DIA 2017 中国

DIA中国疫苗研发临床试验设计及GCP研讨班

Seminar on Clinical Trial Design and GCP for Vaccine Research and Development of DIA China

11月5-6日 | 北京新疆大厦

November 5-6 | Beijing Xinjiang Plaza

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2017

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首届DIA中国疫苗研发临床试验设计及GCP研讨班

11月5-6 日 | 北京新疆大厦

DIA 中国

组委会成员

史力 博士
上海泽润生物科技公司首席执行官，前DIA中国区顾问委员会成员

姜晶
思睦瑞科医药信息咨询有限公司副总经理（疫苗临床研究部和新药临床研究部）

疫苗对于预防疾病、保障人类生命安全和身体健康具有十分重要的意义。近年的中国疫苗产业飞跃无疑是中国医学史上的奇迹。从科研实力薄弱的当初到进步卓著的今天，疫苗的常规生产、紧急研发等都在众多疾病预防领域上演着“中国制造”和“中国创造”。这些与中国迄今为止所取得的监管改革、审评机制与科技发展的成果密不可分。

为响应国务院办公厅于2017年2月颁布的《关于进一步加强疫苗流通和预防接种管理工作的意见》，及总局52-54号文对药物推动创新和临床试验的政策要求，DIA中国定于2017年11月5-6日在北京新疆大厦举办首届DIA中国疫苗研发临床试验设计及GCP研讨班。本研讨班邀请来自监管机构、疾控、学术界、工业界等多方知名专家就疫苗监管法规的变化、伦理审查与质量控制的要点、不良事件/反应的处理、数据管理与统计等内容进行讲授，并结合案例讨论和分析。同时，研讨班邀请相关专家对世界卫生组织（WHO）预认证对临床资料的要求，分享成功经验。此次活动，旨在通过专家讲解、实用案例分析、跨国企业专家及疫苗临床研究者分享经验等形式，推动我国疫苗研发生产企业或机构的自主研发工作，促进我国疫苗生产企业提高质量管理水平和规范生产能力，保证并持续提升疫苗产品质量。

学习目标

- 了解在中国开展疫苗临床试验的质量管理规范、相关法规要求以及对临床试验方案设计的要求；
- 了解疫苗临床试验机构建设与研究者培养的重要性；
- 掌握疫苗临床试验伦理审查重点及与处方药临床试验的异同；
- 疫苗临床试验在实施及现场核查关注点上与处方药临床试验的异同；
- 如何处理疫苗临床试验中发生的不良事件/反应；
- 了解疫苗临床试验数据管理与生物统计学分析的基本原则。

参会人员

- 疫苗/生物制品公司及CRO公司医学与临床研究及注册团队人员；
- 疫苗/生物制品公司及CRO公司药物警戒部门人员；
- 疫苗/生物制品公司及CRO公司数据管理与生物统计团队人员；
- 疫苗临床试验质量控制/质量保证人员；
- 疫苗临床试验实施单位（如省市县一级CDC）；
- 相关政府机构的工作人员。

