2017 DIA中国年会

演讲者介绍

专题研讨会1

李元念

博士
江苏豪森药业集团有限公司高级副总裁
上海翰森医药生物有限公司执行总经理

刘萍

PhD, Head of Clinical Pharmacology of Pfizer China

Dr. Ping LIU joined Pfizer global Clinical Pharmacology Department in 2003 (Groton, CT, USA), and had served as a Clinical Pharmacology Lead over 13 years before transferring back to Pfizer China. She has been responsible for design, analysis, interpretation and reporting of pharmacokinetic and pharmacodynamic data and results, including population modeling/

simulation, and their impact on development and clinical use of drugs. She has extensive experience in supporting regulatory submissions/approvals and interacting with worldwide regulatory agencies. She has published 30 peer-reviewed articles.
Ping Liu received her Ph.D. in Pharmaceutics (2002) from University of Florida, USA, M.Sc.in Pharmaceutics from Memorial University of Newfoundland, Canada, and B.Sc.in Pharmacy from Beijing Medical University, China.

雷继峰

上海安必生制药技术有限公司董事长及总经理

雷继峰，上海安必生制药技术有限公司董事长及总经理，青岛百洋制药有限公司董事，化学工程硕士和工商管理硕士学位。ISPE（国际制药工程协会）中国区2015-2016年度主席。雷继峰曾任职多家跨国制药公司。1988年至1999年历任西安杨森制药公司工程技术部经理，生产部经理和运营总监；2000年至2003年任法国赛诺菲(杭州)制药公司的工厂总经理，2003年至2007年任葛兰素史克(天津)制药公司的工厂总监；2007年，创办的上海安必生制药技术公司，已经为国内多家制药企业在美国市场研发和申报了二十余个制剂产品（ANDA），获批10个。其30多年的制药经历涵盖了制药工程和生产、药品工艺开发和优化、制药工厂管理和制药研发公司的创建和经营.
雷继峰先生还是北京大学国际制药工程硕士项目（IPEM）的授课老师和ISPE（国际制药工程协会）口服固体制剂和工艺验证课程的培训师。雷继峰担任国家药品食品监督管理总局（CFDA）药品认证中心的GMP讲师和专家，二十余次为国家药监局GMP认证检查员的提供培训，参与了我国2010版GMP的修订工作。担任2010版GMP三个技术指南编写小组的组长。

Dale CONNER

Pharm.D, Director, Office of Bioequivalence (OB), Office of Generic Drugs, FDA Center for Drug Evaluation and Research (CDER)

Dr. Dale CONNER received his B.Sc. in Pharmacy from the Massachusetts College of Pharmacy in 1979, and a Pharm.D. in 1983 from the University of Florida. From 1983 to 1985, he completed a postdoctoral fellowship in Clinical Pharmacology in the Division of Clinical

Pharmacology of Thomas Jefferson University. He then joined the faculty of the Uniformed Services University of the Health Sciences as an assistant and later associate professor in the Division of Clinical Pharmacology. From 1992 to 1994, he was Director of Pharmacokinetics for Scios Nova, Inc. From 1995 to 1997, he held the position a FDA of Team Leader for Clinical Pharmacology and Biopharmaceutics in the areas of Pulmonary, allergy, drug abuse, anesthesia and critical care drug products. His current position is Director Office of Bioequivalence, Office of Generic Drugs, FDA. He is board certified in Applied Pharmacology by the American Board of Clinical Pharmacology. Research interests has included pharmacokinetics, drug metabolism, analytical methods, transcutaneous measurement of drugs, measurement of drug effects on the skin, and drug therapy of sepsis and ARDS.

