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China marches ahead with regulatory approvals

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After five years of amendments and two rounds of public consultations, the State Food and Drug Administration (SFDA) issued Good Manufacturing Practice for Drugs that came into effect on March 1, 2011. As per the guideline, the newly built drug manufacturers and the newly built (reconstructed or extended) workshops of drug manufacturers shall comply with the requirements of the new version of GMP.

Improving the situation of existing facilities, the SFDA has instructed that the existing drug manufacturers will be granted a transition period of not more than five years to meet stage-by-stage the new version of GMP in accordance with the product risk level.

In 2011, WHO did an assessment and declared that China is complying with international standards for biologics regulation.

Stringent steps taken by the SFDA indicate that China has dramatically changed its regulatory environment and the manufacturing facilities have to go through much stricter laws.

Commenting on the changing landscape of China, Dr Wu Ke from Shanghai BravoBio, says, "The new version of GMP is effective, which is quite close to European cGMP and also the International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use guidelines in most aspects. With the development and globalization of the Asian economy, more and more countries will upgrade their regulatory system adapting to the demands of

new technology and higher standards."

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He adds that the ICH may gradually open its gate wider to other parts of the world, including Asia, and "the whole world can comply with a single standard for biologics manufacturing, such as the ISO system".

Sharing a brighter side of China's regulatory compliance, Bio Plan Associates shares that Chinese biologics are approved for export to Africa, Middle East, Nepal, and some other countries. However, China is not exporting to developed regions, because it does not qualify the cGMP guidelines for biopharmaceutical manufacturing.

"This is changing because some companies are now designing and installing fully compliant cGMP facilities for contract biopharmaceutical manufacturing. Those are led by capable teams with experience from the US and Europe and will be in line for domestic operations in the next three to five years. In addition, multinational pharmaceutical companies continue to look at potential CMO partners in China. Some of the interest in China outsourcing may be derived from general interest in establishing such relationships," says Mr Eric S Langer of BioPlan Associates.

Biological manufacturing has been recognized as a promising field by the government and several measures have been taken by the central and local governments on different aspects, such as financial, regulatory and services. National funds, including the National Twelfth Five-Year-Plan and the National '863' Program are the local funds that strongly support the development of biomanufacturing. Funding from the government combined with other private funds are now actively seeking opportunities in the biomanufacturing area.