George Lee – Vice-President of Clinical Operations and Country Leader, PAREXEL China



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George Lee, vice-president of clinical operations and country leader of PAREXEL in China, discusses the impact of the recent ownership and management changes of the group, the value that PAREXEL can bring to Chinese biotechs and how the company is uniquely positioned to compete against both local and global CROs. He also explains how new technologies will revolutionize the clinical research landscape in the coming years.

PAREXEL's co-founder and CEO Josef von Rickenbach retired last year after 35 years at the help with industry veteran Jamie Macdonald stepping into the position. How has this leadership change affected PAREXEL's Chinese operations?

With Jamie Macdonald, a very experienced leader within the CRO industry with extensive experience at INC Research and Quintiles, PAREXEL is in a very good position. Another notable milestone for the company prior to this leadership change was actually PAREXEL's acquisition by Pamplona Capital Management in 2017, making us a private company again. As a public company, we used to be heavily focused on quarterly earnings and shareholder value. Now we are able to adopt a more long-term vision. Looking at the past three years, PAREXEL has experienced substantial growth in China.

APAC is actually the fastest-growing region for the group globally, has the highest number of employees with a headcount of over 8,000 in total, and China is the fastest-growing market within the region. For this reason, three years ago, the company decided to invest strategically in China, and under the new management, PAREXEL is even more committed to the country. In fact, since our new CEO Jamie Macdonald took the reins in March 2018, he has already visited China twice, meeting with our employees and participating in a roundtable with top executives from key client companies and other key industry stakeholders including KOLs and patient advocacy groups in China.

We have introduced more service capabilities to China, and our service offering here covers almost the entire global service portfolio. We have also invested in people. In the past three years, we doubled our workforce, welcoming our 1000th employee in mainland China. As you might know, talent competition is fierce in China so, in addition to recruiting the cream of the crop, we also look at graduate recruitment and training programs. For instance, we have a global initiative called the PAREXEL Academy that we have introduced here in China through partnerships with top Chinese universities to grow the professionals for the clinical research industry. As a global CRO, we understand that we also have a social responsibility to develop the next generation of talent for the local industry and the country.

Secondly, we also invest a lot with other local stakeholders, especially hospitals, which are key partners for CROs like us. Up to now, we have master agreements with 24 top-tier hospitals to facilitate bringing them more high-standard global studies. Moreover, PAREXEL also supports the cultivation of the local innovative ecosystem. In the last three years, China has introduced sweeping reforms to help develop local pharmaceutical innovation, with a focus on aligning the local industry with global quality and safety standards in drug development and manufacturing. The turning point was when China joined the ICH in 2017. As a global company, we are able to share our global experience and expertise with the local ecosystem. A concrete example is our PAREXEL Consulting Services, which consists of experts including ex-U.S. FDA and ex-NMPA employees, to help our global and local clients make decisions regarding the Chinese market, as well as helping to bring the most innovative Chinese products to the global market.

Additionally, we recently announced a collaboration with Eli Lilly on a clinical research learning and development program in China, aimed at addressing the strain put on sites and investigators as a result of the influx of studies.

We have also expanded our geographic coverage significantly. When I joined the company seven years ago, PAREXEL was only present in four cities: Beijing, Shanghai, Guangzhou and Chengdu –

already a larger presence than other global CROs. Today we have more than 20 locations in China, including a presence in cities where key personnel like clinical research associates (CRAs) and medical staff can work more closely with provincial and peripheral clinical trial centres. This geographical spread also allows us to expand the talent pool we can attract talent from.

Globally, PAREXEL has launched a new business unit focusing on biotechs, PAREXEL® Biotech. How can this meet the specific needs of the Chinese biotech industry?

Across the world but especially in China, the biotech segment is growing rapidly. This is why PAREXEL globally recently announced the launch of a dedicated Biotech division built with the needs of emerging biotech companies in mind. Our team and solutions are specifically focused on and tailored to this segment.

The Chinese affiliate will play a critical role in this development because nearly all of the new and innovative pharma companies in China – and most of our local customers – are biotech companies.

Many of the local biotech companies in China are actually very well-financed and able to invest huge resources in innovative drug research and development. Money is therefore not always their main concern. Their top priority is really fast delivery. They are usually laser-focused on their assets and are working to very short timelines. In China, biotech companies are in a cut-throat race to get their drugs to market. The level of competition is like nowhere else in the world. For instance, in immuno-oncology, we found that, as of January 2018, there were 126 PD-1 clinical studies being conducted by Chinese biotech companies! In order to succeed commercially, biotechs are usually competing to be first or second to launch on the market. As a result, they want service providers to respond quickly. Also, biotechs usually prefer simple direct communication channels and small teams unlike multinational corporations (MNCs), where we would typically have multiple channels and contact points work with them.

