

大会详细日程

日期 Date	分会场主题 Theme	时间 Time	演讲主题 Topic	演讲嘉宾 Speaker	
9月6日 Sep. 6th	无菌药品污染控制策略（CCS）技术与 实践分会场 Sterile Products Contamination Control Strategy (CCS) Technology and Practice Parallel Session	08:30-09:00	GMP附录一《无菌药品》的变化趋势 The changing trend of GMP Annex 1 "Sterile Products"	夏禄华 先生, 重庆誉颜制药有限公司副总裁 Mr. Luhua Xia, Vice President, Chongqing Yuyan Pharmaceutical Co., Ltd.	
		09:00-09:30	如何降低微生物、内毒素和颗粒物污染的风险 How to Minimize Risk of Microbial, Endotoxin and Particulates Contamination	Richard Chai 先生, 美国STERIS Corporation 生命科学部门 高级技术服务经理 Mr. Richard Chai, Senior Technical Service Manager, STERIS Corporation	
		09:30-10:00	清洁消毒 - 污染控制策略 (CCS) 中的核心元素 Core Elements of Clean Disinfection Contamination Control Strategy (CCS)	薛骏 先生, 礼来苏州制药有限公司无菌保障资深工程师 Mr. Jun Xue, Principal Engineer TSMS SA, Lilly Suzhou Pharmaceutical Co., Ltd.	
		10:00-10:20	茶歇 Tea Break		
		10:20-10:50	生物制药和ATMP生产设施洁净室良好清洁与消毒实施指南 CCS : Guidelines to good cleaning and disinfection implementation in BioPharma/ATMP	Jim Polarine 先生, 美国注射剂协会 (PDA) 科学顾问委员会 成员, 美国STERIS Corporation生命科学部门高级技术服务经 理 Mr. Jim Polarine, Member of the Scientific Advisory Committee of the Parenteral Drug Association (PDA), Senior Technical Service Manager of STERIS Corporation	
		10:50-11:20	CCS质量风险管理和实践分享 CCS Quality Risk Management and Practice Sharing	许建辰 博士, 诺和诺德 (中国) 制药有限公司监管政策和合规 总监 Dr. Jianchen Xu, Director of Regulatory Policy and Compliance, Novo Nordisk (China) Pharmaceutical Co., Ltd.	
		11:20-11:50	药品共线生产的质量风险评估和基于生命周期的清洁验证模 型 Quality Risk Assessment of Co-production of Pharmaceuticals and Cleaning Validation Model Based on the Product Lifecycle	张进 先生, 香港奥星集团污染控制技术总监 Mr. Jin Zhang, Technical Director of Contamination Control Business Unit, AUSTAR	
		11:50-12:00	答疑 Q&A		

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		13:00-13:30	气流流型研究优化无菌操作动作的实践 Practice of Optimizing Sterile Operation Actions through Airflow Pattern Research	宋启国 先生, 苏州康衡医药科技有限公司高级咨询师 Mr. Qiguo Song, Senior Consultant, Kangheng Pharmaceutical Technology Co., Ltd.
		13:30-14:00	药品容器检漏的最新法规动向 The Latest Regulatory Trends in Drug Container Leak Detection	黄涛 先生, Nikka Densok株式会社次长 Mr. Tao Huang, Assistant Manager, Nikka Densok Limited
		14:00-14:30	细胞治疗产品微生物污染检查法探讨 Exploration of Microbial Contamination Detection Method for Cell Therapy Products	厉高懋 先生, 上海市食品药品检验研究院生化药品生物制品/微 生物所微生物室副主任 Mr. Gaomin Li, Deputy Head, Department of Microbiology Division of Biochemical Drug, Biological Products/Microbiology, Shanghai Institute for Food and Drug Control
		14:30-15:00	茶歇 Tea Break	
		15:00-15:30	启动CCS——如何引导 Getting Started on your CCS – a How to Guide	Marcia Baroni 女士, 美国注射剂协会 (PDA) 科学顾问委员会 药物微生物学专家讨论组首席特约成员, 美国Emergent BioSolutions公司企业GxP合规与系统质量副总裁 Ms. Marcia Baroni, Chief Contributing Member of Pharmaceutical Microbiology Expert Discussion Group of Scientific Advisory Board of PDA, VP Quality of Enterprise GxP Compliance & Systems of Emergent BioSolutions Inc.
		15:30-16:00	交流&答疑 Exchange and Q&A	