Chinas Bold Step Toward Parity

Chatterjee discusses the factors driving China's transformation from low-cost manufacturing to more sophisticated quality matters.

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I have made several trips to China in the last year to provide training and guidance to large and small pharmaceutical companies. After each trip I have returned with a renewed respect for the economic transformation taking place there. This is a country in transition.

Construction in the major cities continues at a feverish pace. In Shanghai, new hotels are erected seemingly overnight and construction continues 24 hours a day, rain or shine. The drive to push forward comes partially from an indigenous workforce that has never known the comforts this new society can provide, and from the government mandate that all construction be completed by March 2010, three months prior to the World Expo in Shanghai. Transformation has become almost commonplace, but this did not happen overnight. The government is on its 11th five-year plan to change China into a world power that can compete in the global marketplace.

The approach has been methodical, recognizing that to foster sophisticated market sectors like the pharmaceutical industry, it is essential to have a strong academic foundation that supports both innovation and the drug development process. China's Project 211 and Project 985, two significant initiatives from the 9th five-year plan were geared to creating universities which could compete on a world scale, targeting over 100 different institutions to improve the quality of education, scientific research, management and institutional efficiency. These elements would lay the foundation for a workforce capable of supporting the rapidly developing pharmaceutical industry in China.

The Chinese government has declared that it wants to transform the economic basis in its manufacturing sectors away from low tech industries to focus on more sophisticated industries, specifically the pharmaceutical industry. For a culture with a long and entrenched history of folk remedies, this is a significant statement. In January 2010 the SFDA, China's regulatory authority, took another major step forward. Attempting to close the gap between the U.S. and European quality and regulatory standards, they issued a new and updated GMP guidance called GMP 10.

Underscoring the rapid change in China's pharmaceutical market sector the last GMP Guidance—GMP 8—was issued less than two years ago. This new guidance is a significant departure from the previous guidance which largely reflected rules and regulations borne from cumulative experience within the Chinese marketplace. It borrows heavily from European guidance for finished drug products and has been in available in draft form for several months soliciting comments from within and outside China.

The new guidance is significant because it places great emphasis on the quality management system, specifically on the need for Deviation Control, Corrective Action and Preventative Action (CAPA) systems and a Product Quality Review (PQR) system. This may seem like a small point at first, given our familiarity with the importance of these systems in establishing an effective Quality Management System (QMS). However, these systems are largely a foreign concept in the current Chinese pharmaceutical QMS. In addition to the GMP 10 guidance the SFDA has also created an annex to the main guidance which specifies the requirements for sterile API, sterile manufacturing and terminally sterilized product. What is interesting about this document is the specific requirements called for concerning facility design and environmental conditions.

To date, the GMP guidances have relied on a general discussion of the end result, e.g.: "*Article 6, Annex*

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1; The Manufacture of products should be carried out in clean areas, entry to which should be carried out through airlocks for personnel and/or equipment and materials." This has allowed each inspector to interpret the requirements as they saw fit for each manufacturer.

The big question looming before us is this: can China develop a quality mindset that is compatible with the Western markets? Can they move toward a uniform expectation in terms of QMS and operational execution? The drivers for this evolution may not come from the SFDA alone. According to a report by the Chinese Academy of Social Sciences, China's middle class will be remarkably expanded in the coming decade. Of the estimated 80 million people that currently make up China's emerging middle class, that number is slated to swell to nearly 290 million people by 2011. While the demand for Chinese remedies remains strong and an integral part of the culture, the demand for high quality western therapies is escalating as this new middle class takes shape.

As the gap between the haves and have-nots widens, ultimately, fear of social unrest may be the most effective catalyst for change. In 2007, the Chinese government made a bold statement that it was not going to tolerate corruption in the SFDA when it executed Zheng Xiaoyu, the former head of the SFDA for taking bribes and approving an antibiotic that killed 10 people and allowed other substandard therapies into the market. In retrospect, the failure of the former SFDA chief can be partially attributed to trying too hard to enforce the GMP 8 regulations in place at the time. The enforcement strategy among compliance inspectors was unrealistic: it expected Chinese manufacturers and suppliers to rapidly transform their QMS and operating philosophy to comply with latest GMP regulations. The lack of coordination between the main office in Beijing and the regional offices scattered around the country exacerbated the problem which still faces the agency.

So, can China make the adjustment to compete on a playing field where quality and cost are equally important? One positive step is the government's decision to allow Chinese manufacturers and suppliers time to come into compliance. They are applying this enforcement strategy on a case-by-case basis. Internal communications within the agency indicate they intend to adopt a risk-based strategy for enforcement, focusing on high risk processes such as sterile API, sterile manufacturing and therapies critical to the health and well-being of the country.

This seems like a more prudent approach, but the devil is in the details. Despite the fact that China arguably represents one of the greatest capitalist engines the world has seen in a long while, it is housed within a communist government framework. This difference is substantial when compared to free-market governments and economies. Specifically, all companies, private or government-based, must live up to what the government calls "their social obligation." This is partially driven by the country's deep-seated fear of social unrest, which is so prevalent in the 11 five-year plans. The second driver is the clear mandate to not do anything that would disrupt the fastest growing economy in the world. This was the case with former chief of SFDA, and spawned too much international attention from a string of high profile issues ranging from pet food to counterfeit drugs.

There can be no doubt these are powerful motivators for change. But none of them speak to a foundation of quality. Until the manufacturers and regulators realize there is no other way to be successful than to do it right, the portent for change from GMP10 remains in doubt, and China's bid for parity will likely fall short.

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