附件 1：

2017 中美药包材药用辅料研讨会主要报告

2017 ChP-USP Drug Packaging and Excipients Workshop Topics

一、药包材技术研讨分论坛

Packaging Workshop

国内讲题（更新中）

Topics from China (Being Updated)

1.中国药包材与药品关联审评审批改革

Bundling Review and Approval Reform for Drug Packaging Materials and Systems

2.化学药品与包材相容性研究指导原则

Guideline for Compatibility Study of Chemical Drug and Packaging Materials

3.中国药典药包材标准体系建立及工作进展

System Establishment and Progress for the Drug Packaging Standard of Chinese Pharmacopoeia

4.药包材稳定性研究技术探讨

Stability Study and Exploration for Technique of Drug Packaging Material

5.吸入制剂与包装系统同步发展

Synchronous Development of Inhalation Preparation and Packaging System

6.药用胶塞提取及其配方一致性研究

Matching Study Between Extractable and Formula for Elastomer

7.高风险药品包装系统风险控制

Risk Management for Drug Packaging System used in High Risk Drugs

美国讲题（更新中）

Topics from USP (Being Updated)

1.部分 1：美国药典针对药包材和给药系统的选择和确认的策略和标准：起点

Part1: USP Strategy and Standards for the Selection and Qualification of Packaging and Delivery Systems: The Starting Point

部分 2：理化表征测试- 药典检测方法的应用

Part2：Physicochemical Characterization Testing–Application of Compendia Tests

2.容器密封完整性(CCI)的最新发展

Latest Development on Container Closure System Integrity （CCI）

3.部分 1：理化表征测试－提取研究、模拟提取研究和浸出物研究的设计和实施

Part1: Physicochemical Characterization Testing–Designing and Performing Extraction, Simulation and Leachable Studies

部分 2：理化表征研究–鉴别和确证未知物

Part2: Physicochemical Characterization Studies: Identifying and Quantifying Unknowns

4.部分 1：化学组分的毒理评估–限度和文献研究的应用

Part1: Toxicological Evaluation of Chemical Compounds–Use of Thresholds and Literature Studies

部分 2：生物学反应研究的设计和评估

Part2: Design and Evaluation of Biological Reactivity Studies

5.注射用包装系统/给药系统用弹性组件标准：理化性能和功能性检测

Baseline Standards for Elastomeric Components used in Injectable Pharmaceutical Packaging/Delivery Systems: Physicochemical and Functionality Testing

二、药用辅料技术交流分论坛

Excipients Workshop

国内讲题（更新中）

Topics from China (Being Updated)

1. 我国药用辅料监管的发展方向

Development Direction of Pharmaceutical Excipients Administration in China

2. 中国药典药用辅料标准体系的建立及未来工作重点

ChP Excipient Standard System Establishment and Working Focus in Future

3.药用辅料功能性评价及方法的建立

Evaluation and Measurement Establishment for Functionality of Excipients

4.制剂研究如何开展药用辅料的研究和选择

How to Implement Research and Selection of Pharmaceutical Excipients for Formulation

5.高风险制剂在选择药用辅料的关注点

Key Points of Selection for Pharmaceutical Excipients used in High Risk Drug Formulation

6.药用辅料安全性评价研究策略

Safety Evaluation Study for Pharmaceutical Excipients

7.动物来源药用辅料的质量控制和考虑要点

Quality Control and Consideration Points for Animal-Derived Pharmaceutical Excipients

8.新型药用辅料研究和应用进展

Novel Pharmaceutical Excipients Research and Application Progress

9.注射剂和眼用制剂辅料的质量控制及制剂中的应用

Quality Control and Application of Excipients for Injection and Ophthalmic Drugs Used

10.注射用辅料的分级管理和技术要求

Classified Management and Technique Requirements on the Excipients for Injection Used

美国讲题（更新中）

Topics from USP (Being Updated)

1.药用辅料和美国药典标准建立流程的介绍

An Introduction to Pharmaceutical Excipients and USPs Standards Setting Process

2.药典标准之外的改进的辅料特性- USP 通则辅料性能<1059>的介绍

Improved Excipient Characterization beyond the USP Monographs - Introduction to Excipient Performance <1059>

3.新型和预混辅料- 为患者提供新的疗法和产品；对连续生产的成功的贡献

Emerging Topics with Respect to Excipients: Novel and Coprocessed Excipients–Enabling New Therapies and New Products for Patients; Contributing to the Success of Continuous Manufacturing

4.药用辅料中的元素杂质

Elemental Impurity on Excipients

5.辅料标准更新的挑战：如何设定有意义的辅料标准？利益相关方参与的重要性

Challenges to Updating Excipient Monographs: How to Set Meaningful Specifications for Excipients? The Importance of Stakeholder Engagement with USP

6. 美国药典辅料认证项目

USP EXC-IVP Program

7.化工厂如何能同时满足针对食品、膳食补充剂、辅料成分的所有监管要求

How to Operate a Chemical Plant to Meet All the Regulatory Requirements for Food, DS, Excipient Ingredients All at the Same Time

备 注：报告内容和演讲人信息会即时更新，请关注国家药典委官网 www.chp.org.cn 和协会官网 www.cnppa.org。