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会议议程 | 三层，多功能一厅

第一天 | 11月5日 • 星期日

9:00-10:30	**第一部分 疫苗临床试验设计和评价指导原则的解读**

1.1 对疫苗临床试验相关指导原则的解读及对新政法规变化的介绍。

杨焕 医学博士
中国国家食品药品监督管理总局药品审评中心
高级审评员/临床主审人

10:30-10:45	茶歇
10:45-11:45	**第二部分 世界卫生组织疫苗预认证对临床资料的要求**

张磊
成都生物制品研究所有限责任公司医学事务部经理

11:45-12:00	**上午问答环节**
12:00-13:30	午餐	四层，知味馆
13:30-14:30	**第三部分 疫苗临床试验的质量控制**

3.1 结合疫苗临床研究与处方药临床的不同，进而造成出现的违反GCP问题的不同而展开讲解和讨论。

陈华
强生公司质量策略亚太总监

14:30-15:45	**第三部分（续） 疫苗临床试验的伦理审查要点及案例分析**

3.2 疫苗临床试验伦理审查重点；疫苗与处方药临床研究的伦理审查的异同；以及如何体现对弱势群体的保护。

沈玉红 博士，副主任药师
北京康信科威医药科技有限公司总经理，创始人
原审核查验中心药品临床试验核查专家

15:45-16:00	茶歇
16:00-17:15	**第四部分 疫苗临床试验中不良事件/反应的处理**

4.1 疫苗临床试验不良事件/反应的报告及处理
4.2 案例分析

丘远征 博士
默沙东（中国）临床研究部副总监

17:15-17:25	**问答与互动**
17:25-17:30	**总结，第一天结束**

第二天 | 11月6日 • 星期一

9:00-10:30	**第五部分 疫苗临床试验的机构建设与研究者培养**

5.1 疫苗临床试验机构资格认定申请及机构建设要点（含具体案例的讨论环节）

李荣成
广西壮族自治区疾病预防控制中心疫苗临床研究所原所长，主任医师

10:30-10:45	茶歇
10:45-11:45	**第五部分（续） 疫苗临床试验的机构建设与研究者培养**

5.2 疫苗临床试验研究者培养（含具体案例的讨论环节）

李艳萍
广西壮族自治区疾病预防控制中心疫苗临床研究所原副所长，主任技师

11:45-12:00	**上午问答环节**
12:00-13:30	午餐	四层，知味馆
13:30-14:30	**第六部分 疫苗临床试验生物样品的采集、处理与检测**

王丛 博士
凯杰（苏州）转化医学研究有限公司副总裁

14:30-15:45	**第七部分 疫苗临床试验数据管理与生物统计学分析**

夏结来 教授
空军军医大学（第四军医大学）生物统计教研室主任

15:45-16:15	**下午问答环节**
16:15-16:30	**总结，课程全部结束**

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About DIA

DIA（Drug Information Association，药物信息协会）是一个全球性、中立的组织，旨在为业界提供自由交流和分享知识信息的平台，促进医疗产品的创新和开发。

DIA是一家国际性、非营利性、多学科的会员制协会，为医疗产品开发的专业人员提供中立、透明的论坛，推动药品和技术的合作和交流，改善全球健康。DIA的全年活动包括大会（年会和创新药会议）、培训班、研讨班、沙龙、企业内训定制课程和在线学习课程，涉及领域包括：监管科学、转化医学、药学、生物技术、医疗技术等。

DIA总部位于美国首都华盛顿哥伦比亚特区，在美国（宾夕法尼亚州霍舍姆），欧洲、中东和非洲（瑞士巴塞尔），中国（北京和上海），日本（东京）和印度（孟买）均设有地区办事处。

更多信息请见www.DIAglobal.org

DIA (founded as the Drug Information Association) provides is a global, neutral forum where stakeholders can openly and freely exchange knowledge information and insights beyond boundaries to advance innovation in health care product development and lifecycle management globally.

DIA is an interna DIA is based in Washington, DC (US) with regional offices representing the Americas (Horsham, PA, US); Europe, the Middle East and Africa, (Basel, Switzerland); and Asia (Beijing and Shanghai, China; Mumbai, India; and Tokyo, Japan).

For more information, visit www.DIAglobal.org or connect with us on Twitter, LinkedIn, Facebook, and Instagram.

Seminar on Clinical Trial Design and GCP for Vaccine Research and Development of DIA China

November 5-6 | Beijing Xinjiang Plaza

DIA

Program Committee Members

Li SHI, PhD
CEO, Shanghai Zerun Biotechnology Co., Ltd., Former Member of Advisory Council of DIA China

Jing JIANG
Deputy General Manager, Simoon Record Pharma Information Consulting Co., Ltd. (Vaccine Clinical Research Department and New Drug Clinical Research Department)

Vaccine has extremely important significance for preventing diseases and ensuring of public health and safety. The General Office of the State Council promulgated the Opinions on Further Strengthening the Management on Circulation and Preventive Inoculation of Vaccines in February 2017. The National Scientific Development Plan (such as special programs or research funds) has also encouraged the vaccine research and development work, promote the independent R&D capability and quality improvement of vaccine, upgrade vaccine manufacturing enterprise's ability of quality management, and constantly raise the quality of vaccine products. This workshop will invite prestigious experts in Chinese vaccine field to interpret the changes of new policies and rules about vaccines, the requirements of regulations on clinical research, the key points in the design and ethical review of clinical trial, and to analyze the similarities and differences between onsite inspections for vaccine trials sand for drug studies. In addition, experts will explain the requirements of WHO on clinical materials for pre-qualification of vaccines and share experiences.

LEARNING OBJECTIVES

- To know the requirements of quality management specifications and relevant rules on developing clinical trial of vaccines in China, and the schematic design for clinical trials;
- To know the importance to construct the clinical trial sites and cultivate researchers for clinical trials of vaccines;
- To grasp the key points in ethical review of clinical trials of vaccines, and the similarities and differences between the clinical trial of vaccines and the clinical trial of prescribed drugs;
- To know the similarities and differences between the clinical trial of vaccines and the clinical trial of prescribed drugs in terms of concerns in implementation and onsite inspection;
- To know how to handle the adverse events/ effects during clinical trials of vaccines;
- To know the basic principles for data management and biostatistical analysis in clinical trial of vaccines.

