



## **USP International Excipient Workshop**

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### **PRESENTATION ABSTRACT**

**Title of Presentation:** Regulatory Aspects on Pharmaceutical Excipients in China

**Author:** Jiasheng Tu

**Organization:** China Pharmaceutical University, Nanjing 210009, China

**CHP Affiliation:** Member, Pharmaceutics Expert Committee

**Abstract:** Pharmaceutical excipients played key roles in the efficacy, safety and quality of drug products. The regulatory system of pharmaceutical excipients in China includes regulatory on registration, CHP standards, DMFs, GMPs of excipients by SFDA, and excipient audit by user. Pharmaceutical excipients in China must be approved by drug regulatory departments. For new excipients (excipients without pharmaceutical application history or excipients application for injection use), import excipients, application will be evaluated by SFDA. The application of generic excipients (except for injectable) will be evaluated by provincial-level FDA. Voluntary GMP had been published since 2006. Approved excipients need to submit the DMFs to CDE in near future. A DMF number will be assigned to each excipient. China Pharmacopoeia (CHP) played an important role in regulatory of the excipient standards and application. CHP 2010 edition will have a general chapter about excipients, and 205 excipients with more strict standards will be admitted. The regulatory system for pharmaceutical excipients will promote the R&D of new excipients, new dosage forms and globalization of China excipients.