

## The necessity of establishing a harmonized international regulatory system for the control of APIs

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According to the Drug Administration Law, API manufacturers in China have to obtain drug production license. Each API product needs to have manufacture authorization license and GMP certificate before the legal manufacture and sales. APIs exported to China need to get import permission from SFDA. Furthermore, each batch of imported APIs is examined by official drug control laboratories before released to end user. Currently SFDA is not recognized as a MRA and all above licenses and certificates are not accepted by western countries. This becomes a puzzle to the western countries as the APIs from China becomes indispensable especially for many essential medicines. There are two extreme ways to deal with the puzzle. FDA evaluates every API imported from China, completely ignoring the certificates issued by SFDA. This may cause a problem that some Chinese API manufacturers approved by FDA do not have domestic drug production permission and will be out of the control from SFDA. EU takes the other extreme way, which request sin Directory 2011/62/EU that APIs exported into EU market must be accompanied with a written confirmation from competent authority of the exporting third country to ensure the exported API complies with EU GMP. However, SFDA would not agree to inspect Chinese enterprises with EU GMP, if Chinese GMP is not equivalent and take the responsibility for EU people. Therefore, all relevant countries/regions should work together to clarify the responsibilities of import and export countries and establish a harmonized international regulatory system for the control of APIs.

### Biography

SUN Yueping graduated from the Capital University of Medicine Sciences in Beijing in 1982. He stayed in the university as a lecturer of pharmacology for 8 years, including the research in Department of Toxicology, KarolinskaInstitutet in Stockholm. He entered pharmaceutical industry in 1990 and worked for Xi'an Janssen, HELM AG and some consulting companies. In recent years, he has provided consultancy services to SFDA, WHO and some foundations as an independent consultant in GMP guidance, drug registration policies and other regulatory projects. He also works for Chinese pharmaceutical enterprises to provide training and guidance in GMP compliance.

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