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# ‘China is hungry,’ as drug innovation push continues

By Melissa Fassbender, 25 Jan 2016

**Certara’s new consulting firm will rely on modeling and simulation expertise to expedite the drug development process, as China commits to increasing innovation.**

*“In China, there are far fewer new drugs entering the market than in the U.S.,”* Christine Yuying Gao, MD, PhD., and Certara Strategic Consulting China president and CEO told OutsourcingPharma.com.

With 20% of the world’s population, China has only 1.5% of the global drug market.

The market it does have is currently comprised primarily of generic drugs, with generic drug sales representing 80% of all drugs sales in China in 2015.

*“However, the overall percentage of generic drugs is declining in China as more novel drugs are introduced,”* explained Gao – generics comprised 92% of the market in 2007.

Additionally, a recent announcement from the China Food and Drug Administration (CFDA) has introduced new procedures for drug registration and approval, demonstrating a renewed commitment to the drug industry.

**A push for innovation**

Over the past several years China has accrued a massive backlog of drug applications, and although the average review time was three years, some waited as long as eight years.

*“However, the China Food and Drug Administration (CFDA) is working hard to expedite the drug approval process,”* said Gao, and the process seems to be working.

The CFDA reported that it reviewed 9,394 new drug applications in 2015, which is 90% increase from 2014, and in addition to developing new drug approval guidelines, the CFDA is opening a second drug evaluation center in Shanghai to support its main office in Beijing.

*“Currently, there are only 120 employees in CFDA responsible for the technical review, while it receives approximately 8,000 to 10,000 applications each year,”* explained Gao. *“That is far fewer staff than the U.S. FDA.”*

A drug development talent shortage in China has also limited the country’s ability to innovate.

*“China is hungry for experienced research and development professionals that understand the drug development process, have a global view, and can talk the same language as their western partners.”*

**Feeding talent**

Certara Strategic Consulting’s headquarters in Shanghai will provide outsourced drug discovery and development modeling and simulation, and strategic pharmacometric services to biopharm companies, nonprofits, and regulatory agencies.

*“With the Chinese Government’s growing interest in developing novel products, Certara expects to see increased adoption of its modeling and simulation technologies in the drug development process,”* explained Gao.

The company will also leverage Centara’s relationship with the US FDA, which dates back more than 15 years.

*“Certara meets regularly with the FDA so they can collaborate and educate each another on the everincreasing applications for modeling and simulation in drug development,”* said Gao.

Additionally, the CFDA is already using Certara’s Phoenix software for bioequivalence and noncompartmental analyses.

The consulting headquarters are also located close to the CFDA’s new drug evaluation center in Shanghai, and is based in a free trade zone, which has tax benefits and also facilitates financial transactions between China and the US.

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