Katie Lai – Associate Director, Medpace Taiwan

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Katie Lai, associate director of Medpace Taiwan, introduces the company's history in Taiwan and highlights the CRO's unique service offering as a partner of choice to the biotech sector. Lai goes on to give her expert insights in the evolving clinical research environment of Taiwan and the APAC region.

Ms Lai, you have been with Medpace since 2015 with a strong background in clinical research from both the CRO and big pharma sector. Can you begin by introducing yourself and your journey to Medpace?

After I graduated in molecular bioscience, I focused on ATCG sequencing, basic research and, laboratory work. I then realized I did not want to be confined to basic research and decided to specialize in clinical research. I spent four years with MSD and eight years with Covance before moving to Medpace. At that time, the company's tagline "Making the Complex Seamless" was very appealing to me. I also chose Medpace because it is a very therapeutic-focused company, where projects are led by medical doctors and scientific experts. Additionally, integrated efficiency is very important in Medpace and we work together with our different functional teams to successfully deliver on projects.

As a global CRO with a presence in over 35 counties, Medpace has been operating in the APAC region since 2004. What is the company's operational history and relationship with Taiwan?

Company policy is organic growth which means we grow our own staff from the ground, hiring and training junior profiles up so that they have very solid foundations of the "Medpace way" of operations. This ensures overall project quality is properly maintained. Since Medpace Taiwan was established in 2007, growth has not been major, but steady. We have about twenty staff, but they are all experts in the field. For the other parts of services in clinical studies, like safety or medical support, we will work with our global teams.

The APAC region is home to two of Medpace's central labs located in Beijing and Singapore. Comparatively, what is the strategic significance of Taiwan to regional and global operations?

We are very proud of these central labs providing services to all the countries in APAC region. Our central lab in Beijing allows us to export our samples from China, which is quite difficult.

For Medpace, Taiwan, Korea and Australia are the leading countries in the region. These markets are put forward in priority for global studies coming into APAC because infrastructures, manpower, and expert teams are already here.

Medpace has robust expertise in oncology, cardio-metabolic disorders, gastroenterology, infectious diseases, and many other therapeutic areas. What are the most important areas for the business in Taiwan?

Rare diseases are a very important area for us. It is very meaningful for me to try to find medications which can actually contribute to improving the lives of patients and their caretakers. Medpace Taiwan also has a strong expertise in oncology and infectious studies.

Medpace brands itself as built for biotech with 95 percent of clients being SME biopharma companies. When working with biotech companies who have limited

resources how does Medpace ensure that clinical research projects are fulfilled not only on time but on budget?

We have many scientific experts within our company, so we work with our clients hand-in-hand from the very beginning to make their study a success; especially with biotech companies who sometimes have one or few products. At Medpace, we are very transparent with the client. Our medical team works every day with clinical operations to provide input and guidance through the whole project. This is very much appreciated by our clients, especially SMEs, who can then easily re-evaluate their commercialization strategy if needed.

What are your most demanded clinical services in Taiwan?

Our company strategy is to provide full-service solutions, but we cannot compare with our headquarter team in the US. Medpace Taiwan mainly manages clinical operations and monitoring with study submission. So far, we cannot help companies for product registration. If they want to apply for product licensing, they will either need to do it themselves or find another partner.

Asia-Pacific is at the tipping point of an innovation revolution – shifting from what was widely considered a fast-recruitment, low-cost CRO market, where the volume-based approach prevailed to focus on next generation therapies as the number of R&D-driven biotech companies continues to rise. How have you seen this trend shape Taiwan's clinical trial ecosystem?

These new services are not only new to pharma, biotech, and CRO companies but to patients as well. Like Medpace, many companies are part of the Taiwan Clinical Research Association (TCRA) whose goal is to promote clinical research in Taiwan and raise the general public's awareness. There is now a further need to explain the importance of trials in developing new treatments and increasing patient survival. As more innovative treatments are developed, requiring more complex trials, the industry's aim must be to improve the overall clinical environment in Taiwan.

What is your assessment of Taiwan's current regulatory and clinical research environment?

Our country regulators, as well as different hospitals, are making their policies a bit more flexible so the regulatory and clinical research environment is already quite good here. If a client wants to enter APAC for the first time, they will usually think about Korea, Taiwan, Japan and Australia. Korea especially is trying to promote the overall clinical studies. We are in the top tier countries in APAC, but not perfect yet.

Many of the CRO's we have met with spoke about their strategies in creating alliance networks within the region. What opportunities exist for pan-Asian collaboration in the context of clinical research?

Medpace is present in different countries in APAC, so we always try to cooperate. Once in a while, we meet with other senior management teams to discuss together how we can do things more efficiently. We try to simplify and unify our different ways of operating clinical studies within the region in order to grow. We are definitely trying to get to a stronger pan-Asian collaboration but, compared to the EU for example, APAC countries are very individualized and not all gathered in one continent, so we would need a country to initiate this unification. The relationship between China and Taiwan is also very complicated, and we first need to ensure we can share our clinical studies data. We are working on that, but it will take all the countries commitment to work together towards this common goal.

As the demand for outsourcing services in the pharmaceutical industry increases and more players join the clinical research space, the risk of commoditization is a top challenge facing the market. How does Medpace differentiate its services to remain competitive against CROs who may be offering a lower price point?

Our main advantage lies in our capability to offer full and robust service to our clients. This includes our own in-house central lab, imaging, electrocardiography (ECG), in-vitro diagnostics (IVD) and interactive response echnology (IRT) system, as well as clinical trial management systems (CTMS. This allows us to be very flexible and user-friendly experience. If a client wants a report, we will just build it for them with no additional charge. Our IT specialist or designer will just go the system and change or adapt anything the client wants.

How do you ensure the organization you are heading is also aligned with the patient-centric vision of the industry?

At Medpace, we all understand that a trial must be centered around our patients because they are the most important part of a trial. We actively work with testing sites and physicians to convey the importance of making sure patients are safe, comfortable, and well informed each step of the way. This is particularly essential in keeping up high patient enrollment rates.

Looking forward to your next five years in the role, what are your priorities in leading Medpace as a top player in Taiwan's CRO sector?

My first priority is to see the Medpace team grow, not just by number, but by ability as well. We are aiming to be able to take on more complex studies in a wider range of therapeutic areas. Currently, we are working primarily which medical centers, but I would like to expand the Medpace network to regional hospitals which may be interested in conducting trials as well. This way we will be able to further maximize the number of patients who can benefit from participating in clinical studies.

Furthermore, I want to increase our participation in the Taiwan Clinical Research Association (TCRA). By participating in the discussion of the association, Medpace can make its voice heard and contribute to enhancing Taiwan's overall regulatory environment.

What advice would you give to the younger generation just starting their career in the clinical research sector?

This field is growing and growing rapidly. Even if they are building fresh from the ground up it is never too late to join the industry as long as they have passion. One key characteristic I look for in the younger generation is being detail oriented and honest. Of course, there may be errors but the most import thing at the point is to make sure all the procedures are followed and put into place correctly and quickly.

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