Target Attendees

- Medical, clinical research and registration personnels in vaccine/ bio-companies and CROs;
- Pharmacovigilance personnels in vaccine/ bio-companies and CROs;
- Data management and bio-statistical personnels in vaccine/ bio-companies and CROs
- Quality control/ quality assurance personnel for clinical trial of vaccines;
- Vaccine clinical trial implementing sites (such as CDC of provincial, municipal and county levels);
- Staff of relevant governmental agencies

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AGENDA | 3rd Floor, Multi Functional Hall - 1

Day 1 I Sunday, November 5

9:00-10:30	**Part 1: Guiding Principle of Design of Clinical Trial of Vaccines**

1.1 Interpretation of Guiding Principles Clinical Trial Design and Evaluation of Vaccines

The interpretation of relevant guiding principles for clinical trials of vaccines and the introduction of changes in the new regulations.

Huan YANG, MD, PhD
Senior Clinical Reviewer, Center for Drug Evaluation, CFDA

10:30-10:45	Tea Break
10:45-11:45	**Part 2: Requirements of WHO on Clinical Materials for Pre-Qualification of Vaccines**

Lei ZHANG
Director of Medical Affairs, Chengdu Institute of Biological Products Co., Ltd.

11:45-12:00	**Q&A**
12:00-13:30	Lunch | 4th Floor, Gourmet House
13:30-14:30	**Part 3**

3.1 Onsite Inspection and Quality Control of Vaccines Clinical Trial

Considering the difference of the clinical study of the vaccine and prescription drugs, to lecture and discuss the problems on the GCP violation.

Hannah CHEN
Director, AP, Quality Strategies, Johnson & Johnson

14:30-15:45	**Part 3 (Continued)**

3.2 Ethical Review Points for Clinical Trials of Vaccines & Case Study

Key points in ethical review of vaccine clinical trial: The similarities and differences between the vaccine and the ethical review of prescription drug clinical studies; and how to protect the vulnerable or under privileged group.

Yuhong SHEN, PhD, Associate Chief Pharmacist
Founder and General Manager, Beijing KangXin KeWei Medical Technology Co., Ltd.
Former CFDI Audit Expert

15:45-16:00	Tea Break
16:00-17:15	**Part 4: Adverse Events/Reactions in Clinical Trials of Vaccines**

4.1 The report and treatment of adverse events/reactions in clinical trials of vaccines.
4.2 Case Study

Yuanzheng QIU, PhD
Associate Director, Clinical Research Department, MSD

17:15-17:25	**Q&A**
17:25-17:30	**Summary for the First Day**

Day 2 I Monday, November 6

9:00-10:30	**Part 5**

5.1 Construction of Sites/Institutions and Development of Investigators for Clinical Trial of Vaccines

Accreditation of vaccine clinical trials sites/institutions and the key points of sites construction; and Case Study

Rongcheng LI, MD
Former Director, General of Institute for Clinical Research of Vaccines of the Guangxi Zhuang Autonomous Region Center for Disease Control and Prevention

10:30-10:45	Tea Break
10:45-11:45	**Part 5 (Continued)**

5.2 Training and Development of Investigators for Clinical Trial of Vaccines

Yanping LI
Former Deputy Director, Chief Technician, Vaccine Clinical Research Institute of the Center for Disease Prevention and Control, Guangxi Zhuang Autonomous Region

11:45-12:00	**Q&A**
12:00-13:30	Lunch | 4th Floor, Gourmet House
13:30-14:30	**Part 6: The Collection, Processing and Testing Of Biological Samples of Vaccine Clinical Trials**

Chong WANG, PhD
Qiagen (Suzhou) Translational Medicine Co., Ltd.

14:40-15:45	**Part 7: Clinical Trial Data Management and Biometric Analysis of Vaccines**

Jielai XIA, Prof.
Director, Department of Medical Statistics, Air Force Medical University (the Fourth Military Medical University)

15:45-16:15	**Q&A**
16:15-16:30	**Summary and Wrap-up**

组委会、讲者介绍 / Bios of Members of the Organizing Committee and Speakers

杨焕 医学博士 / Huan YANG, MD, PhD
中国国家食品药品监督管理总局药品审评中心高级审评员/临床主审人
Senior Clinical Reviewer, Center for Drug Evaluation, CFDA

杨焕，医学博士，临床医学研究员。自2002年以来在国家食品药品监督管理总局（CFDA）的药品审评中心(CDE)进行化学药品和生物制品的临床专业审评工作；目前是生物制品临床部的高级审评员和临床专业主审人，从事疫苗、血液疾病、基因和细胞治疗等新药临床专业技术审评；还参加CFDA/CDE的多项与药物注册审评审批相关的政策法规、临床指导原则制定及国家课题研究；同时承担十一届药典委员会委员、第一届国家免疫规划专家咨询委员会成员，及《中国新药杂志》编委等工作。

