2018 ISPE-CCFDIE China Conference Agenda

Oct 16 Morning	Plenary meeting		
Oct 16 Afternoon	Center for Food and Drug Inspection Session		
Oct 17 Morning	Forum A Oversea Regulation Updates	Forum B Continuous Manufacturing of Oral Solid Preparation	Forum C Quality Control Points of Cell Therapy Products
Oct 17 Afternoon	Forum D New Trends in Drug R&D and Consistency Evaluation	Forum E Pharmaceutical Production and Engineering Technology	Forum F GxP Compliance and Corroboration Practice
Oct 18	Forum G Clinical Supply Management	ICH GMP（Q7）Seminar	

Oct 16 Morning

Plenary meeting Host　Kecheng Zang, Center for Food and Drug Inspection, CFDA	
09:00 - 09:20	**Opening Ceremony** Leader of Jiangsu Food and Drug Administration Bin Xue, Director-General, China Center for Food and Drug International Exchange, CFDA Jiangping Dong, Deputy Director-General, Center for Food and Drug Inspection, CFDA Timothy P. Howard, Chairman of the ISPE International Board of Directors
09:20 - 09:50	**New Situation of Pharmaceutical Production Safety in China** Department of Drug Safety Supervision, CFDA
09:50 - 10:20	**New Measures for FDA drug regulation** Lane Christensen, FDA China Office
10:20 - 10:40	Break
10:40 - 11:20	**Introduction of ISPE Technical Documents** Timothy P. Howard, Chairman of the ISPE International Board of Directors
11:20 - 12:05	**Policy of Stimulating and Promoting the Development of Pharmaceutical Industry in China** Rong Shao, Executive Vice Dean, Graduate School, China University of Pharmacy

Oct 16 Afternoon

Center for Food and Drug Inspection Session Host Kecheng Zang, Center for Food and Drug Inspection, CFDA	
13:30 - 14:15	**Value and Trend of Drug Inspection** Jiangping Dong, Deputy Director-General, Center for Food and Drug Inspection, CFDA
14:15 - 15:00	**Progress in Inspection of Drug Clinical Trial** Xue Qian, Director, Center for Food and Drug Inspection, CFDA
15:00 - 15:15	Break
15:15 - 16:00	**Drug Inspection Report 2017** Yi Cao, Director, Center for Food and Drug Inspection, CFDA
16:00 - 16:45	**On-site Inspection on Registration and Production** Tiewei Zhai, Center for Food and Drug Inspection, CFDA
16:45 - 17:10	Q&A

Oct 17 Morning

Forum A Oversea Regulation Updates Host Ningning Ma, Jim Lambert	
08:30 - 09:00	**How the Innovations in Filtration Technologies Help to Comply with Recent International Regulatory Trends** Artem Gurvich, Sartorius market development manager
09:00 - 09:35	**U.S. Regulation Update** Jim Lambert, CAI vice president
09:35 - 10:15	**EU Regulation Update** Massimo Eli, ISPE Headquarters Specialist
10:15 - 10:30	Break
10:30 - 11:00	**New Development of ICH** ISPE Headquarters Specialist
11:00 - 11:30	**Research on Implementation of ICH in China** Yalin Liu, ICH China Office, Center for Drug Evaluation, CFDA
11:30 - 12:00	**Application of ICH Q5 in Biopharmaceuticals** Zhengyu Dong, Henlius vice president
12:00 - 12:20	Panel Discussion

Forum B Continuous Manufacturing of Oral Solid Preparation Host Jue Lin, Eli Lilly	
08:30 - 09:00	**Application of Simulation Technology in Experimental-to-Production Process of Compacting Machine** Qiping Zheng, Truking
09:00- 09:30	**Inspection Perspective on the Application of Emerging Technology** Shuang Liu, Center for Food and Drug Inspection, CFDA
09:350- 10:30	**Development and Application of Continuous Manufacturing** Xiaoyu Zhang, David Pappa, Lilly Scientist
10:30 - 10:45	Break
10:45 - 11:15	**Regulatory Requirements and Strategy of Continuous Manufacturing in Drug Registration** Jole Rodriguez, Eli Lilly Chief Scientist
11:15 - 11:45	**Regulatory Requirements for Continuous Manufacturing and on-site Inspection Points** David Mota, Eli Lilly Scientist
11:45 - 12:15	Q&A

Forum C Quality Control of Cell Therapy Products Host Richard Wang, CEO, Fosun Kite Biotechnology Co., Ltd	
08:30 - 09:00	**Considerations of On-site Inspection for Biologicals** Yan Zhou, Center for Food and Drug Inspection, CFDA
09:00- 09:30	**Quality Control of Raw Materials and Excipients and Process Validation for Cell Therapy Products** National Institutes for Food and Drug Control, CFDA
09:30 - 10:00	**Inspection of Cell Therapy Products in EU** Annigje Rietveld, Former Dutch FDA inspector
10:00 - 10:15	Break
10:15 - 10:45	**Challenges with Manufacture and Testing of Gene Modified Cell Therapy Products** Mehrshid Alai-Safar, Kite pharmaceutical
10:45 - 11:15	**Registration Process and Quality Management of CTL-019** Rose Gao, Novartis pharmaceutical
11:15 - 11:45	**Some considerations for Cell Therapy Manufacturing Process Inspection** Zhuoyu Ni, GE Healthcare
11:45 - 12:30	Panel Discussion: Significance of industrialization for cell therapy products quality

