



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

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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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 – 14:50 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