With many of the top biotechs in China, their top management teams bring a wealth of industry experience across the whole value chain. What additional value can PAREXEL bring to them as a true partner of choice?

Indeed, many Chinese biotech companies are well-financed and have highly experienced management teams that used to work for Big Pharma in China and abroad. However, they cannot do everything alone. In order to conduct these critical studies, biotechs compete intensely for

limited resources: hospitals, patients, talents, and so on. For them to get access and manage these resources, they need the assistance of service providers. Apart from clinical resources, they also need access to advanced technological platforms, expertise of data and medical science, regulatory, asset management and market access strategy in the integrated fashion locally and globally, to help them be successful in their clinical development and commercialization journey.

As an international CRO with industry-leading technology and more than 35 years of experience in running global clinical trials globally and especially in the U.S. and Europe, PAREXEL is uniquely positioned to help them overcome these challenges by providing an end-to-end integrated solution and working seamlessly with our clients, so they can be among the first to cross the finish line. We have been in China for more than 20 years now and have been involved in many global studies here. We can assist them in conducting these kinds of studies efficiently so that they can gain the first mover advantage in launching their products first.

The CRO industry in China is also very competitive. Other global CROs such as IQVIA and Syneos Health have made China a strategic priority. Competent local CROs like WuXi AppTec and Tigermed with a global reach have also emerged in recent years and are growing at a fast pace. Moreover, as public companies, many have strong financial backing. What is PAREXEL's competitive advantage?

Competition is indeed quite high in the CRO industry. I am happy to say that in China, PAREXEL is certainly one of the few CROs leading the pack. The main reason is that we offer the most service value across the whole value chain. Local CROs are usually more focused on a few aspects of clinical research. They might be stronger in pre-clinical research and weaker in clinical services, or vice versa, and so on. For global CROs, not all of them have made China a strategic priority and some are actually recent entrants to China – and if we are talking about the biotechs, they are even newer to this space in China.

The positive regulatory changes over the past three years have created unique opportunities for global CROs. In the past, pricing was an issue. As mentioned, local biotechs now have the funding to partner with global CROs – and since many of them are now looking at the global market, they also have the need and desire to conduct high-standard international clinical studies. For this reason, our Chinese affiliate has transformed from a delivery-based unit with mostly operational teams to a full-fledged strategic unit with commercial, marketing, product and legal teams. We have invested a lot to build these teams and ramp up our clinical, scientific, integrated consulting

expertise and technology locally. Moreover, we have built close relationships with key executives of top biotech companies. Our active communication programs were put in place such as our annual PAREXEL symposium, roundtable, Chinese websites, digital outreach, WeChat public relations etc. to increase the awareness of our fast expanding local service portfolio. All these activities have allowed us to stay ahead of the competition.

When we met Brian Mi, president of IQVIA for Greater China, he laid out his ambition to revolutionize the CRO landscape in China by combining clinical expertise with Health Big Data. How will PAREXEL look to play within the health data and tech space?

In 2018, The Economist Intelligence Unit published a research report commissioned by PAREXEL, which found there are four innovations that will dramatically improve the efficiency of clinical development: adaptive trials, patient-centric trials, precision medicine trials and real-world data. At the end of the day, our work is about patients gaining access to clinical trials and ultimately, to important therapies. As such, we are focused on patient centricity. For instance, remote monitoring via wearable technologies can improve early patient engagement by enhancing convenience. Another example is adaptive clinical trials design methodologies that can reduce the number of patients needed, decrease trial duration, and provide more informative results.

Regarding the value of Big Data, which in R&D is really about Real-World Data (RWD), it can help us make better decisions regarding site selection and trial design, as well as interpret results by analyzing routine real-world data. PAREXEL has been in this space for a while now and we even have a separate RWE unit. In China, we launched a workshop last year with our customers and partners to discuss how to leverage this within the Chinese context, particularly in precision medicine, and we are certainly going to advance in our efforts here.

Globally, PAREXEL was involved in the development of 95 percent of the 200 top-selling biopharmaceuticals on the market, an impressive achievement. Is PAREXEL working towards a similarly impressive metric in China, which is likely to be the future of global biopharma innovation?

Our goal is certainly to also help develop a significant number of biopharmaceuticals in the Chinese market. We are well positioned to reach this goal since the overwhelming majority of the top 50 biotech companies are already our customers, at one part of the clinical research process or

another.

That being said, before we engage in any project, PAREXEL goes through a strict screening process to determine if it respects our ethical standards. If it does not, then we would not participate. Beyond that, we are keen to support any and all types of projects, from generic to first-in-class innovative drug development.

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