附件 2

2019 国际药品标准制定和标准认证专题研讨会会议日程

Workshop on International Drug Standards Development and Standards Certification 2019 Agenda

2019 年 6 月 20-21 日　　江苏 徐州

20 -21 June, 2019, Xuzhou, Jiangsu Province ， China

日期 Date/Time	内容 Contents	特邀嘉宾 Invited Speakers
6 月 20 日 **20 June**	主持人： 张伟秘书长，国家药典委员会 Moderator：Mr. Zhang Wei, Secretary General, Chinese Pharmacopoeia Commission	
8:30-8:50	开幕致辞 Opening Remarks	国家药品监督管理局有关领导 National Medical Products Administration
		江苏省药品监督管理局有关领导 Jiangsu Medical Products Administration
		张伟先生，国家药典委员会秘书长 Mr. Wei Zhang,Secretary General of Chinese Pharmacopoeia Commission
8:50-9:30	良好药典规范的制定在国际药典协调中的作用 The Role of Good Pharmacopoeias Practice in the Pharmacopoeias Harmonization	Sabine Kopp 博士，世界卫生组织药品质量保障部负责人 Dr. Sabine Kopp,Head of the Drug Quality Assurance Dept. World Health Organization
9:30-10:10	国际药典标准制定未来发展规划 Plan on the Development of International Pharmacopoeia by WHO	Sabine Kopp 博士，世界卫生组织药品质量保障部负责人 Dr. Sabine Kopp,Head of the Drug Quality Assurance Dept. World Health Organization
10:10-10:50	英国药典最新编制概况 Brief Introduction on the Development of British Pharmacopoeia	James Pound 先生，英国药典委员会秘书长（主任） Mr. James Pound,Group Manager British Pharmacopoeia & Laboratory Services,Secretary & Scientific Director British Pharmacopoeia Commission
10:50-11:00	演讲及特邀嘉宾合影、茶歇 Group Photo & Tea Break	

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11:00-11:40	中国药品检查现状和面临挑战 Current Situation & Challenge on the Drug Inspection in China	董江萍女士，国家药监局食品药品审核查验中心副主任 Ms Dong Jiangping,Deputy Director of Centre for Food and Drug Inspection of NMPA
11:40-12:20	美国药典标准建立流程及膳食补充剂和植物药标准开发进展 Technical Requirements and Review Process of Standards building for DS & HM by USP	Gabriel I. Giancaspro 博士，美国药典委员会副总裁 Dr. Gabriel I. Giancaspro, Vice President of United State Pharmacopoeia Convention
12:20-13:30	午餐 Lunch	
	主持人： 宋宗华博士，国家药典委员会副处长 Moderator：Dr. Zonghua Song， Deputy Director, Chinese Pharmacopoeia Commission	
13:30-14:10	欧洲药品标准认证更新及修订 Requirements for revision/renewal of Certificates of Suitability	Pascale Poukens-renwart 博士，欧洲药品质量管理局认证部主任 Dr. Pascale Poukens-renwart,Head of Quality Assurance and Scientific Support Section of EDQM
14:10-14:50	欧洲药品标准认证解读 How to read a CEP	Pascale Poukens-renwart 博士，欧洲药品质量管理局认证部主任 Dr. Pascale Poukens-renwart,Head of Quality Assurance and Scientific Support Section of EDQM
14:50-15:30	美国药典药用辅料及膳食补充剂认证 Requirements for the USP Excipient and Dietary Supplements Verification	Stephen W.Andruski 博士，美国药典委员会高级经理 Dr. Stephen W.Andruski ,Senior Manager of United State Pharmacopoeia Convention
15:30-15:40	茶歇 Tea Break	
15:40-16:20	《中国药典》药用辅料适用性和标准认证的思考 Consideration on the Excipients Suitability and Standards Certification by Chinese Pharmacopoeia	涂家生教授，国家药典委员会药用辅料和药包材专业委员会主任委员、中国药科大学教授 Pro.Tu Jiasheng,Chief Committee of Excipients & Ddrug Packaging Materials Committee of ChP / China Pharmaceutical University
16:20-17:00	世界卫生组织实验室认证技术要求 Technical Requirements of the WHO Prequalification Laboratory	Sabine Kopp 博士，世界卫生组织药品质量保障部负责人 Dr. Sabine Kopp,Head of the Drug Quality Assurance Dept. World Health Organization

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6 月 21 日 20 June	主持人：洪小栩博士，国家药典委员会副处长 Moderator：Dr. Xiaoxu Hong， Deputy Director, Chinese Pharmacopoeia Commission	
8:30-9:00	原料药、药用辅料及药包材与药品制剂共同审评审批及国家药品标准执行 API Excipients and Drug Packaging jointly Evaluation and Approval with Pharmaceutials as well as the Implement of Natioal Drug Standards	李江宁先生，国家药品监督管理局药品注册司处长 Mr. Li Jiangning,Director of the General Division,Drug Registration Dept. NMPA
9:00-9:40	药品技术审评中药典标准的地位和考量 Position and Consideration on the Pharmacopoeia Standards in the Drug Evaluation	Howard R. Sklamberg 博士，美国 AKIN GUMP 律师事务所合伙人，美国食品药品监督管理局前主任 Dr. Howard R. Sklamberg,Partner of AKIN GUMP, Former Director of FDA
9:40-10:10	我国药品现场检查对标准合规性检查考虑要点 Consider Points on Drug Standards Compliance in the Inspection on Site	陈桂良博士，上海药品审评查验中心主任 Dr. Guiliang Chen,Director of Shanghai Center Drug Evaluation and Inspection
10:10-10:30	茶歇 Tea Break	
10:30-11:00	药品质量控制实验室申请 WHO 预认证策略和要点 Strategy and Consideration on Application of WHO Prequalification Laboratory	王晓炜博士，深圳市药品检验研究院副院长 Dr. Wang Xiaowei,Deputy Director of Shenzhen Institute for Drug Control
11:00-11:20	药品生产企业对国际药品核查的应对策略 Strategy on the Drug Inspection for Pharmaceutical Enterprises by International Authority	丁恩峰先生，上海复星医药产业公司副总经理 Ms Ding Enfeng,Vice Manager of Shanghai Fosun Pharmaceutical Development Co.,Ltd.
11:20-11:40	药品境外注册标准符合性的应对策略 Strategy on the Standards Compliance in the Application Drug Registration Oversea	谢红艳女士，山东齐鲁制药集团有限公司副总裁 Ms Xie Hongyan ,Vice President of Shandong Qilu Pharmaceutical （Group） Co., Ltd.
11:40-12:10	答疑 Q&A	部分有关专家及全体参会代表 Parts of Speakers ,All Representatives