Why China?

Growth in China high standard pharma manufacturing capability

The growing number of Chinese CMOs obtained US Food and Drug Administration (FDA) approval for their operations and completed good manufacturing practice (GMP) certification. Some CMOs operating in China have obtained approval from the FDA or COS gaining credibility for their quality standards. At the end of 2005, more than 5,000 Chinese drug manufacturers had obtained their Chinese GMP certificates 16. With an increased commitment to international standards, China CMOs are securing more outsourcing orders from big pharmaceutical companies. The commitment to Western standards is also being reflected in the modernization of plants, and moves to innovate through the development of technologies, such as PAT are necessary to ensure facilities are ready to meet future manufacturing needs.

The region has a large pool of educated and appropriately qualified talent with the ability to run manufacturing plants equaling western complexity and quality.

The significant cost advantage of CMO in China from 30% up to 60% of the cost in the Europe or US. China's attractiveness for API manufacturing has convinced companies like AstraZeneca to step up outsourcing investment. David Brennan, chief executive, said all "active pharmaceutical ingredients" (API) would be produced externally within a decade as part of his strategy of "maximizing the efficiency of our supply chain while maintaining the highest possible standards of quality and security of supply." The firm has set up a dedicated sourcing center in Shanghai.

Pre-clinical Development

The growing capabilities in pre-clinical trials in a wide variety of species and capabilities residing with government-sponsored institutes and privately owned companies. It is approximately 20 labs with good laboratory practice (GLP) certification; new regulations should boost this number.

Clinical Trials and Large Patient Pool in China

High-quality SFDA-approved hospitals exist
Several multinationals conducting global trials at Chinese sites
Low-cost and efficient enrollment compared with the United States and Europe
Trial approval times will improve in the future

China has large populations of patients who are able to participate in studies. Many such patients are 'treatment naïve', and therefore, fulfill the needs of many trials. Another key advantage of conducting trials in some Asian territories is that many hospitals or doctors are serving large numbers of patients. So companies can recruit more quickly from a smaller number of sites. By June 2008, China had 428 clinical trials registered on the website as under way and a cumulative total of 870 completed or ongoing trials compared with 737 in India.