

## 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5日 Sep. 5th	第七届血液制品会议 The 7th Plasma Derived Products Conference	13:30-14:00	血浆制品的药用价值和前景 The Medicinal Value and Prospects of Plasma Products	刘忠 教授, 中国医学科学院输血研究所副所长 Professor Zhong Liu, Deputy Director of the Blood Transfusion Research Institute, CAMS
		14:00-14:30	国际血浆分离监管和法律框架的最新发展 对库存持有发展的监管观点。主要市场中用于分离的血浆与用于输血的血浆/血液的比较分析: 历史和当前的发展 Recent Developments in the International Regulatory and Legal Framework for Plasma Fractionation. Regulatory Perspectives on the Development of Inventory Holds. Comparative Analysis of Plasma Used for Fractionation vs. Plasma/Blood for Transfusion in Major Markets: Historical and Current Developments	Jens Rehbein 先生, CSL全球注册事务部和实验室运营血浆药理学 (CMC) 主管 Mr. Jens Rehbein, Director, Plasma Lead, Global Regulatory Affairs (GRA) CMC, CSL
		14:30-15:00	利用真实世界(RWE) 数据支持缩减检疫期 病原体安全设计 血浆源性免疫球蛋白和血友病治疗产品的病毒安全性 Inventory hold reduction with Real-World Evidence data Pathogen Safety by Design Virus Safety of Plasma derived Immunoglobulins and Haemophilia treatment products	Denis Klochkov 先生, CSL全球病原体安全产品及战略负责人 Mr. Denis Klochkov, Head of Global Pathogen Safety Product Ownership & Strategy, CSL
		15:00-15:30	茶歇 Tea Break	
		15:30-16:00	ICH Q12 上市后变更管理方案 (PACMP)/可比性方案 (CP) 在美国的实施和案例分析 ICH Q12 Post-approval change management protocol (PACMP)/Comparability Protocol (CP) implementation and case studies in the U.S.	Mikhail Ovanesov 先生, CSL全球注册事务部药理学 (CMC) 产品开发高级顾问 Mr. Mikhail Ovanesov, Senior Advisor for Product Development, Global Regulatory Affairs (GRA) CMC, CSL
		16:00-16:30	血液制品的临床应用 Clinical Application of Plasma Derived Products	卢奎林 先生, 成都蓉生药业有限责任公司副总经理 Mr. Kuilin Lu, Deputy General Manager, Chengdu Rongsheng Pharmaceuticals Co., Ltd.
		16:30-17:00	交流&答疑 Exchange and Q&A	