Huan YANG, MD, PhD, Clinical Medicine Researcher. Since 2002, Dr. YANG has been conducting clinical reviews of chemicals and biological products in the Center for Drug Evaluation (CDE) of the China Food and Drug Administration (CFDA). She currently is the Senior Clinical Reviewer in the Office of Clinical Evaluation of Biological Products and the chief review member, who is engaged in the clinical review of new drugs such as vaccines, hematological diseases, gene and cell therapies. Dr. YANG also participated in the review and approval of various CFDA/CDE's policies and regulations related to the drug registrations and the formulation of clinical guidelines & national research projects. Moreover, she is the member of the 11th Chinese Pharmacopoeia Committee, member of the 1st Advisory Committee on National Immunization Planning, and member of Editorial Board of the Chinese Journal of New Drug, etc.

李荣成 / Rongcheng LI, MD
广西壮族自治区疾病预防控制中心疫苗临床研究所原所长，主任医师
Former Director, General of Institute for Clinical Research of Vaccines of the Guangxi Zhuang Autonomous Region Center for Disease Control and Prevention

曾任广西卫生防疫站肝炎研究室副主任、主任、预防医学门诊部主任、广西疾病预防控制中心病毒科科长。原广西疾病预防控制中心疫苗临床研究中心主任，主任医师。

国际病毒性肝炎学术会议学委会成员、国家药品审评咨询专家、广西壮族自治区科技项目、科技成果进步奖评委、广西壮族自治区医师资格实践技能考试考官、广西疾病预防与控制人才小高地疫苗临床研究学科平台副台长。

Rongcheng LI has acted as vice director and director of Laboratory of Hepatitis of Guangxi Health and Epidemic Prevention Station, director of preventive medicine out-patient department, and section chief of Department of Virology, Guangxi Center for Disease Control and Prevention. He was the director of Vaccine Clinical Research Center of Guangxi Center for Disease Control and Prevention, and chief physician.

He is a member of International Committee of Academic Conference on Viral Hepatitis, a national expert on drug review and consultation, a rater of scientific & technological projects and scientific & technological achievement rewards in Guangxi Zhuang Autonomous Region, an examiner of Practical Skill Test for Qualifications of Physicians in Guangxi Zhuang Autonomous Region, and vice president of Vaccine Clinical Research Subject Platform of Guangxi Small Highland for Disease Prevention and Control.

组委会、讲者介绍 / Bios of Members of the Organizing Committee and Speakers

李艳萍 / Yanping LI

广西壮族自治区疾病预防控制中心疫苗临床研究所原副所长，主任技师

Former Deputy Director, Chief Technician, Vaccine Clinical Research Institute of the Center for Disease Prevention and Control, Guangxi Zhuang Autonomous Region

曾在广西壮族自治区疾病预防控制中心肝炎研究室、病毒性疾病防治科、疫苗临床研究中心任职，为中心首席专家。从事疫苗临床研究三十余年，组织和参与完成乙型、甲型、戊型等肝炎疫苗，肺炎、流脑、流感、风疹、嗜血流感杆菌等呼吸道疫苗，乙脑、出血热等自然疫源性疾病疫苗，伤寒霍乱、轮状病毒等肠道传染病疫苗，狂犬病疫苗，艾滋病（HIV）疫苗、脊髓灰质炎灭活（IPV）疫苗、肠道病毒疫苗（EV71）、人乳头状瘤病毒疫苗（HPV）等创新疫苗的临床研究，擅长临床试验方案设计和临床试验报告撰写。发表相关论文仅四十篇。

Yanping LI, female, Chief Technician. She ever served as Chief Expert of Guangxi Zhuang Autonomous Region Center for Disease Prevention and Control in the hepatitis laboratory, department for viral disease prevention and control, and vaccine clinical research center. She has been devoted to vaccine clinical study for over 30 years, involved in organization and completion of innovative vaccine clinical study, including but not limited to hepatitis A\B\E vaccines, respiratory vaccines for pneumonia, epidemic meningitis, flu, rubella, haemophilus influenzae, etc., natural focal disease vaccines for epidemic encephalitis B, hemorrhagic fevers, etc., intestinal infectious disease vaccines for typhoid, cholera, rotavirus, etc., rabies vaccine, HIV vaccine, IPV vaccine, EV71 vaccine, HPV vaccine, etc. Besides, she is adept at clinical trial scheme design and clinical trial report writing. She has released 40 clinical trial related papers.

