

O'Neill Institute

for National and Global Health Law

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“Regulatory Oversight of Drug Clinical Trials in China”

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Introduction by: Philip Chen, Georgetown University Law Center

Xiufang Ruan

*Section Chief, Department of Drug Registration,
Shanghai Municipal Food & Drug Administration
Visiting Researcher, Georgetown University Law Center*

Lijun Hu

*Deputy Section Chief, Drug Regulatory Office
Shanghai Municipal Food & Drug Administration
Visiting Researcher, Georgetown University Law Center*

Drug development has become a world-wide enterprise. Pharmaceutical companies are continually developing new drugs. Because of the growth in innovative centers across the globe, more and more clinical trials, a key part of drug development, are being conducted outside the United States. China is one of the most significant countries where these trials are being conducted. This talk will address the perspective of China's Food and Drug Administration, the agency that regulates these trials.

Ms. Ruan and Ms. Hu will introduce the Chinese legal system, landmark regulations on drug safety and the role of regulatory departments in China. They will use examples of initial new drug applications, good clinical practice, institutional review boards, clinical trial on-site inspection and the reporting system of adverse drug effects to illustrate how the oversight system works in China.