Alexander HONEL

Quality By Experts, The Inspectors Network. Consulting and Training Services

- Audits in GCP, GMP, GLP, Blood, Tissue and Medical Devices, and Trainings (since 2014)

10 years Head Inspectorate & Enforcement, Federal Office for Safety in Health Care, Austria, Europe (2004-2014)

- Responsible as inspector, Areas of Expertise GMP, GLP, GCP, Blood and Tissues, Advanced Therapies, Medical Devices, Hemo- and Tissue Vigilance, Quality Defects and Drug Shortages, Pharmacovigilance, Narcotics (for OECD), Import of Medicines to Austria, Enforcement, Specialty GCP inspections / audits around the world. Several hundred inspections in the mentioned fields during these years, main areas Quality Management Systems in Hospitals, functioning of Quality Assurance and Management Oversight, companies, special areas under the mentioned laws and guidelines
- As head of Enforcement link to police and border police, speeches at congresses of the WGEO, Working Group of European Enforcement Officers. EMA Expert (PHV and GCP), Medical Devices, and PIC/S Executive Committee member.
- Several years in Industry, Clinical Liaison Manager and Senior Medical Manager
- Clinical Trials Management, Project Management, Quality Assurance and Quality Control for Clinical Development, Opinion Leader Contact Point
- Background: Medical Law (Lawyer), Veterinary Medicine: Dr. med. Vet, Master of Business Administration, MBA, Master of Laws, LL.M, Master of Science, MSc, PharmaManagement, ISO Quality Manager and Quality Auditor

李雪宁

主任药师，教授，博士生导师
复旦大学药学院教授
复旦大学附属中山医院临床试验机构副主任兼机构办主任

李雪宁，主任药师，博导，复旦大学药学院教授，现任复旦大学附属中山医院临床试验机构副主任兼机构办主任。分别负责“十五”~ “十三五”重大新药创制科技重大专项GCP平台各1项、上海市科委项目2项，负责完成的各类新药的I期临床试验近百项，其中新药的首次人体（或中国人体）试验13项。发表论文98篇，其中SCI论文23篇。分别于1998年在英国和瑞典Quintiles AB及2010年在美国西部伦理委员会进修学习。担任多本核心期刊的编委、是中国药理学会药物临床试验专业委员会常务委员和上海市药理学会药物临床试验专业委员会主任委员。

谢雨礼

博士
苏州偶领生物医药有限公司总经理

谢雨礼，毕业于南开大学化学系，获得中国科学院上海药物研究所博士，曾在美国哥仑比亚大学化学系从事博士后研究。美国期间，在哥仑比亚大学医学院与Merck合作的孵化中心担任项目主管，从事立项和新药研发工作。回国后，先后在制药公司担任多个职务，包括扬子江药业集团上海研

究所所长，日本大冢上海药物研发中心副总监，和药明康德CMC办公室主任和制剂部运营主管。现担任苏州偶领生物医药有限公司总经理。从事运营,新药立项，项目管理以及市场研究等工作。曾发表学术论文30余篇，获国际专利5项和中国发明专利3项。有15年新药和仿制药开发经验，熟悉治疗领域和新靶点，以及法规，政策和市场。

专题研讨会2

磨筱垚

北京人和广通资讯有限公司药物安全顾问

她有19年的国际大药企(强生，辉瑞，默克，阿斯利康）的医学部和R&D药物研发经验， 从事过药物临床研究监察， 医学信息处理与应用；近15年专注于药物安全和风险管理， 对于制药公司药物安全职能建立和运营有丰富经验，风在药械风险管理方面能提供有效解决方案。 在加入制药行业前，她是一名临床内科医生。
她也是国内药物安全行业的带头人，自2005年至今2014年被推选为RDPAC药物警戒工作组组长; 于2009-2012年是中国ICH学习小组M组专家；2008-2012曾为北大国际创新药物研发和管理课程讲师。她不断结合我国药监特点和实际情况，介绍和发展国际药物安全的技术知识和理念，长期致力于推动中国药物安全事业的发展。

