



NEWS

FDA To Issue Three Guidances on Biosimilars in 2011

Janet Woodcock, director of FDA's Center for Drug Evaluation and Research, announced that FDA would release three separate guidance documents on biosimilars "before the end of the year." In a report from *BioCentury*, Woodcock did not specify what issues the guidance documents will address, but FDA spokesperson Julie Zawisza explained that the guidances will "cover the most pressing scientific issues facing a manufacturer as they contemplate developing a biosimilars program." Woodcock made the remarks during a recent conference on rare diseases and orphan products in Washington.

AstraZeneca to Build New Manufacturing Facility in China

AstraZeneca is investing \$200 million in a new manufacturing facility, located in China Medical City (CMC), Taizhou, Jiangsu province in eastern China. CMC is regarded as the only national level, hi-tech development zone focusing exclusively on the biomedical field. According to a company press release, the new facility is the largest investment AstraZeneca has ever made in a single manufacturing facility globally. The site will produce both intravenous and oral solid medicines and should be completed at the end of 2013.

Astra Zeneca's facility will include a state-of-the-art manufacturing and supply site in the Wuxi New District; the AstraZeneca Innovation Centre China (ICC), which is a leading-edge translational science center that targets biomarker research into cancer therapies specifically pertinent to Chinese and Asian patients, in addition to other therapies; large-scale clinical development capabilities; and a broad network of collaborations with top medical and academic institutions. According to the IMS, the Chinese pharmaceutical market grew from \$10 billion in 2004 to \$41 billion in 2010 and is expected to grow to over \$100 billion by 2015.



Technology Identifies Genetic Disorders Linked to X Chromosome

A genetics team at Emory University School of Medicine has discovered a technology that allows the rapid and highly accurate routine sequencing and identification of the exons of the human X chromosome genes, reported Senior author Michael Zwick, Ph.D., in the Oct. 2011 issue of *Genomics*. Exons are all of the genes that are read out and made into RNA. The team's sequencing method does not read all the letters of the genetic code in the X chromosome from beginning to end, but it targets more than 800 exons.

The Emory team's experiments showed that their technique could read 97 percent of targeted sequences at high depth with an accuracy of 99.5 percent. *Business Wire* wrote that the method was developed in collaboration with RainDance Technologies, which has discovered a single molecule microdroplet-based technology that allows scientists to target up to 20,000 genomic loci in a single sample. Zwick is using the method to identify genetic variants that are a factor in autism spectrum disorders.