**Chinese and European Pharmacopoeia Joint Workshop**

**What’s New in the field of excipients in China**

**18 September 2018**

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

**Working languages:** English

**FINAL PROGRAMME**

Moderators – Morning session:

- **Mr Zhang Wei**, Secretary General, Chinese Pharmacopoeia Commission &
- **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 – 10:10** Chinese Pharmacopoeia (ChP) and Progress in the Compilation of ChP 2020

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

**10:10 – 10:25** Questions & Answers

**10:25 – 10:45 Coffee break**

**10:45 – 11:35** Guidance on Pharmaceutical Excipient Suitability Studies (PESS) with Chinese Pharmacopoeia (Volume 4): Basics and Examples

- **Dr Jiasheng Tu**, Director of excipients and packaging committee of ChP, Professor of China pharmaceutical university

**11:35 – 11:50** Questions & Answers

**11:50 – 12:30** Establishment and Progress of the Standard System of pharmaceutical excipients in Chinese Pharmacopoeia

- **Dr Xiaoxu Hong**, Deputy Director, Comprehensive department, Chinese Pharmacopoeia Commission

**12:30 – 12:45** Questions & Answers

**12:45 – 13:45 Lunch break**
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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 - 14:50  Risks, Classifying Management and Technical Requirements for Pharmaceutical Excipients
   Dr Xiaoxu Hong, Deputy Director, Comprehensive department, Chinese Pharmacopoeia Commission

14:50 - 15:20  Submission Requirements for the Registration Application Dossier of Pharmaceutical Excipients
   Dr Jiasheng Tu, Director of excipients and packaging committee of ChP, Professor of China pharmaceutical university

15:20 - 15:40  Regulations of Pharmaceutical excipients In China
   Dr Jiasheng Tu, Director of excipients and packaging committee of ChP, Professor of China pharmaceutical university

15:40 - 16:00  Considerations for Production and Quality Control of Animal Derived Pharmaceutical Excipients
   Dr Xiaoxu Hong, Deputy Director, Comprehensive department, Chinese Pharmacopoeia Commission

16:00 - 16:15  Questions & Answers

16:15 - 16:35  Coffee break

16:35 - 16:50  Pharmacopoeial Convergence and Harmonisation
   Dr Susanne Keitel, Director, EDQM

16:50 - 17:00  Closing remarks
   Dr Susanne Keitel, Director, EDQM, Council of Europe
   Mr Zhang Wei, Secretary General, Chinese Pharmacopoeia Commission

End of the event