赵子贤

博士，阿斯利康美国药物安全监测部门主管

赵子贤博士具有超过18年在医药企业多领域工作经验的高级管理者。他有久经证实的专业技能包括：全球药物安全，药物安全监测，药物流行病学，危险评估及控管，上市后研究，药物安全标准化及程序步骤的建立与提升，药物经济学及循证医学的研究，药物临床研究。他成功地在不同的大，中，小型医药以及生物医药企业中建立和领导了全球药物安全部门，药物安全监测单位，以及药物流行病研究组；有效地管理了同药物开发及销售合作伙伴之间的药物安全工作；以及有效地管理了药物安全外包公司承包的所在药企之工作。 他对美国（FDA）, 欧洲共同体（ EMA），加拿大（health canda），日本等药物监管部门的法律，法规，指南有深刻地理解，并有大量同这些监管部门工作的经验。 并应邀参与了许多药物企业协会和药物监管部门组织的药物安全研讨会，专家论坛，和具体的安全方法及指南建立的工作组。曾在各种学术杂志和会议上发表过超过百篇以上的科研论文。

专题研讨会3

郭翔

Senior Director, Biostatistics,
MSD R&D (China) Co, Ltd.

Dr. Guo currently is a Senior Director of MSD R&D China, head of the Asia-Pacific Statistic Group of Merck Research Laboratories. Before joining Merck, Dr. Guo started his industrial career with Sanofi in 2005 in Bridgewater, New Jersey. He was the lead statistician for Sanofi's bestselling drug Lantus.

Dr. Guo received his Ph.D. degree in Statistics from North Carolina State University. His research interests focus on statistical inference in Multi-regional Clinical Trial, benefit risk assessment, missing data analysis and adaptive design. Besides his industrial position, Dr. Guo also holds adjunct teaching positions in Peking University and Beijing Normal University. Dr. Guo is the chair of DIA China statistical community, a member of DIA Advisory Committee of China, a member of China Clinical Trial Statistics Working Group (CCTS) and the secretary general of Beijing Biometrics Association.

李智

Medical Affairs China Group I Director,
Clinical Development and Medical Affairs
Boehringer Ingelheim

Dr Zhi LI is Director, Medical Affairs group I with Boehringer Ingelheim China since 2015. He was Medical Advisor, and Sr, Manager of Medical Affairs including MSL function with MSD and Roche in China. He was trained as clinical physician and practiced clinical medicine for more than 10-year with leading teaching hospital in China.

邱婧君

Senior Statistician, Data Sciences & Analytics
Bayer Healthcare Company Limited

Jeannie is currently providing statistical supports in Bayer Healthcare Company; and has been working in Biostatistics Department of MSD China for over 5 years. Jeannie has rich experience in various therapeutic areas for different regions; and has worked on epidemiological studies and clinical trials which were covering drug development stages from strategy planning to post-marketing analysis. As a member of DIA Young Member Advisory Council (YMAC), Jeannie has actively co-organized DIA Quantitative Science Forum (QSF) and DIA China Stats Community seasonal Seminars working together with Experts in Statistical Community and various pharmaceutical functions. Before entering pharmaceutical industry, Jeannie has gotten the master degree in Epidemiology and Biostatistics from Capital Medical University, China; then has been working as a post-graduate associate in School of Medicine, Yale University.

卫芳

Senior Director, Medical Affair, MD
China Medical Affair-Women Health/Bone/Pain/MSS Franchise
Hangzhou MSD Pharmaceutical Co. Ltd

Knightley was awarded her Bachelor degree in clinical medicine and Master degree in Ophthalmology, at Shanghai Jiao Tong University. She was attending Ophthalmologist at Shanghai Renji Hospital for eight years, responsible for clinical research in eye care, whilst also responsible for clinical education and surgery.
Knightley joined MSD China medical affair as Medical Advisor and has over twelve years of industry experience, in all aspects of pharmaceutical medicine including the management of company sponsored clinical trials, IITs, training and educational programs and product crisis

management. She has a track record of success in roles of increasing responsibility, most recently as Senior Medical Affair Director for MSD China. Here she led Bone/Pain/Women Health and Medical Service Scientist Team over 30 staffs. She comes to us with a breadth of experience across multiple therapeutic areas including osteoporosis, women health, dermatology, ophthalmology, urology and pain.

