

# 2019 美国药典 “一次性使用系统” 研讨会

## “一次性使用系统” 在药品制造和新型监管中的角色

### USP Single Use Systems Workshop 2019

#### The Role of SUS in Drug Production and Emerging Regulations

February 27 & 28, 2019 Beijing, China

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#### Day 01 - 27<sup>th</sup> February 2019

09:00-09:15 开幕致辞 Opening

#### 主题一- “一次性使用系统” 监管现状和药典考量

#### Session 1: Regulatory Landscape and Compendial Consideration for SUS

Chairman: Dr. Desmond Hunt, Principle Scientific Liaison, USP

09:15-10:00 “一次性使用系统” 在制药工业中的应用概述：益处与挑战  
Single Use Systems and Their Use in Biopharmaceutical Manufacturing: Benefits and Challenges  
丁卫兵博士，美国药典委员会专家组成员；GSK 公司一次性使用系统总监  
Weibing Ding, Ph.D., USP Expert Panel Member; Director, Single Use Systems, GSK

10:00-10:15 茶歇 Coffee Break

10:15-11:00 中国 “一次性使用系统” 工业标准和监管概述及展望  
Overview and Forward Looks of SUS Industry Standards and Regulations in China  
周新华博士，嘉和生物药业首席执行官，北京大学 IPEM 客座教授  
Dr. Joe Zhou, CEO of Genor Biopharma, IPEM Visiting Professor at Peking University

11:00-12:00 USP 通则<665>和<1665>：美国药典对制药生产系统的选择和确证的观点及标准  
USP General Chapter <665> and <1665>: USP Perspective and Standard for the Selection and Qualification of Pharmaceutical and Biopharmaceutical Manufacturing Systems  
Dennis Jenke 博士，美国药典委员会包材和流通专家委员会委员、药物生产用塑料系统专家组主席，Triad Scientific Solutions 公司首席科学家  
Dennis Jenke, Ph.D., USP Packaging and Distribution Expert Committee Member; USP Expert Panel Chair: Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel; Chief Executive Scientist, Triad Scientific Solutions.

12:00-13:00 午餐 Lunch

## 主题二-多个角度探讨“一次性使用系统”的角色

### Session 2: Role of SUS from Different Perspectives

Chairman: Dr. Michael Eakins, USP Packaging and Distribution Expert Committee Member

- 13:00-13:45 **中国“一次性使用系统”的监管现状及期望**  
**My Understanding of Regulatory Landscape and Expectations for SUS in China**  
张均利博士, 上海复宏汉霖生物技术有限公司高级副总裁兼首席运营官  
Junli Zhang, Ph.D., senior Vice President and Chief Operating Officer, Shanghai Henlius Biotech, Inc.
- 13:45-14:30 **执行通则<665>的益处和案例：设备供应商的视角**  
**Benefits and Examples of Generating <665> Data: Equipment Supplier's Perspective**  
James Hathcock 先生, 美国药典委员会药物生产用塑料系统专家组成员, 颇尔公司法规和验证高级总监  
James Hathcock, USP Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel Member; Sr. Director, Regulatory and Validation, Pall Biotech
- 14:30-15:15 **执行通则<665>：药品制造商的视角**  
**Utility of Generating <665> Data: Drug Manufacturer's Perspective**  
Ken Wong 博士, 美国药典委员会药物生产用塑料系统专家组成员, 赛诺菲巴斯德公司一次性使用系统验证副总监  
Ken Wong, Ph.D., USP Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel Member; Deputy Director, Single-Used Systems Qualification, Sanofi Pasteur
- 15:15-15:30 茶歇 Coffee Break
- 15:30-16:15 **可提取物数据的合理运用**  
**The Proper Use of Extractables Data – Aspects Beyond Extractables Measurement**  
Armin Hauk 博士, 赛多利斯斯泰帝生物技术公司首席科学家  
Armin Hauk, Ph.D., Lead Scientist, Sartorius-Stedim-Biotech GmbH
- 16:15-17:00 **评估“一次性使用系统”可提取物数据以支持其在药物生产过程中的确认与安全风险**  
**Evaluating Extractables Data to Support Qualification and Safety Risk Assessment for Effective Adoption of Single-Use Systems in Drug Manufacturing Processes**  
盖群女士, 默克化工技术(上海)有限公司 E&L 实验室经理  
Queenie Gai, E&L Laboratory Manager, Merck Chemicals (Shanghai) Co., Ltd.
- 17:15-17:30 讨论 Panel Discussion Q&A

## Day 02 – 28<sup>th</sup> February 2019

- 08:45-09:00 **第一天会议小结与第二天会议介绍**  
**Summary of Day 1 and Introduction of Day 2**  
Desmond G. Hunt 博士，美国药典委员会科学部门通则标准首要科学事务联络人  
Desmond G. Hunt, Ph.D., Principal Scientific Liaison, Science-General Chapters, USP

### 主题三-符合新型监管要求的制药工业实践

#### Session 3: Industry Practices to Comply with the Emerging Regulations

Chairman: Dr. Dennis Jenke, USP Packaging and Distribution Expert Committee Member; Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel Chair

- 09:00-09:45 **监管机构可如何使用 USP 通则<665>**  
**How Regulators Could Utilize USP Chapter <665>**  
Michael Eakins 博士，美国药典委员会包材和流通专家委员会委员，Eakins & Associates 公司首席顾问  
Michael Eakins, PhD., USP Packaging and Distribution Expert Committee Member, Principal Consultant, Eakins & Associates
- 09:45-10:30 **案例分析 – 商业阶段的“一次性使用系统”应用**  
**Case Studies of SUS Applications in Commercial Stage**  
崔铁民博士，卓见医药科技（上海）有限公司联合创始人-首席执行官  
Tiemin Cui, PhD., CEO, Jugean Pharm (Shanghai) Co., Ltd.
- 10:30-10:45 茶歇 Coffee Break
- 10:45-11:20 **“一次性使用系统”在生产中的实践与挑战**  
**The Adoption, Deployment and Associated Challenges of SUS in Manufacturing**  
李锦才博士，药明生物技术有限公司生产副总裁  
Jincai Li, Ph.D., Manufacturing VP, WuXi Biologics, Inc.
- 11:20-11:50 讨论 Panel Discussion Q&A
- 11:50-12:00 结语 Wrap up

*This agenda is subject to change. 具体日程以最后版本为准*