Published on *Controlled Environments Magazine* (http://www.cemag.us)

The China Quality Challenge

Bikash Chatterjee

After a recent trip to China, I returned more impressed than ever with the rapid level of development within the major markets there. The maturity of the infrastructure in place, ready to support global commerce, was something I was not expecting.

Much has been said of China's commitment to developing and competing in the world market for the regulated life sciences. A recent market analysis ranked China as the top destination in Asia for Big Pharma (2008 PricewaterhouseCoopers report "The Changing Dynamics of Pharma Outsourcing in Asia: Are You Readjusting Your Sights?"). While both clinical trial activity and investments by pharmaceutical companies to expand their presence in Asia are accelerating, the report suggests that Asia outsourcing is moving up the value chain. Low-cost production is eclipsed by a broad range of factors, including market potential and R&D capacity, as the new drivers of growth.

Still, with all the hype surrounding China's low-cost manufacturing potential, Big Pharma is not really looking to China for low-cost manufacturing for the global market, but rather for early discovery. The phrase "made in China" is evolving to "discovered in China."

This evolution is due in no small part to the recent quality issues associated with Chinese API suppliers and manufacturers. The grave quality issues related to the willful adulteration of Heparin by a key API supplier for Baxter and the very high profile Melamine adulteration of milk, a key ingredient in baby formula for the world market, have raised serious concerns about the viability of China to compete in the U.S. and European markets.

To date, China's regulatory authority, the State Food and Drug Administration (SFDA) has developed many of its cGMP and related regulatory guidance based upon transgressions by manufacturers within their own market. The result is an amalgam of recommended best practices that, in many cases, make sense theoretically but are difficult to implement practically. Unlike the U.S. guidance for good facility design, which is based upon pressure cascades as a foundation for preventing crosscontamination, or the European guidance philosophy of escalating air quality, the SFDA's guidance does not follow a single rationale or approach.

Now, the SFDA has proposed a new set of cGMP guidances that closely resemble WHO and European guidance which will be issued formally in January 2010. This new guidance attempts to lay a foundation for quality systems that will be consistent with the requirements of the world market.

CHINA'S QUALITY HURDLE

The challenge facing China is broad quality education. The new SFDA cGMP guidance

could easily provide the direction the industry is looking for, with regard to what must be established to build a compliant quality system: but it cannot always describe how to achieve it or — more importantly — why it is necessary. This last element is the greatest obstacle to China's ability to establish a consistent quality philosophy. It is impossible to establish a "critical to quality" attribute if you can only think of quality in terms of meeting specifications. Not so long ago, much of China's compliance oversight was tainted by corruption. It took several high profile casualties within the country to bring embarrassment to the government's efforts to establish credibility as a regulating authority and to crack down on this practice. The march toward cGMP understanding may have been further hampered by sixty years of communist structure, in which personal accountability was absent from the culture. Until a foundation of understanding quality is firmly established, it will be difficult to have confidence in any product manufactured there for the global market.

CHINA'S CHANGING SOCIAL FABRIC

China's economic reform has brought about a brandnew society, in which people with fortune and a background of good education have quickly found their positions and formed the middle class in China. The knowledge-based economy in China today, in conjunction with the central government's strategy of constructing the country with science and technologies, has boosted the rapid development of higher education, which is the incubator of the middle class.

According to a report by the Chinese Academy of Social Sciences, China's middle class will be remarkably expanded in the coming eight to ten years. Of the estimated 80 million people that currently make up this emerging middle class, that number is slated to swell to nearly 290 million people by 2011. However, such exponential growth comes with a price. China's focus on profit and growth is creating a capitalist engine unlike anything the world has ever seen. While there are alternatives for raising capital within the current economic environment, large capitalization requirements are, more often than not, achieved through an IPO strategy. The added pressure of shareholder performance further catalyzes the drive for financial performance. One interesting consequence of adopting an IPO strategy in China is the requirement to establish a heightened level of social obligation. It is important to remember we are dealing with an agrarian economy in the midst of a transition to a major industrial economy. Many people in the more rural areas are not familiar with how to use westernized medicine. They may not understand what an expiration date means or what an overdose is, for example. These are tangible risks to any company that goes public and risks the ire of the government if a broad quality issue were to arise.

The difficulty in China is that it is only now beginning to form its social conscience. Senior executives struggle to define a quality vision that resonates with their staff and that can be reconciled with the still fresh mandate for profitability. While this is to be expected to some extent, the key hurdle yet to be overcome is executive understanding of the role quality plays in business performance and profitability. For example, senior executives may want to create a unified vision that can serve as a foundation for quality, their motivation may not be public safety, but rather fear of government retribution.

Bikash Chatterjee addresses attendees at conference hosted by Pharmatech Associates in Shanghai. The conference focused on new regulatory guidelines issued by the People's Republic of China's State Food and Drug Administration (SFDA) and how corporations can comply with such regulations.

NEXT STEPS

If China is to compete in the global marketplace several things must happen. First, executives must be educated on the critical role quality plays in the regulated life sciences in terms of business performance. The massive shift towards Operational Excellence in Europe and the U.S. is testimony to this reality. Second, there must be a willingness to invest in systems and expertise that can harness China's growing intellectual horsepower and gather empirical experience within the country. Gaining a thorough understanding of why quality systems are important, not just what systems are required, is critical to generating a culture of excellence.

If these two steps can get traction within the Chinese marketplace, coupled with the new SFDA guidance, parity may be possible with westernized companies. Until then, it will be difficult for China to compete in terms of quality in the global life sciences marketplace.

Bikash Chatterjee *is the president of Pharmatech Associates, Inc. He has been involved in the bio-pharmaceutical, pharmaceutical, medical device and diagnostics industry for over 20 years. His expertise includes site selection, project management, design, and validation of facilities for both U.S. and European regulatory requirements.*