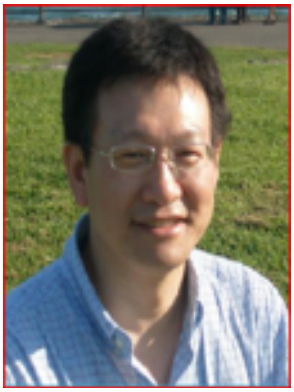
专题研讨会4

孙华龙

博士
美达临床数据技术公司总经理

日本东京大学医学博士，美达临床数据技术有限公司总经理，17年余行业经验，曾先后就职于默克雪兰诺、 PAREXEL等跨国药企和CRO，担当生物统计、数据管理、项目主管、数据部门负责人等职 。全球药物信息协会（DIA）中国区顾问委员会委员，中国临床试验数据管理学组（CDMC）成员，中国医疗器械行业协会数据分析专业委员会委员。

颜崇超



博士

江苏恒瑞医药股份有限公司数据管理部资深总监

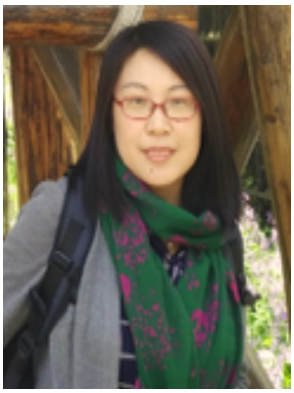
颜崇超，营养学博士，现任恒瑞临床数据科学中心负责人。中国中医药研究会临床研究分会常务理事，中国临床研究数据管理学组（CDMC）核心成员。曾是辉瑞（中国）研发中心数据服务部的技术运营负责人，并曾在上海医药临床研究中心任数据管理部高级总监。 曾在美国勃林格殷格翰制药公司从事临床研究的生物统计与数据管理的技术应用和管理工作。先后在意大利高级卫生研究院、美国亚利桑那大学医学院和纽约大学医学院从事医学研究，并在国内外期刊上发表过40余篇学术论文。

浦迪

精鼎医药研究开发（上海）有限公司，数据管理部门经理

8年临床数据管理经验，毕业于中国药科大学，曾就职于美迪西生物医药研发部门，2009年加入精鼎医药。

代囡



美达临床数据技术公司临床数据管理部经理

10年以上行业经验，曾就职于精鼎医药（PAREXEL International）、上海津村等跨国药企和CRO，具有丰富的欧美、日本和中国国内的I-IV期的临床试验经验以及EDC、CDMS系统使用经验。

特别论坛

Theresa MULLIN

Office of Strategic Programs
FDA Center for Drug Evaluation and Research (CDER)

Dr. Mullin serves as Director of OSP, whose mission is to transform and modernize drug regulatory operations, playing a lead role in a number of CDER's strategic initiatives including the human drugs international program, data standardization, business informatics, lean management, development of benefit-risk and other decision support tools, program analysis, and major user fee negotiations. Having led successful negotiations for the previous 3 cycles of reauthorization, Dr. Mullin is currently serving as FDA's lead negotiator for the 2017 reauthorization of the Prescription Drug User Fee Act (PDUFA), a program that currently provides more than $800 million per year in fee funding for new drug review. She is also serving as FDA's lead negotiator for the 2017 reauthorization of the Biosimilar User Fee Act (BsUFA).
Dr. Mullin leads the FDA Patient Focused Drug Development Initiative, an effort begun in 2012 to better incorporate the patient's voice in drug development. She also heads the FDA delegation to the International Council on Harmonization, the primary venue for international harmonization of drug regulatory standards. Before joining CDER in September 2007, Dr. Mullin was Assistant Commissioner for Planning in the FDA Office of Commissioner, where she served as Director of the Office of Planning.
Since joining FDA Dr. Mullin has received numerous awards including the Senior Executive Service Presidential Rank Award for Distinguished Service in 2011, and the Presidential Rank Award for Meritorious Service in 2006. In addition, she has recently been named as one of the 2016/2017 recipients of the US Food and Drug Law Institute's Distinguished Service & Leadership Award. Before joining FDA, Dr. Mullin was a Senior Manager with The Lewin Group, specializing in health care consulting, and prior to that, Principal Scientist at Decision Science Consortium, specializing in decision research and analysis. Dr. Mullin received her B.A., magna cum laude, in Economics from Boston College, and Ph.D. in Public Policy Analysis from Carnegie-Mellon University.

