HE Ming – CEO, SAPS, China

Maintaining quality standards is not just about having the right regulations or knowhow, it boils down doing the right thing every time, day in, day out

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HE Ming, founder and CEO of Sino-American (Suzhou) Pharmaceutical Services (SAPS), shares his commitment to bringing international quality standards to the Chinese pharma industry, the comprehensive portfolio of quality management, verification and compliance services SAPS offers to the pharma, biotech and medical device industries in China and the US, as well as the importance of employee mindset when it comes to maintaining high-quality and safe manufacturing practices and processes.

Mr He, could you briefly introduce SAPS to our international audience?

We are a service provider to the pharma industry, focusing on offering comprehensive quality management, verification and compliance services for the pharma, biotech and medical device industries. Our mission has always been to provide value to our clients and to keep them happy. When I first returned to China in 2009, my goal was to help the Chinese pharmaceutical industry improve their quality systems. However, it has certainly not been an easy journey over the past decade.

Looking back at our beginning, I would say the biggest challenge was the mentality of the industry here. Ten years ago, even if Chinese companies considered quality to be very important, they were more reluctant to pay for the services of a quality systems consultant. They would be happy to invest a significant amount in heavy-duty equipment from international brands but would not

consider paying a premium for services. This was partly due to the labour-intensive nature of Chinese industry and the relatively lower costs of labour in China. The market was not necessarily used to paying for someone's expertise or experience. Therefore, it took a number of years for SAPS to convey our value to the industry.

As a result, we focused more on multinational companies as well as smaller, more innovative companies, both of which were more used to working to international standards.

In the past few years, with the Chinese pharma industry developing rapidly, the environment is certainly changing and I see even more opportunities for SAPS to offer our services to the industry here.

What kind of services or solutions can you offer to the industry?

We offer a comprehensive range of services that meet both US FDA and MNPA GxP policies and regulations. A recent change in regulations in China relates to the Marketing Authorization Holder (MAH), which allows for companies to use third-party or external manufacturing facilities to produce their drugs. This means that they would not need to invest significant resources in managing their own manufacturing facilities. However, they would need to audit or assess the third-party facilities to see if the site meets their requirements. This is where we can assist. In many cases, we can also offer our expertise to companies to help them establish their own quality management systems and related processes. We are already working on such projects for both innovative Chinese biotechs as well as pharma MNCs in China.

Today, there has been an explosion in innovative Chinese biotech companies. To take a specific example, looking at companies with PD-1/PD-L1 products alone, we already see many. Some of them are looking to export to the US and other international markets. Quality is fundamental, in that case. We can help these companies ensure that their manufacturing facilities and products meet international quality standards. For instance, just today, I was at a client's factory to help them prepare for an upcoming US FDA inspection.

In addition to companies, we are also hoping to work with local FDA and government bodies to support their regulatory work. Particularly with all the regulatory changes, we can help municipal and local government entities change their processes in line with the new regulations more in line with international standard, train their employees and develop their internal operations.

Another group of clients we work with is not-for-profit organizations and patient associations. For instance, we have worked with the Bill and Melinda Gates Foundation to inspect and improve the quality systems of the local manufacturers they are working with, to meet WHO standards to deliver women health products to African countries.

Would you say that the overall quality systems and standards within the Chinese pharma industry have improved over the past decade?

Undoubtedly! The entire industry has certainly come a very long way. Companies and employees have gained a lot of knowledge and experience over the past ten years. This is very positive. That said, maintaining quality standards is not just about having the right regulations or knowhow, it boils down doing the right thing every time, day in, day out. You have to have the right mindset and mentality, which is not always easy.

The challenge in recent years is that in the past, China had tended to follow European industry regulations and practices but now we are much more aligned with the US. US regulations tend to be much more principle-based. Instead of telling companies a specific process to follow, they lay out key principles. This can make it challenging for companies to follow if they do not have enough experience to interpret the regulations accurately.

For instance, there is a component called ‘data integrity’, which has become a rather common issue. Data integrity is not a new concept but just been emphasized recently, and it means data need to be attributable, legible, contemporaneous, original, and accurate, which ensures the product’s quality and safety. The principle is clear. However, companies sometimes struggle to implement this without clear processes. The bottom line of the matter is that if all employees maintain good record-keeping practices during the entire process, there should be no problems at the end when it comes to ‘data integrity’. Of course, this is harder to implement in practice.

You mention that when it comes to quality, the right mindset is very important. What kind of training programs can SAPS offer to your clients to inculcate the right kind of mindset?

Changing the mindset of employees is not an easy task. SAPS does offer training programs to companies. In addition to improving their quality systems and processes, we will also train their employees in the right way of doing things. After the training program, we will stay and observe

the employees for a period of time so that we can make any corrections if necessary. We will usually also follow up with them a few months later to see if the changes are still being implemented.

With the Chinese pharma industry growing quickly, how do you expect SAPS to expand and grow in the future?

We certainly hope to expand in the next few years. At the moment, when the need arises, we also work with other industry service providers to deliver projects for our clients, particularly if they are larger or require other types of services. We have collaborated with many of our peers within the industry – in that sense, they may be competitors but they are also collaborators! This enables us to deliver the best service and value to our clients.

With the industry in China changing so quickly, we must always stay on our feet and adapt. All the recent regulatory changes and developments are positive for the Chinese industry, and I hope we can support the industry in meeting international quality standards and requirements, as China looks to develop a world-class innovative pharmaceutical industry.

Where would you like to see SAPS in the next few years?

My mission for SAPS has always been to bring my international experience and knowledge of quality standards and management systems to benefit the Chinese pharma industry. Today, the pharma industry is so global. The Chinese and US pharma industries are interlinked. To manage this global supply chain network well, both countries' industries need to be well-integrated, and standards should be aligned. This will benefit drug discovery and development, manufacturing and distribution – and at the end of the day, patients.

I hope that SAPS can continue to be a bridge linking the US and Chinese pharma industries. At the moment, we are still a small company but I look forward to growing further over the next few years so that we can better support our clients and partners, across the pharma, biotech and medical device industries in China and the US!

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