沈玉红 博士，副主任药师 / Yuhong SHEN PhD, Associate Chief Pharmacist

北京康信科威医药科技有限公司总经理，创始人，原审核查验中心药品临床试验核查专家

Founder and General Manager, Beijing KangXin KeWei Medical Technology Co., Ltd. Former CFDI Audit Expert

2016年创办北京康信科威医药科技有限公司并担任总经理，致力于为国内外制药企业提供高质量临床试验稽查服务，帮助企业及时发现问题，降低风险，提高临床试验质量。公司项目涵盖中国大陆、台湾地区，涉及生物等效性试验，疫苗临床试验，药物临床试验等多个领域。先后与十余家药企合作完成了数十项临床药物试验的稽查工作，专业水平和服务质量获得广泛赞誉。

沈玉红博士原为国家食品药品监督管理总局食品药品审核查验中心研究核查处专职检查员，从事GCP/GLP认证检查工作多年，在疫苗临床试验项目及药物临床试验项目方面具有丰富检查经验，在临床试验伦理委员会的建设、审查及儿童临床试验等方面进行了多年的研究。

曾于华中科技大学同济医学院医药卫生管理学院获得博士学位，此前就读于第四军医大学临床医疗系，获学士学位。

Dr. Shen is the founder and general manager of Beijing Kangxin Kewei Medical Technology Company, which focuses on providing high-quality clinical trial audit services for pharmaceutical companies and helping them find the problems timely, reduce risks and improve the quality of clinical trials. Her business reaches mainland China and Taiwan, involving bioequivalence trials, vaccine clinical trials, medicine clinical trials and so on. Dr. Shen and her group have accomplished clinical trial audit work of dozens of investigational products for domestic pharmaceutical enterprises, and received widespread praise for professional standards and service quality.

Before starting the company, Dr. Shen served as full-time inspector for Center for Food and Drug Inspection of CFDA, where she gained years of experience in inspections of vaccine and drug clinical trials, GCP/GLP certification and so on. In the past decade, she has been studying the construction and review of ethics committee of clinical trials, pediatric clinical trials, and the like.

Dr. Shen obtained her doctorate from Huazhong University of science and Technology and her bachelor's degree from The Forth Military Medical University.

组委会、讲者介绍 / Bios of Members of the Organizing Committee and Speakers

夏结来 博士，教授 / Jielai XIA, PhD, Prof.
空军军医大学（第四军医大学）卫生统计学教研室主任
Director, Department of Medical Statistics, Air Force Medical University (the Fourth Military Medical University)

夏结来，博士，空军军医大学（第四军医大学）卫生统计学教研室主任、教授、博士生导师，国家食品药品监督管理总局审评咨询专家(生物统计)、中国信息协会统计理论与方法专业委员会副主任委员、中华预防医学会生物统计学分会侯任主任委员，中国卫生统计杂志编委、CCTS副组长、CDMC组长。

先后获7项国家自然科学基金项目资助，参与3项十一五科技创新项目研究，与CDE联合申报获得十三五重大科技专项一项。获国家科技进步二等奖一项、军队科技进步一、二等奖各一项、陕西省科技进步二等奖一项。

提出了回归系数有偏估计方法—根方估计和广义根方估计。先后在香港中文大学威尔士亲王医院临床与流行病学研究中心、美国鲁易斯安娜州立大学医学中心遗传与统计系访问研究。主要研究方向是临床试验设计与统计分析方法。参与了数十项的涉及化药、中药、生物制品、医疗器械等临床试验相关指导原则制定。

为一类创新药物—新的质子泵抑制剂艾普拉唑和EV71疫苗的研发以及H1N1疫苗临床研究数据汇总分析做出了重要贡献。目前正承担轮状病毒灭活疫苗、HPV疫苗等大规模临床试验的试验设计和后续的统计分析工作。在Statistics in Medicine, The New England Journal of Medicine等SCI收录的期刊上以共同第一作者或通讯作者发表论文40余篇。

Jielai XIA, PhD, Prof., the Air Force Medical University (the Fourth Military Medical University), doctoral supervisor, Director of the Medical Statistics, review consultant (biometric) of the CFDA, Deputy Director Member of the Statistical Theories and Methods Committee of Chinese Information Association, Director-Designate Member of the Biostatistics Branch of Chinese Preventive Medical Association, Editorial Board Member of Chinese Journal of Health Statistics, Deputy Working Group Leader of CCTS, Working Group Leader of CDMC.

Prof. XIA was awarded seven funding of National Natural Science Fund Project, participated in the three studies of 11th Five-year Plan of Science and Technology Innovation projects, one “13th Five-year Plan Major Science and Technology Projects by joint declaration with CDE. Prof. XIA won one 2nd Prize of National Science and Technology Progress, one 1st Prized of Military Science and Technology Progress, one 2nd Prize of Military Science and Technology Progress and one 2nd Shaanxi Province Science and Technology Progress.