安田尚之

Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA)

Mr. Naoyuki Yasuda is currently Office Director, Office of International Programs in Pharmaceuticals and Medical Devices Agency (PMDA), Japan. He took his position from July 2015. He works as representative of most of the multilateral meetings on pharmaceuticals and medical devices including one of the Japanese representatives of Assembly and the Management Committee of ICH.
He graduated from Osaka University, Faculty of Pharmaceutical Sciences in 1991 and joined Ministry of Health and Welfare (former Ministry of Health, Labour and Welfare (MHLW)). His career includes chemical safety assessment work as OECD Secretariat in 1998, Medical devices evaluation policy in MHLW in 2003, Narcotics and Psychotropic Substance control as First Secretary, Permanent mission of Japan to the international organizations in Vienna in 2005, Blood and Blood Product supply as Planning Director for Blood and Blood Products in 2010, and the international pharmaceuticals and medical devices policy in MHLW as International Planning Director in 2011, and GLP/GCP/GPSP compliance as Office Director, Office of Non-Clinical and Clinical Compliance, PMDA.

Barbara KUNZ

全球首席执行官

本着改善全世界人民健康福祉的使命，昆茨女士专注于推动创新并制定和完善DIA战略。她负责领导DIA全球运营业务并向DIA的全球董事会汇报。昆茨女士曾在营利性和非营利机构担任管理职务。在加入DIA前，她在世界上规模最大，最受推崇的非营利的研发机构之一的Battelle 研究所，担任“健康和生命科学”部的总裁，该机构遍布100多个区域，研发经费高达65亿美金。她还曾担任Thermo Fisher Scientific的生物科学高级副总裁和总经理职位，建立了该组织的知名度，通过收购及战略联盟与生物制药领域，诊断领域和学术协会达成合作伙伴关系，并建立了14亿美金的投资战略组合。她还曾负责ICI/Uniqema's的拉美区域业务，通过建立区域的贸易业务，提高了整个地区的成本效益，进而领导该公司在历史上最动荡的时期成功地实现了商业增长。
昆茨女士是一位科学家，拥有14项专利。她曾在美国俄亥俄州立大学的Wexner医学中心，BiOhio，国际科学标准（一家与韩方的合资企业），医疗器械公司Levitronix和POCARED等组织，担任不同的董事会职务。她积极支持儿童健康，在儿童联盟学校委员会任职，致力于解决俄亥俄州中部有发育障碍的儿童的需求，并成为全国儿童医院研究所和国家儿童研究所的受托人。昆茨女士持有阿克伦大学硕士、特尔大学学士学位，并获得欧洲工商管理学院（INSEAD）的国际管理项目的学位。

李自力

FDA药品评价和研究中心（CDER）
仿制药办公室全球事务副主任
医学博士、公共卫生硕士

李自力博士是美国FDA仿制药国际事务负责人。他肩负着建立一个以绩效为导向的仿制药国际事务工作模式的重任，从战略上有计划的应对美国仿制药项目所遇到的全球性挑战。
在2015年底重新回到FDA前，李自力博士曾担任比尔及梅琳达•盖茨基金会高级项目官及CFDA 项目负责人，基金会中国办公室副主任和研发部负责人。他还曾任美国默克公司中国医学部总监，

