Injectables for the Chinese market manufactured to Western standards

Stuart Rose, founder and CEO of **PaizaBio**, discusses the opportunities for growth in China and a new approach for rapid entry into the country's growing sterile injectables market.

How did you become interested in China?

Stuart Rose: Most of my pharmaceutical career has been spent in manufacturing and logistics outside of the US, including 18 months in Moscow managing networks of manufacturing facilities. The most valuable lesson I learnt is that forcing US systems, methods and values upon operations in other countries does not work; you have to learn to do business their way. I became interested in China 25 years ago, and committed myself to acquiring a deep understanding of how China does business and making connections so that I could start a contract manufacturing business there.

The global pharmaceutical industry is currently focused on China. What is driving this interest?

First and foremost is the sheer size of the population. With 1.4 billion people, China is larger than North America, South America and the European Union combined. It's now the third-largest drug market in the world, valued at $150 billion. If it continues its double-digit growth rate, it will be equivalent in value to the US as early as 2021, with a projected market value of approximately $570 billion.

What's also compelling is that China's expansion comes at a time of stagnant, and in some cases contracting, volume growth in the US and Europe, where maturing products – lucrative drugs coming off patent – and the reality of paying for the healthcare of an aging population threaten traditionally strong sales. Global pharma knows it has to be in China, with market-specific offerings, to maintain healthy balance sheets.

What's stopping Western companies from entering the Chinese market?

There are a number of global pharmaceutical companies already manufacturing in China, although they are largely focused on APIs and oral products for export. Exceptions are Novo Nordisk, Lilly and Bayer, which are making insulin in China for China. A number of things hold Western companies back. Like other countries, China has its nuances in culture, how it does business and in its regulatory system. If a company expects to enter the market following Western practices, they won't be successful. It's very expensive to 'greenfield' a new manufacturing facility and staff it with a knowledgeable local workforce. The Chinese Government is also putting pressure on drug pricing.

Western companies must think very carefully about how best to enter the market, and they must understand that, to be successful, they will have to learn to do business the Chinese way while incorporating Western best practices.

With 1.4 billion people, China is larger than North America, South America and the European Union combined. It represents a significant opportunity for Western pharmaceutical companies to manufacture and market in China.

PaizaBio's CMO partner, Ausia BioTech, has an annual capacity of 300 million units – vials, cartridges and syringes – of sterile injectables at its sophisticated production facility in Hangzhou, near Shanghai.

You are launching a new Chinese contract manufacturing organisation at CPhi in Madrid. What is the vision behind PaizaBio?

In the 13th century, Emperor Kublai Khan presented Marco Polo with a golden paiza that assured the Venetian merchant of safe travel across China. We adopted the paiza as our brand as it reflects what we're offering Western companies: safe entry into the Chinese sterile injectables market. PaizaBio serves as the strategic partner to Western companies that want to rapidly establish a manufacturing presence in China with a minimum of risk and produce sterile injectables for the Chinese market to Western standards. To my knowledge, other than insulin, no other Western company is producing sterile injectables for the Chinese market in China, so PaizaBio represents a significant opportunity.

What are the advantages of working with PaizaBio in China versus starting one's own manufacturing facility?

Establishing a new manufacturing operation in China is costly, time-consuming and risky. PaizaBio has a deep knowledge base of China's manufacturing and regulatory requirements, and a two-decades-long presence producing sterile injectables via Ausia BioTech. Our clients will enjoy rapid entry to the Chinese market with no significant capital outlay, and with a partner that provides manufacturing innovation and quality products that meet China's regulations, in the formats and packaging the market prefers. We envision that some drug companies will want an ongoing relationship, while others will use PaizaBio to test the market before constructing their own manufacturing operations.

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Can you explain PaizaBio's relationship with Ausia BioTech?

I met Ausia BioTech's founder, Shaofeng Huang, in 2008. In under a decade, he built Ausia BioTech into one of the most respected manufacturers of sterile injectables in China. Huang is a visionary: he realised that China couldn't compete long term on price alone and asked for my advice on how to make Ausia BioTech able to compete globally. What began as a consulting relationship evolved into mutual respect and trust. When I created PaizaBio as a portal to the Chinese drug market, Huang and Ausia BioTech were natural partners.

Stuart Rose
Stuart Rose is the founder and CEO of PaizaBio. He has over 40 years' experience in the pharmaceutical industry with extensive direct experience in the sterile injectables contract manufacturing space.

What is PaizaBio's scope of services?

PaizaBio offers complete fill-and-finish services for sterile injectables in a state-of-the-art facility in Hangzhou, which is just an hour away from Shanghai. This includes aseptic filling of vials, syringes and cartridges, with a daily volume in excess of one million units; lyophilisation using sophisticated processes, including a cycle-time development lab that helps to dramatically reduce cycle time and costs; analytical and validation services; regulatory support; and packaging and warehousing.

Sterile injectables require exact manufacturing processes. What is PaizaBio doing with regard to quality assurance?

PaizaBio is manufacturing to Western standards – there is no compromise. Firstly, we invested $8 million in the Trans-Pacific Aseptic Institute of Training (TPA-IT), a university of sterility on Ausia BioTech's campus in Hangzhou, where our employees, along with the Chinese FDA, learn the principles of sterile manufacturing, quality management and regulatory compliance through lectures and hands-on training in a full-scale training facility.

Secondly, we have implemented the pharmaceutical industry's most comprehensive real-time remote management execution system. The Bioanalytical Operations Global Observation and Navigation Guidance System, which we call BAO-Gong, is based on Hitachi's technology, and enables clients anywhere in the world to monitor the manufacture of their product in real time via live video feedand equipment monitoring just as if they were present in our operation suites. Simply stated, we enable a virtual, real-time person in the plant.

Finally, we have a team of Western and Chinese alliance managers who work closely with clients throughout the engagement to ensure complete confidence and the desired end results.

Where do you see PaizaBio in a year? And how about in five years?

By this time next year, we will have Western companies using our production at our plant in Hangzhou. In five years, we will have multiple production facilities in China, with an expanded CMO service offering and many Western clients enjoying success in China. ■

Further information
PaizaBio
www.paizabio.com