Edward Wang – Chief Production Officer, Sirnaomics

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The Guangzhou production site of HKEX-listed RNA therapeutics biotech Sirnaomics is overseen by pharma industry veteran Edward Wang. Here, Wang explains his contribution to the development of good manufacturing practices (GMP) in China and why southern China makes sense as a manufacturing location for a local biotech with global ambitions.

You worked overseas for several decades before deciding to return to China, what was the reasoning behind this decision?

I was fortunate to have been around when the Chinese government put in place policies that opened up the country and its people to the world. My first foray into the international ecosystem was travelling to Japan for two study trips for chemical engineering training, which was funded by UNESCO, after I was selected as a young scientist by the Chinese Academy of Science. After this, I went to the US in 1987 as a visiting scholar and completed my PhD and postdoc work in biotechnology in 1998.

However, it was only through working in industry that I grew my expertise in Good Manufacturing Practices (GMP), which is my primary focus today. I worked in both Big Pharma and biotechnology companies with a focus on the manufacturing process, mainly on the engineering side of things, and gained familiarity with the techniques required in bioprocesses. Chinese scientists tend to be excellent at research and publishing, but often lack an understanding of the product and how it can

be manufactured in a GMP manner – making my experience and knowledge particularly valuable in a Chinese context.

What benefits did all these experiences bring to the local manufacturing landscape?

In the past, China's regulatory environment for manufacturing was substantially less advanced than the Western world, and China had limited knowledge regarding how to manufacture biologic therapies. As mentioned earlier, China was advanced in publishing world-class papers in some areas, but not advanced in the manufacturing process control. When I came here in 2012 there were no US FDA-approved biologic manufacturing plants. WuXi Apptech had selected me as a consultant to help develop a contract manufacturing site and get it up to the required standards. By 2017, WuXi was able to produce the first-ever Chinese-made and US FDA-approved biologic treatment.

All this has led me to the role today as chief production officer of Sirnaomics, with responsibility for the firm's Guangzhou production site. Once you enter the industry, you see that building products from the ground up is a very rewarding process.

Manufacturing expertise is becoming more important as the production process becomes more complex. Tell us a bit more about the technology at Sirnaomics.

We are in the small interfering (silencing) RNA business, or siRNA, an area which is still unproven in terms of being druggable. There are several RNA drugs on the market, but with our platform we will select a dual target. We have two delivery platforms in the company, the first is our proprietary polypeptide nanoparticle (PNP) platform and the second is our novel GalNAc delivery platform.

Our PNP has become very advanced in early-stage clinical development, and we had a meeting with the US FDA in May to complete phase 2b and move onto phase 3 clinical trials. There are difficulties from an engineering side of things, and we need to establish processes for regulatory compliance, quality control, release specifications, and stability testing. We already have confirmatory studies in the plan and now we must move onto a larger population in phase 3 to give clarity to the FDA.

Guangzhou is home to Sirnaomics' pilot plant clinical manufacturing facility. This facility's production capacity is sufficient to support planned clinical trials and demonstrates our feasibility

to scale up for commercialisation.

An issue in the past for nanoparticles was stability. Has this been resolved?

Yes. We have actually published data for nanoparticles and shown at the clinical site that drug modality is stable for many months in storage and for a good number of days within clinical sites. This is required for certification to move into commercialisation, and this is why we were able to plan for the phase 3 and the larger population group.

What are the major differences between the US and China when setting up a facility?

Having built my experience in the US, I learnt that it does not matter who you are, you must always be learning and be an expert to stand out. When I came here to work with WuXi I was able to guide them through the process of US FDA approval. One of the key advantages in China is that things happen quickly, and so once the decision was made to construct the site, it was done rapidly.

When you look at Sirnaomics we are only in the pilot scale clinical manufacturing stage, so for the last two years we have been focussed on training staff and putting systems in place for the future.

Why did you choose Guangzhou as the location for your pilot site?

If you look at other parts of China, the South of the country has always been the most open to the rest of the world, having a close proximity to Hong Kong and Macau. This makes us more attractive in terms of employing and working with foreigners and doing business abroad.

At the start we had clinical R&D in another part of China, but the local government in Guangzhou has given us incentives to conduct business and has given us their backing and support. This is critically important when dealing with complex industry projects like pharmaceuticals.

Another point to consider is that the lifeblood of the pharmaceutical industry is talent, and this region has a solid history of attracting people and helping them blossom and grow, so this is an important factor as we evolve as a company.

All in all, the government has seen that they must look ahead when investing and our initial business setting here was made in 2011/2012, but the lifecycle of investors in pharmaceuticals is

long, and today we are seeing the results of this patience. Furthermore, this government support has seen the proliferation of private investors in biotechnology in the region, looking to fund start-ups coming from hubs like the Guangzhou International BioIsland.

The Guangzhou International BioIsland is one of many such investment parks in China. What benefits does it bring for start-ups?

Companies that are here get subsidies on the land as they look to develop. The island itself is not isolated but provides other services such as training centres for medical doctors and training for certain processes, while providing a facility for clinical research. Furthermore, the government provides laboratory resources for materials and animals. Local universities on the island have connected with companies such as Sirnaomics and offered to provide use of their academic facilities for a much lower rate. Connections have also been made with local hospitals so that companies can develop translational research to enable products to be brought into the local healthcare system.

You are right that there are many parks in China, and it is very competitive, so the island aims to be a catalyst for these companies' growth by providing services and subsidies so they can focus on creating innovation for the marketplace, and hopefully becoming a commercial success in the long term.

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