亚太地区药品注册政策负责人，和全球新兴市场药品注册战略策划部执行总监等职位。2000-2005年期间，他在FDA新药办公室担任临床审评员和临床审评组负责人。
2009年，李自力博士和一些前美国FDA同事，成立了美国FDA同仁会国际部，致力于促进新兴市场药监机构的科学审评能力提高的培训工作。他于 2013 和 2014 年七月，分别获得中国国家食品药品管理总局药审中心颁发的“法规科学特别贡献奖”和美国FDA颁发的“特别贡献奖”。
李自力博士毕业于北京协和医学院八年制临床医学专业，在约翰•霍普金斯大学完 成了住院医师的培训，获得执业医师资格。他还取得了两个公共卫生硕士学位。

斋腾宏畅

PhD
Vice President, Oncology Clinical Development Department, Daiichi Sankyo Co., LTD, Janpan
Vice Chairman, ICH Committee, Japan Pharmaceutical Manufacturers Association (JPMA)

Dr. Saito received his Ph.D. from Chiba University in Japan.
He has been working legacy Sankyo and Daiichi Sankyo for almost 30 years.
At first, he was the member of Research division, focusing on Drug Delivery System and Drug Eluted Stent. He got Ph.D. degree based on the research of “diffusion mechanism of Prostacycline from Silicon coated Stent”.
After that, he moved to clinical strategic team and became team leader of anti-hypertensive agents named Olmesartan in Japan from 1997 to 2005. He experienced global development with US/EU colleagues. From 2006, he also had the responsibility for Asian development section and became senior vice director to register Olmesartan in the rest of world (Asia, South and central America and Saudi Arabia etc.). From 2012, he became vice president of new drug regulatory affairs Department in Japan and co-chairman of Global Regulatory Affairs Committee.
From 2016, he has become vice president of oncology clinical development in Japan.

He has been the core member of DIA advisory Committee in Japan from 2000. He had been Chairman of DIA Asian Workshop in Japan for 5 years. He got DIA outstanding award in 2007. He is now member of DIA advisory Committee of Japan in 2015.
He has been JPMA rep. of ICH steering Committee and chairperson of ICH project committee in JPMA from 2012 to 2016. Now He is Vice chairperson of this committee in JPMA.

Vibeke BJERREGAARD

Senior Regulatory Affairs Manager, Novo Nordisk A/S

Vibeke managed Regulatory Affairs functions in industry head quarter functions since 1980 and join Novo Nordisk A/S in 1988.
Vibeke has a Master of Science and diploma in biological sciences from Copenhagen University and a diploma in business administration from the Copenhagen Business School.
Vibeke Bjerregaard works with international regulatory science, new development projects as well as lifecycle management. Her responsibilities involved Novo Nordisk' diabetes and growth hormone treatments and include project – and lifecycle planning to ensure the company's authorisations on a global basis. Vibeke Bjerregaard is engaged in external affairs activities, involving strategic discussions focusing on legal and medical aspects.
Vibeke has chaired and joined taskforces, courses and conferences on GCP requirements, therapeutic guidelines and regulatory science.
Vibeke joined the ICH E 17 expert working group, when it was established of the ICH meeting in June 2014, and attended the first Face to Face with the expert working group in December 2014.
This is Vibeke's first experience as member of an ICH expert working group. She has follow the ICH development of guideline and ongoing discussion since the first ICH conference in 1990 in Brussels, and joined a few ICH international conferences since then.

Wassim NASHABEH

Ph.D., Vice President, Technical Regulatory Policy & International Operations; F. Hoffmann-La Roche, Basel, Switzerland

Dr Wassim Nashabeh received his Ph.D. in Analytical Chemistry from Oklahoma State University in 1993, and his post-doctoral fellowship from "Barnett Institute of Chemical and Biological Analysis" at Northeastern University where he developed new approaches for the separation of closely related recombinant protein variants. Thereafter, he joined PerSeptive Biosystems as a Senior Scientist from 1994-1996, where he co-developed new schemes for antibody modification with fluorescent and enzymatic labels for use in micro-fabricated chips based immunoassays.

