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16.01.2019

Tags: China, CRO, Fountain Medical Development, Research, Clinical Trials

Dr Dan Zhang, CEO of Fountain Medical Development (FMD), details the transformation China's recent membership at the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) will bring to the drug development and clinical research landscape in China, the pressures and opportunities local companies will face, the unique position of FMD as the partner of choice for international companies conducting clinical research in China and his ambitions for FMD to become the first global CRO headquartered in China.

One of the most significant highlights amidst China's healthcare reforms is China joining ICH in 2016 and subsequently becoming an executive member of the board last year. What impact will this have on the Chinese pharmaceutical landscape?

China became a member of ICH last year and this year, it became a major member of the executive regulatory committee at ICH. This has had a tremendous impact on the current research and development activities in China as well as on the globalization of China's pharmaceutical R&D sector. Now that China is a part of ICH, the Chinese biotech sector will be exposed to uniform global regulatory and technical development standards. Both clinical and pre-clinical data are mutually recognized among all the members of ICH, which allows us to speed up innovative

product penetration in the Chinese market.

At the same time, this also means fiercer global competition in the domestic market as all innovative products can now enter the Chinese market. A remarkable example is Merck's new HPV vaccine, which was given a conditional green light by the then-CFDA (now NMPA) just nine days into its review, compared to the ten years it took for the previous version and for GSK's own HPV vaccine! Naturally, the true beneficiary of this change are Chinese patients. In the past, they might have needed to travel to receive innovative treatments – if they can afford it – but now, the whole society can enjoy high-quality innovation as a more affordable price.

The consequence, however, is that Chinese innovative players, now subject to global competition, now have to consider how to survive and compete in their own country. The positive thing is, yes, in the short turn, it will bring more challenges to domestic firms but in the long run, it will strengthen the industry and allow R&D-focused Chinese companies to grow. It will also lead to local companies taking a step forward and starting global operations in order to survive, regardless of their readiness towards international expansion.

My prediction is that in only another few years' time, the Chinese market and regulations will be significantly different from today's picture. We all have to adapt. It is also why only R&D companies with international operations will be able to survive as they will have global capabilities to support them.

The environment is clearly getting more competitive. What challenges or opportunities does this change bring to a company like Fountain Medical Development, which is a Chinese CRO focused on helping innovative companies conduct clinical research to international standards?

Fountain Medical Development is a local Clinical Research Organization (CRO) founded in 2006. By that time, many global CROs were already in China such as Covance and Quintiles. I knew these global CROs well as I had previously been with Quintiles myself. At that time, I asked myself, why does China need another CRO?

In order to succeed, we found a market niche that had been overlooked by both foreign and local companies. Global CROs often worked mainly, if not exclusively with MNCs, because their prices were not affordable for local companies. On the other hand, domestic CROs were only serving local companies for domestic trials that focused mostly on generic products, as they lacked the

capabilities to conduct global multi-centre trials.

Therefore, I created FMD to answer the needs of innovative, single compound companies entering the clinical stage. They are mainly local and international start-ups that are not fully established yet so most of their financing comes from the government or grants. Normally, they would be looking to start phase I clinical trials. FMD, therefore, positioned itself as the strategic partner for such companies specifically.

At that time in China, there were not as many such companies as there are now, so we mainly focused on government R&D and innovation programs in the first few years. We also obtained government financial support to start its activities while attracting other private investors as well. This allowed us to advance to the next level with our limited resources.

Our second unique advantage is the globalization of the company. From the beginning, our goal was to work internationally. This was partly driven by necessity as at the time, China was a smaller market with less homegrown innovations. Therefore, we soon opened offices in Hong Kong, South Korea and Taiwan. Subsequently, we acquired small companies in both the US and the UK.

Today, thanks to our dual strategy of organic growth and acquisitions, we now have more than 1,700 employees in 20 locations worldwide after 11 years in the industry.

What is the next stage of growth for the company now?

Our fundamental value proposition is that we serve our clients with innovative, high-level capabilities at affordable pricing. This was how we started and it remains the core of our business today. We understand the budget constraints small innovative companies are facing when doing clinical research. We have an international presence as well as comprehensive knowledge of the Chinese market. Therefore, we believe that we are in a very unique position to help Chinese companies go global – and to help global companies enter China.

We are now approaching our market through the prism of ICH. Firstly, we want to help more local companies expand internationally as it will be a decisive step for their success.

However, we are now focusing on a new niche. The whole world is looking at China now. We want to bring more global companies into China, especially from the USA. I am speaking about the same kind of single-compound, innovative biotech companies that we had previously served, but this time focusing more on the US or even Europe. Previously these companies would see China as too

large or difficult a market for them to enter directly, so they would out-license their products to the MNCs or to local Chinese companies. However, with China standardizing their clinical research systems and processes now through ICH, they now have this new opportunity to conduct trials in China themselves without necessarily having to establish their own Chinese affiliate.

This is where FMD can help them. We know the China market extremely well and we are familiar with international standards. We are able to offer the services and solutions to help these companies enter the Chinese market.

We see that many global and even successful local Chinese companies like Wuxi AppTech have a very diversified offering. In the new environment, what do you see as a successful business model for Chinese CROs?

This is indeed the case, and Wuxi AppTech has a great business model. Clinical research is, however, the main focus of most CROs. As the largest outsourced segment in the world, we can see that out of the top ten global CROs, eight are focused on the clinical stage.

At FMD, we want to use our resources to the best of our capabilities and our team is specialized in clinical research. We know what we do very well. I want to maintain this clear focus. In any case, the market is big enough for different players.

I see that we also have much-untapped potential in the newest therapies being discovered like gene therapies and immunotherapies. What is striking is that many, if not most of them, have not yet been tested in Asian populations, so there is a huge need for clinical trials to be conducted in these markets. In particular, as China is now the second-largest pharma market, this need will only grow. Considering future growth, China might become the largest market in the next five to ten years. Multinationals need to do clinical trials here.

In this space, FMD is also the best partner for these companies as we have a proven track record of success working with both multinationals and smaller companies. Around 60 to 70 percent of our clients now is with multinationals. Over the last 11 years, our approval rate for New Drug Application (NDA) in China has been excellent; amongst the over 150 applications, we have received approvals except in one instance.

It is old thinking to assume that you should automatically go with the global CROs. Now China is open. In this new arena, it would not be wise to automatically dismiss China as not a global player. For instance, this year, the Chinese government invited 48 products deemed to be “clinically

urgently needed new drugs” to apply for NDA without any clinical trials data required! Some were from MNCs but some are from smaller, orphan drug companies like Biomarin as well as biotech companies like Spark Therapeutics. China is opening its arms to the global pharmaceutical industry – so why should companies say no?

Do you have a final message for our international audience?

There is huge potential in China because we have such valuable resources. Firstly, we have to use China’s membership at ICH to welcome more innovation in the country. China was isolated before ICH but now it’s a new game. We want all of our clients to know that it is the right time to come to China and that we can help them be successful. FMD is welcoming all companies and we know China better than any other global company.

Secondly, we should take advantage of China’s vast patient population. If you think about it, China is over 20 percent of the world’s population. We have more patients in China that in the USA, so it can be an even better place to conduct research than the US. Patients are a unique resource that cannot be replicated so China should use that advantage.

Finally, our ambition now is for FMD to become a global CRO that is headquartered in China!

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