Oct 17 Afternoon

Forum D New Trends in Drug R&D and Consistency Evaluation Host Long Cheng, PAREXEL	
13:30 - 14:00	**Application of National Health Care Big DataPlatform** Hui Xiao, Vice President, China Electric Data Service Co., Ltd
14:00 - 14:30	**Full Cycle Evaluation of Drugs based on Clinical Value** Long Cheng, PAREXEL
14:30 - 15:00	**Application of Complex Survival Analysis Model to Evaluate nonlinear effects of the factors affecting overall survival rate and its dynamic effects** Naiqing Zhao, Professor, Fudan University
15:00 - 15:30	**The Key Role of Oral Solid Process Equipment in Consistency Evaluation and the Considerations of Process Amplification** Zhizhen He, General Manager, Chanse Mechatronics
15:30 - 15:45	Break
15:45 - 16:15	**Experience Sharing in Consistency Evaluation** Wanhe Deng, Registration Director, Johnson (China)
16:15 - 16:45	**How to Develop Consistency Evaluation of Medicinal Excipients** Yong Bi, Anhui Sunhere Pharmaceutical Excipients Co.
16:45 – 17:10	Panel Discussion

Forum E Pharmaceutical Production and Engineering Technology HOST Ping Zhang, Lei Zhu, Sanofi	
13:30 - 14:00	**Smart Automation Solutions for Bioprocess Control System** Guofeng Xu, Thermo-Fisher
14:00 - 14:30	**MAH introduction in US and EU** Daniel Zang, Sanofi China
14:30 - 15:00	**Quality Culture** Xuelin Yin, Boehringer Ingelheim
15:00 - 15:30	**How to develop and qualify a scalable, robust single use process in biomanufacturing process** Siyi Liao, Merck
15:30 - 15:45	Break
15:45 - 16:15	**Application of ICH Q7 in API production** Ervin Vajda, Sanofi Hungary

16:15 - 16:45	**Impact of Process Induced crystal transformation on Pharmaceutical Formulation** Jun Han, Shandong Liaocheng University
16:45 - 17:15	**Computerized System Validation Life Cycle** Ping Niu, Abbott
17:15 - 17:45	**Strategy for Comparability Research of Biologicals** Kochling, Sanofi US
17:45 - 18:00	Panel Discussion

Forum F GxP Compliance and Corroboration Practice Host Xin Zhang, Austar	
13:30 - 14:15	**QbD-based Biosimilar Research and Development** Scott Liu, President and CEO of Henlius
14:15 - 15:00	**Investigation and Research on Laboratory OOS** Hongyang Li, Novartis
15:00 - 15:15	Break
15:15 - 15:45	**The Whole Process Automates the Raw Material Drug Lean Production** Xin Wang, Vice President, Qilu Pharmaceutical
15:45 - 16:15	**New Concept of Verification and Validation based on ASTM E2500 and Current Regulations in Pharmaceutical Industry** Zhengxian Ke, Austar
16:15 - 16:45	**Application of Sterile Technology Simulation Test in Aseptic Liquid Medium** Haiyi Chai, Nodbio
16:45 - 17:15	**Optimization and Amplification Strategy of Process Engineering from GLP Laboratory to GMP Pilot-scale Test and cGMP Production** Xiaoyun Dai, Vice Chairman of China Medical Biotechnology Association
17:15 - 17:45	Panel Discussion

Oct 18 Morning

Forum G　Clinical Supply Management Host　Lin Wang	
8:45 – 9:00	**Forum Introduction** Lin Wang
9:00 – 9:30	**China GMP Regulation on Clinical Supply Management: Catalent's Experience** LEO Zhang, Head of APAC Quality, Catalent
9:30 – 10:00	**Regulatory, Clinical and Supply Chain Challenges of ATMPs (Cell and Gene Therapies)** Andrea Zobel, Senior Director, PAREXEL global clinical trail supply
10:00 – 10:15	Break
10:15 – 10:45	**Regulatory Requirement and Ethical Review in Clinical Supply Management** Li Yang, Director, Peking University Third Hospital
10:45 – 11:15	**Regulatory, Clinical, Technological and Supply Chain Challenges of Direct-to-Subject Trials** Jeff Ten, Head of APAC clinical trial supply, PAREXEL
11:15 – 11:45	**CSM Strategy and Local Practices** Paul Cao, General Manager, ClinsChain (shanghai) Clinical Services
11:45 – 12:15	Panel Discussion: Interpretation of CFDA GMP Guide for CTM (draft) Speakers and Center for Food and Drug Inspection, CFDA

ICH GMP（Q7）Seminar Host　Kecheng Zang, Center for Food and Drug Inspection, CFDA	
08:30 - 08:40	**Welcome Speech** Pending
08:40 - 10:40	**ICH Q7 Introduction** Stephan Ronninger　EWG Expert
10:40 - 11:00	Break
11:00 - 12:00	**Laboratory Control including Data Integrity according to ICH Q7** Dinesh Khokal　EWG Expert

Oct 18 Afternoon

ICH GMP（Q7）Seminar Host　Kecheng Zang, Center for Food and Drug Inspection, CFDA	
13:00 - 14:00	**CFDI Inspectors' perspective on GMP of APIs including comparison of ICH Q7 and Chinese GMP** Tiewei Zhai, Center for Food and Drug Inspection, CFDA
14:00 - 14:45	**Local company perspective on GMP of APIs and experience sharing**
14:45 - 15:00	Break
15:00 - 15:45	**Supervision and inspection of APIs** Meng Yu, Jiangsu Food and Drug Administration
15:45 - 16:45	**Recent Quality topics in the implementation of GMPS for APIs——Cleaning Validation** Ervin Vajda, Sanofi Hungary
16:45 - 17:15	Q&A Session