In 1996, Dr Wassim Nashabeh joined Genentech (A member of the Roche Group) as a Scientist and had since held several positions of increasing responsibilities including Associate Director, Methods validation group, Director Quality Control Clinical Development, Director in the CMC Regulatory Affairs Group, Sr. Director of CMC Policy & Strategy, Global Head, Technical Regulatory Policy & Strategy for the Roche Pharma Medicines Group and most recently as Vice President, Technical Regulatory Policy and International Operations. His current primary responsibilities include the development of global innovative regulatory strategies, as well as the development of key positions on a variety of subjects of significant impact to Pharma Technical Operations, and management of Roche CMC regulatory global international operations. Dr Nashabeh chairs the Pharma External Interactions Steering Committee with responsibility for the oversight of all external outreach activities with global health authorities, industry associations and scientific organizations on technical matters.

Dr Nashabeh is the author/co-author of over 30 scientific publications, reviews and patents in the field of separation science and biotechnology. Wassim is a member of the Expert Working Group for the International Committee on Harmonization representing the BIO organization on Quality topics (Q11,Q3D and Q12). Wassim is also the Vice-President and member of the Board of Directors of CASSS (an International Separation Science Society), co-founder and chair of the "International Symposium of CE in the pharmaceutical and Biotechnology Industries", Chair of the CMC strategy forum conference series Global Advisory Committee, co-founder of the CMC Forum Europe Conference Series and founder of the CMC Forum Japan series. Dr Nashabeh has co-chaired several biotechnology forums and events that focused on a variety of CMC related issues over the last 10 years including "Lifecycle approach of Setting Product Specifications", "Changing paradigms for process validation", "Design of Stability Studies", "Quality by Design for Biotechnology Products" and "Comparability for Biotech Products".

宋瑞霖

中国医药创新促进会执行会长

宋瑞霖，中国政法大学法学学士学位，中欧国际工商学院工商管理硕士。现任中国医药创新促进会执行会长，中国药学会常务理事、中国国际经济贸易仲裁委员会仲裁员、中国国际商会常务理事及生物医药委员会副主席、中欧国际工商学院和沈阳药科大学兼职教授，曾任国务院法制办公室科教文卫法制司副司长。

2008年他由海外返回中国，参与建立中国药学会医药政策研究中心的工作。同年担任卫生部"健康中国2020战略规划"药物政策研究专家组副组长。长期从事卫生与药物政策、法律研究，参与了大部分现行卫生医药法律、法规的起草、审查工作。任首都卫生政策专家咨询委员会委员，北京医改专家委员会成员。

王磊

阿斯利康全球执行副总裁，国际业务及中国总裁

王磊先生于2017年4月28日被任命为阿斯利康全球执行副总裁，国际业务及中国总裁，全面负责中国、亚洲国家、澳大利亚、新西兰、拉丁美洲、巴西、俄罗斯、欧亚大陆、中东及非洲市场的整体战略及业务增长。作为全球管理团队成员，王磊先生直接向全球总裁Pascal Soriot先生汇报。
王磊先生于2013年3月加入阿斯利康中国，担任消化、呼吸和麻醉业务部副总裁，并于2014年升任阿斯利康中国总裁。在王磊先生的领导下，中国一举成为阿斯利康全球的第二大市场。阿斯利康中国也发展成为中国处方药市场第二大跨国制药企业和在华增速最快的跨国制药企业。2017年1月，王磊先生升任阿斯利康全球执行副总裁，负责亚太区（中国、亚洲国家、澳大利亚及新西兰）的战略及业务发展。
作为一位从本土成长起来的领导，王磊先生成长、求学、奋斗于上海，始终致力于为阿斯利康在中国的长远发展以及中国医药行业的进步献策献力。
任职阿斯利康中国总裁期间，他倡导并大力推动阿斯利康在中国商业领域的创新战略，围绕“以患者为中心”的核心价值观，积极探索与诊断、设备及互联网企业的战略性合作，推动个体化治疗与诊疗一体化，致力于提供疾病的全程管理解决方案，将阿斯利康打造成创新的医疗企业。
王磊先生拥有二十余年的行业管理经验，对中国的医疗及制药行业有着深刻和独到的认识。在加入阿斯利康之前，王磊先生曾在罗氏中国任职，负责市场营销及业务发展，并一步步成长为业务部门副总裁。
王磊先生拥有多个社会职位，包括无锡市第十六届人民代表大会代表、上海市外商投资企业协会第七届理事会副会长、中国外商投资企业协会药品研制和开发行业委员会执行委员会成员等。
王磊先生拥有中欧国际工商学院高级工商管理硕士（EMBA）学位及上海外国语大学文学学士学位。