Prof. XIA proposed the regression coefficient biased estimation method – root estimation and generalized square root. He successively visited and did the researches in the Clinical and Epidemiological Research Center of Hospital Prince of Wales Affiliate to the Chinese University of Hong Kong, in the Genetic Research and Statistics Department of the State University of George Louisiana Medical Center in the United States. The main research direction is clinical trial design and statistical analysis methods. He also involved in dozens of guidelines formulation of medicine, Chinese medicine, biological products, medical devices and other related to clinical trials.

Prof. XIA has made great contributions to the Class I of Innovative Drugs -- new proton pump inhibitor Ilaprazole and EV71 vaccine research and development as well as the H1N1 vaccine clinical research data summary and analysis. Prof. XIA is now undertaking the large-scale clinical trials design and subsequent statistical analysis of rotavirus inactivated vaccines, HPV vaccine and others. He has published more than 40 pieces papers as the co-first author or corresponding author in SCI journals, such as the Statistics in Medicine, The New England Journal of Medicine.

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陈华 / Hannah CHEN
强生公司质量策略亚太总监
Director, AP, Quality Strategies, Johnson & Johnson

Hannah于2012年9月份加入强生亚太与中国研发机构的生物学研究质量与合规部门（BRQC),目前担任强生公司质量策略亚太总监，她及她的团队负责：非监管部分、良好实验室规范（GLP） 、临床试验规范（GCLP)、药物临床试验管理规范（GCP)和药物警戒(PV)方面的审核工作；她还负责从战略层面上确保亚太地区的相关风险能在审核项目中得到反馈与沟通。2016年9月起，她担任生物学研究质量与合规部门中国区负责人，负责亚太区和中国区研发部门质量管理系统中战略性地整合质量保证与合规性的内容。

在加入强生公司之前，Hannah曾在葛兰素史克公司工作15年，其中有10年时间从事审核工作。她曾在亚太地区的很多国家从事药物临床试验管理规范方面的审核工作，也在美国、欧洲、拉丁美洲和非洲的很多国家工作过。她还从事过药物警戒系统和临床实验室方面的审核工作。此外，她还多次参与公司内部与外部的培训项目。2010年4月至2012年10月，她协助了FDA的中国培训项目。自2009年起，她就与FDA中国办公室密切合作，在药物临床试验管理规范方面提供了大量的咨询并起草指南性文件。她还在临床研究方面工作过将近五年。在加入葛兰素史克公司之前，Hannah在美赞臣公司做过八个月的销售代表。

Hannah在首都医科大学获得医学学位。1996年加入本行业之前，她是一名儿科医师。

Hannah is leading a team of auditors in AP region covering: non-regulated, GLP, GCLP, GCP and PV audits; she also provides strategic input to audit program to ensure risks in AP region are communicated and reflected in the audit program.

She joined Johnson & Johnson in September 2012 from GlaxoSmithKline (GSK). She has worked for GSK for more than 15 years, including 10 years in the area of auditing. Hannah conducted a variety of GCP audits in many AP countries, as well as in US, Europe, Latin America and African countries. She also has experience in PV system audits and clinical lab audits. She has been involved in many internal and external training programs, assisted US FDA inspection training workshop in China from April 2010 to Oct. 2012.

Hannah has been working closely with China FDA since 2009, provides consultation and involves in the development of guidance documents in GCP area. Hannah has also spent approximately 5 years in Clinical Research. Prior to joining GSK, Hannah worked for almost 8 months as a sales representative in Mead Johnson.

Hannah obtained her Medical Degree from Capital University of Medical Sciences in China and worked as a Pediatrician for years before joined industry in 1996.

组委会、讲者介绍 / Bios of Members of the Organizing Committee and Speakers

丘远征 博士 / Yuanzheng QIU, PhD
默沙东（中国）临床研究部副总监
Associate Director, Department of Clinical Research, MSD R&D (China)

丘远征现任默沙东研发（中国）有限公司临床研究副总监，从事疫苗临床研究工作。

加入默沙东之前，丘远征曾任职于赛诺菲巴斯德医学部，从事疫苗临床研究、医学事务，以及AEFI的监测和管理工作。在此之前，曾先后任职于葛兰素史克、北京科兴、北京生物制品研究所，从事疫苗研发、临床研究、医学事务工作。先后参与了人用禽流感H5N1疫苗、甲流H1N1疫苗、脊髓灰质炎灭活疫苗、甲肝疫苗、Tdap疫苗、HPV疫苗、轮状病毒疫苗的临床研究。

丘远征本科毕业于北京大学医学部，博士毕业于清华大学。

Yuanzheng Qiu is associate director of clinical research at MSD R&D (China), and responsible for vaccine clinical study in China.

