



国家药典委员会  
Chinese Pharmacopoeia Commission



## **Chinese and European Pharmacopoeia Joint Workshop**

### **What's New in the field of excipients in China?**

**Duration:** 1 day (18 September 2018)

**Location:** EDQM premises, Strasbourg, France

**Working language:** English

#### **DRAFT PROGRAMME** *(subject to change)*

Moderator – Morning session:

**Dr Susanne Keitel**, Director, EDQM, Council of Europe

**09:00 - 09:20** Welcome and Opening remarks

**Dr Susanne Keitel**, Director, EDQM

**Mr Zhang Wei**, Secretary General, Chinese Pharmacopoeia Commission

**09:20 - 10:00** Regulatory system and the latest development of the Chinese Pharmacopoeia (40 min)

**Mr Zhang Wei**, Secretary General, Chinese Pharmacopoeia Commission

**10:00 - 10:30** China National Drug Administration (CFDA) : Role and missions (30 min)

**Mr Zhang Wei**, Secretary General, Chinese Pharmacopoeia Commission (TBD)

**10:30 - 10:45** Questions & Answers

**10:45 - 11:15** *Coffee break*

**11:15 - 11:45** The implementation of the examination and approval system for the association of the package, preparation and excipients (30 min)

**Dr Jiasheng Tu**, Director of the Excipients and packaging committee of the ChP,  
Professor at China Pharmaceutical University

**11:45 - 12:15** Questions & Answers

**12:15 - 14:00** *Lunch break*

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### **What's New in the field of excipients in China?**

Moderators – Afternoon session:

**Mr Zhang Wei**, Secretary General, Chinese Pharmacopoeia Commission &  
**Mrs Cathie Vielle**, Head of the European Pharmacopoeia Department and Secretary to the  
European Pharmacopoeia Commission, EDQM

**14:00 - 14:30** Establishment of the standard system for Pharmaceutical excipients in the Chinese pharmacopoeia (30 min)

**Dr Xiaoxu Hong**, Deputy Director, Comprehensive Department, Chinese Pharmacopoeia Commission

**14:30 - 15:00** Risk grading management and technical requirements for pharmaceutical excipients (30 min)

**Dr Huimin Sun**, Member of the Excipients and packaging Committee of the ChP; Director of the Institutes for Control of Packaging Material and Pharmaceutical Excipient in NIFDC (National Institutes for Food and Drug Control)

**15:00 - 15:30** The applicability of excipients (30 min)

**Dr Jiasheng Tu**, Director of the Excipients and packaging Committee of the ChP, Professor at China Pharmaceutical University

**15:30 - 16:00** Questions & Answers

***16:00 - 16:20 Coffee break***

**16:20 - 16:50** Requirements for the declaration of technical materials for pharmaceutical excipients (30 min)

**Dr Huimin Sun**, Member of the Excipients and packaging Committee of the ChP; Director of the Institutes for Control of Packaging Material and Pharmaceutical Excipient in NIFDC (National Institutes for Food and Drug Control)

**16:50 - 17:20** The quality control of pharmaceutical excipients, of animals and plant sources (30 min)

**Dr Xiaoxu Hong**, Deputy Director, Comprehensive Department, Chinese Pharmacopoeia Commission

**17:20 - 17:50** Questions & Answers

**17:50 - 18:00** Closing remarks

**Dr Susanne Keitel**, Director, EDQM, Council of Europe

**Mr Zhang Wei**, Secretary General, Chinese Pharmacopoeia Commission

*End of the event*