CERTARA

Be Honest, Be Reliable, Be Human: Insights from a Global Drug Development Expert

By Suzanne Minton

One of the most exciting things about working in the pharmaceutical industry is the ability to meet and work with colleagues all over the world. In particular, China is one of the fast-growing centers for drug development. Indeed, a report from McKinsey last year estimated the Chinese biopharma market to be worth $130B. I recently had the chance to interact with someone with deep understanding of this topic, Dr. Ye Hua. He is currently the Founder and CEO of BioNova Pharmaceuticals Limited in Shanghai, China but has spent time as a senior clinical research physician at pharma companies in the West including Celgene, Novartis, and AbbVie. Here are the highlights from our conversation.

Suzanne Minton: How have you found the transition from working in large pharmaceutical companies in the US to smaller pharmaceutical companies in China?

Ye Hua: The transition is exciting and challenging! This is because innovative drug development is relatively new in China, and there is a lot of work needed to catch up to Western countries with long track records. Smaller biotech/biopharma companies can move projects quickly and efficiently, and it is even more so in China thanks to its culture. On the other hand, the limited talent pool of scientists and developers becomes the bottle neck of new drug development in China. Over the past few years, many entrepreneurs have applied their knowledge and experience from the past and built up start-up biotechs in China.

SM: You have worked in American and Chinese drug development companies. Are there any notable differences in the approach to drug development between American and Chinese companies?

YH: I worked for 16 years in global large pharmaceutical companies in North America, and then have spent the last 6 years in the Chinese biotech industry in Shanghai. The difference is huge in terms of development strategy and business conduct. At a high level, global large pharma companies tend to nail big indications and dare to bet on novel agents. Whereas in China, most start-up companies or even public biotechs usually adapt to a “fast-follow strategy” to de-risk potential development failures. In addition, the in-license business model has been widely implemented by many Chinese start-ups to jump into the clinical stage of development.

SM: What are some major regulatory trends coming out of China's health authority, the National Medical Products Administration (NMPA)?

Ye: The goal of NMPA's policy reform is to encourage innovation and to speed up drug development. Because of this, more and more new regulatory guidelines have been released over the past 2 years. The new drug application process now uses the same criteria for all applicants, regardless of whether they are domestic or foreign companies.

SM: In November, Certara opened an office Shanghai's Pudong District, China's epicenter for biopharmaceutical research and development (R&D). Do you have any comments about this move?

YH: I think Certara having an operation in China is a sensible strategic decision. In the past few years, Chinese biotech start-ups and domestic pharma companies have advanced early discovery/basic research projects to the clinical stage of development. With an increasing appetite for securing licensing deals as well as more demands in drug development and DMPK [drug metabolism and pharmacokinetics], Certara can fill the gap for many companies lacking relevant expertise.

SM: What do foreign companies get wrong most frequently when seeking marketing authorization for a drug in China and vice versa?

YH: There are multiple reasons that foreign companies fail to attain marketing authorization for their products in China. Some of the most common reasons include 1) when the global trial is being submitted to the NMPA, standard of care differences between the two regions cause trial design and outcomes to get different regulatory opinions. 2) failure to show that a drug has no racial or ethnicity differences for its efficacy, safety, or PK between Caucasian and Chinese populations.

SM: What advice would you give to a drug developer just starting out in his or her career?

YH: Learn whatever it comes in your path although it may appear irrelevant to your job. Never stop learning. Be wise and brave enough to seek help when you need it.

SM: Having worked with the Certara team for many years, can you comment on the value that they bring to their clients?

YH: Certara delivers a high level of professionalism that can be an excellent external resource for supplemental knowledge and skills for start-up companies as well as enhancing the quality and overall expertise for large domestic pharma companies. We appreciate Certara's customer-focused mind-set and rely on its wealth of knowledge and expertise in asset due diligence, DMPK and other drug development-related fields.

SM: Is there anything else that you'd like us to know about you?

YH: My motto which is "be honest, be reliable, be human."

I really appreciate Dr. Hua sharing his perspective with us. From my own experience, I would agree with his advice to seek help when you are truly lost at work. You can waste a whole lot of time and energy trying to figure things out that someone else might easily have the answer to. And being honest, reliable, and human is a great reminder that character and integrity are just as important to be a successful drug developer as technical knowledge. To learn more about how Certara is supporting rapid growth and collaboration with customers in China to accelerate biopharmaceutical R&D, please read this press release.
https://www.certara.com/pressrelease/certara-opens-new-china-office-in-shanghai/

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