Prior to joining MSD, Yuanzheng Qiu worked for Sanofi Pasteur (China), and responsible for vaccine clinical study, medical affairs and AEFI surveillance and management. Before that, Yuanzheng Qiu worked for GlaxoSmithKline China, Sinovac Biotech and National Vaccine and Serum Institute, and responsible for vaccine pre-clinical research, clinical research and medical affairs. Yuanzheng Qiu had worked with pre-pandemic H5N1, pandemic H1N1, IPV, hepatitis A, Tdap, HPV and rotavirus vaccines in clinical studies.

Yuanzheng Qiu received his bachelor degree of medicine from Health Science Centre of Peking University, and PhD degree from Tsinghua University.

组委会、讲者介绍 / Bios of Members of the Organizing Committee and Speakers

王丛 博士 / Chong WANG, PhD
凯杰（苏州）公司副总裁
Vice President of QIAGEN (Suzhou)

王丛博士，担任凯杰（苏州）公司副总裁（VP）（负责公司药企和临床研究方面的事务）。

王丛博士于1988年毕业于北京医科大学获医学学士学位，同年赴美国做科研工作。王丛于1997年获得美国威斯康星大学麦迪逊分校博士学位，后入职Altea Therapeutics Inc.，从事皮肤贴剂疫苗，治疗分子（蛋白质，多糖）传递和小分子药物持续给药产品的研发。涉及流感病毒，乙肝和破伤风病毒疫苗产品研发项目。

王丛博士于2007年加入CRO科文斯中心实验室，担任科学事务高级研究员。为全球主要药厂客户提供中心实验室检测服务。王博士于2012年加入科文斯上海中心实验室担任实验室总监，负责实验室管理和支持药物临床试验，建立和发展伴随诊断测试服务，生物标记物检测与精准医疗应用。

王丛博士拥有纽约州实验室负责人资格证书，ABMLI Diplomate（美国医学实验室免疫学协会会员），美国病理学家学院的CAP证书持有人，涉及主持实验室CAP认证和 ISO15189的实验室认证。

Dr. Chong Wang, Vice President (VP) of QIAGEN (Suzhou) is responsible for pharmaceutical research and development of translational medicine.

Dr. Wang graduated from Beijing Medical University in 1988 with a bachelor's degree in Medicine. He went to the United States for scientific research in the same year. Chong Wang received his Ph.D. degree from the University of Wisconsin-Madison in 1997 and worked as a senior scientist at Altea Therapeutics Inc., where he worked in developing skin patch vaccines, therapeutic molecules (proteins, polysaccharides) and continuous infusion of small molecule drugs. Dr. Wang involved in influenza virus, hepatitis B and tetanus virus vaccine product development projects.

Dr. Wang joined the CRO Covance Center Laboratory in 2007 as a senior scientist in Scientific Affairs, providing technical support to the world's major pharmaceutical companies for central laboratory testing services, presided over immunology and flow cytometry detection method validation. Dr. Wang joined Covance Shanghai central laboratory in 2012 as Laboratory Director, responsible for laboratory management and operation, worked in developing companion diagnostic testing services, biomarker testing and precision medical applications.

Dr. Chong Wang has a New York State Laboratory Qualification Certificate, ABMLI Diplomate, Member of the CAP Certificate of the American College of Pathologists, and served in laboratory accreditation and ISO15189 laboratory accreditation processes.

张磊 / Lei ZHANG
成都生物制品研究所有限责任公司医学事务部经理
Director of Medical Affairs, Chengdu Institute of Biological Products Co.,Ltd.

张磊1992年加入卫生部成都生物生物制品研究所（现中国生物技术集团成都生物制品研究所有限责任公司），从事疫苗的研发工作。2003年至2004年，作为国家公派访问学者，在比利时布鲁塞尔巴斯德研究所从事新型结核病疫苗的研究工作。2004年10月回到成都生物制品研究所有限责任公司后，负责出口疫苗产品的国际注册、海外临床试验以及技术支持工作。

张磊有着多年的疫苗国际注册和临床研究经验， 在负责出口疫苗产品的国际注册和临床试验期间，在十多个国家成功注册了多个国产疫苗产品，并参与了乙型脑炎减毒活疫苗世界卫生组织预认证项目， 负责临床试验资料的准备，参与或主持了多个乙型脑炎减毒活疫苗的国际、国内疫苗临床试验项目。2013年，乙型脑炎减毒活疫苗成为中国第一个通过世界卫生组织预认证的疫苗产品。

张磊现任成都生物制品研究所有限责任公司医学事务部经理，负责药物警戒工作。

ZHANG Lei joined Chengdu Institute of Biological Products of Ministry of Health in 1992 (present Chengdu Institute of Biological Products Co., Ltd., China National Biotec Group), worked at vaccine R&D division for long time. Then he had worked on researching new tuberculosis vaccine in Pasteur Institute in Brussels, Belgium as a government-sponsored visiting scholar from 2003 to 2004. After returned to Chengdu Institute of Biological Products Co., Ltd. in 2004, he took charge of international registration, clinical trials and technical support for vaccine products export.

