Si²C, PAREXEL provide the strategic advisory services, which not only provides global standard clinical trial process. But also help Si²C establish the mechanism for talent development to train the local biotech start-ups, who align with PAREXEL & Si²C and hold same passion & mission, to boost Taiwan's Biopharmaceutical R&D Ecosystem.

PAREXEL already stands as the indisputable market leader in Taiwan and the largest CRO in the country. What do you identify as the main challenges that you will have to overcome to consolidate this leadership?

In Taiwan, PAREXEL, along with many other companies in the industry, are challenged to recruit and develop top talent. This challenge relates to the translation of the government's ambitions into tangible policies and regulations. For example, the continuous growth of Taiwan's healthcare industry as a whole could soon be hindered by the difficulties that local and international companies in the country face when attracting foreign talent. Constraining local regulations contrast with those of neighboring countries which adapted their taxes and incentives structures a long time ago to become some of the most business-friendly countries in the world, boasting the levels of attractiveness needed to gather the most talented professionals in the industry. It is critical for Taiwan to ensure that our education system and the level of local expertise available do not fall behind that of our neighbors, whereas both aspects used to stand as two of our country's main strengths.

Taiwan remains PAREXEL's expertise hub in APAC and many of our department heads are Taiwanese. Nevertheless, it will be critical to maintain the country's current positioning, both among PAREXEL's global ecosystem and within the industry as a whole.

In a CRO sector where service portfolios have been expanding and boundaries are blurring between service providers and drug developers, what is the approach favored by PAREXEL?

At PAREXEL, we will continue to develop our expertise and technical capacity, investing in building our talent pool and knowledge base, and continuously improving our processes to meet the needs of our partners more efficiently than ever.

In addition to strengthening of our consulting and informatics services offering, we have been evolving our drug development approach. Nowadays, receiving market approval does not guarantee that a given drug will generate value for the company. Rather, clients are seeking quality pharmacoeconomic studies to attain expected reimbursement rates.

In 2016, PAREXEL acquired TMAC, Execupharm and Health Advances, which offer specialized services such as portfolio planning, product positioning, market assessment and forecasting, and strategic and business planning to complement our long-standing leadership in drug development, market access, and lifecycle management services for our clients. By strengthening our expertise at the reimbursement stage, we want to ensure our customers integrate this critical step from the beginning of their drug development approach, to avoid more efficiently support pricing submissions. In this regard, PAREXEL, as a truly international company, can bring a global perspective to the reimbursement approach for our clients. We can help Asia-based companies anticipate reimbursement requirements in the U.S. and the EU, where some of our customers have not yet submitted any dossier.

For our smaller clients, this expertise is even more critical. Many emerging biotechs are out-licensing the development and marketing rights of their products once they get interesting Phase II trials. However, they have limited resources and cannot take risk repeat clinical studies. We are helping clients better target and integrate reimbursement requirements in the early design of trials. For our smaller clients, this is helping them display more appealing clinical data, and, as a result, negotiate better deals.

In 2014, PAREXEL was named best performing CRO in Taiwan for innovative drug development strategies and healthcare industry leadership. What do you see as the most crucial success factors to be recognized as the best performing CRO?

We were particularly proud to receive this award from the Foundation of Medical Professionals Alliance in Taiwan (FMPAT), as it came as recognition of our ongoing commitment to simplifying drug development for our customers and supporting their efforts to prevent and cure disease. In this regard, it is also particularly important to us that medical professionals, who are truly the core of drug development, praised PAREXEL's contribution to the Taiwanese ecosystem.

In my opinion there are three main metrics to achieve such industry leadership. First, the quality of the delivery is crucial to ensure drugs move forward as swiftly as possible along the R&D pipeline. Second, unrivalled industry knowledge is needed to support doctors throughout the execution of the trials and train GCP-approved hospitals. Finally, we need to make our expertise accessible and

our technology easy to use for all stakeholders who contribute to the drug development process.

In the grand scheme of things, PAREXEL's outstanding commitment echoes my personal convictions. I am particularly proud to contribute to the development of an industry that has developed many life-changing treatments, alleviating pain and curing diseases all around the world. I see physicians as front-line soldiers, and my role is to provide them with the innovative tools weapons they need to ensure patients can live better and healthier lives.

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