Zhang Lei has many years of experience on international registration and clinical study for vaccines. While he was taking charge of registration and clinical trials for vaccine export, his team successfully obtained marketing approvals for multiple vaccine products in more than 10 countries. He was involved in WHO prequalification project of live attenuated Japanese Encephalitis Vaccine to prepare clinical trial material. He participated in or managed multiple clinical trials of live attenuated Japanese encephalitis vaccine in China or other countries. Live attenuated Japanese encephalitis vaccine was qualified by WHO In 2013 and became the first WHO prequalified vaccine product made in China.

Zhang Lei is the director of medical affairs at Chengdu Institute of Biological Products Co., Ltd, and responsible for pharmacovigilance.

临床研究中的供应商选择，认证和管理研讨班

2017年12月7-8日 | 上海齐鲁万怡大酒店

DIA 中国

组委会成员

顾娟红
阿斯利康（中国）临床研究总监

Fannie Lai
Senior Director, Business Development Asia Pacific, PRA Health Sciences

任科
药明康德津石医药科技有限公司副总裁

张艳
Q Squared Solutions中心实验室副总裁，亚太区总经理

张玥
博纳西亚临智（上海）数据科技有限责任公司总裁

参会人员

- 临床项目管理人员
- 临床研究规划和战略策划人员
- 数据管理专业人员
- 临床研究专业人员
- 供应商选择人员
- 临床研究者和协调员
- 临床监查员
- 临床质控和质保专业人员
- CRO商务发展和市场部人员

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随着国内各制药公司对新药研发的日益关注，如何选择临床研究的供应商，确保试验数据的真实规范，以及与各个供应商更有效的沟通，成了摆在医药研发企业面前的问题。DIA中国将于2017年12月再次召开 “临床研究中的供应商选择、认证和管理研讨班”，邀请业界资深专家和相关公司负责人进行讲课。

会议重要日程

供应商选择概述
从sponsor和procurement等的角度，谈谈如何选择供应商。

新型供应商的重要性
介绍临床研究中的小众供应商，分享执行管理中的特点、流程，风险要点等，增加对小众供应商的了解。

SMO的选择和管理
介绍和分析SMO在中国的现状，包括行业概述、机会、问题和挑战。从供应商角度和申办方角度分享在SMO的选择和管理经验，并就面临的问题提出解决办法。

CRO的选择和管理， CRO的资质以及绩效管理的供应商评估工具
制药企业-CRO的关系一直受到重视，供应商关系与绩效管理对外包临床研究至关重要。会议将概述如何加强战略采购与谈判方面的专业知识，为我们的客户提供端到端的服务，使我们成为业务目标执行中的重要合作伙伴，并讨论如何运用采购、质量控制的原则来建立一种机制，使供应商能够提供一流的产品和服务，并提高供应风险的可管理性，同时增加供应商的可信度。

中心实验室的选择和管理
将基于实验室服务的市场需求及趋势讨论如何选择和管理中心实验室，关注以下几个方面：

- 来自CFDI稽查的经验
- 中心实验室和诊断实验室在生物标记物检测服务上的异同
- 中心实验室在伴随诊断项目中的角色和责任

数据统计供应商的选择和管理
随着药监局临床数据管理和统计分析法规的强化和完善，国内临床试验数据管理和统计分析的专业性要求已经和国际水平一致，需要由有经验的专业团队来执行，数据管理和统计外包的需求很高。如何寻找符合资质并最适合项目需要的数据统计供应商，同时在项目执行过程中有效监督供应商的工作质量，是项目成功的关键。将邀请经验丰富的数据管理和统计专家主讲甄选数据管理和统计供应商是应涉及的技术细节，采用实例模拟的方式请参会人员进行实战练习。

供应商管理圆桌论坛

10th Years Anniversary

DIA

2018中国国际药物信息大会
暨第十届DIA中国年会

The 10th DIA China Annual Meeting

2018年5月22-25日 | 北京国际会议中心

May 22-25, 2018

Beijing International Convention Center