李正卿

博士
全球副总裁, 默沙东研发（中国）有限公司 总经理
默克实验室

作为默沙东全球副总裁及默沙东中国研发总经理，李正卿博士负责北京研发中心的整体运营和战略方向的把控。李正卿博士带领的研发团队肩负着将创新药物和疫苗以最有效和快捷的方式满足中国病患需求和引领默克实验室在中国建立全球研发能力的使命。同时, 李正卿博士领导建立与外部科研机构，专业协会和行业伙伴的合作。在李正卿博士的带领下，在过去的六年里，中国研发中心实现飞速发展，目前有500余名科研人员，工作在临床研究，注册事务，临床试验运营，药物安全，项目管理，信息技术及科学, 生物统计，流行病学和数据管理等职能部门。
在加入默沙东之前，李正卿博士曾在施贵宝担任多个管理职位，包括中国临床研究副总裁，全球肿瘤及神经部门执行总监。在施贵宝任职之前，正卿曾在美国辉瑞和美国宝洁公司就职并积累了相当丰富的药物研发和管理经验。
正卿发表过40余份科研和临床试验论文，他也在中国和美国为十余种药品的研发和审批做出卓越领导和贡献。
正卿生长于中国，本科毕业于中国科技大学，之后在美国威斯康星大学获得生物统计学博士学位。博士毕业后，正卿曾在美国纽约州立大学公共卫生学院担任教职。

Kerry L BLANCHARD

Ph.D., M.D.
Sr. VP – China Drug Development and External Innovation
Eli Lilly & Company
Lilly China

Dr. Blanchard is responsible for development of medicines in Lilly China, the delivery of innovation across all therapeutic areas, and the execution of the external drug development portfolio. He also works closely with Lilly Asia Ventures to help expand the China innovation ecosystem. His interests include discovering and developing medicines and the application of translational research principles to drug discovery. He is a co-founder and a member of the Board of Directors of the Asian Cancer Research Group, a not-for-profit company focused on the generation and dissemination of genetic and clinical data on cancers of importance in Asia. Dr. Blanchard received a BS degree in chemistry in 1977, a PhD in Biochemistry in 1982, and an MD in 1985 from Indiana University. He completed a residency in Internal Medicine and fellowships in Hematology and Medical Oncology at the Brigham and Women's Hospital, the Dana Farber Cancer Center, and Harvard Medical School in 1990. Dr. Blanchard was a Damon Runyon Fellow and a Fellow of the American Cancer Society. Prior to coming to Eli Lilly and Company in 2000, he was a tenured Professor of Medicine and Biochemistry & Molecular Biology at Louisiana State University Health Sciences Center in Shreveport, LA. He has had multiple roles in Lilly Research Laboratories including Senior Clinical Research Physician in Program Phase Oncology, Chief Scientific Officer Cancer Discovery, Executive Director of Cancer Discovery & Lilly Systems Biology-Singapore, & Chief Operating Officer/Vice-President of Discovery Research and Vice-President of Integrative Biology, and Vice-President of Tailored Therapeutics. He is a member of the board for Lilly China, Zymeworks INC and Confucius Institute in Indianapolis; and he is a member of the scientific advisory board for CBmed GmbH in Graz, Austria.

苏岭

沈阳药科大学教授、药品监管科学研究所所长，礼来亚洲基金风险合伙人
沈阳药科大学亦弘商学院理事、研究员

毕业于上海医科大学药学院药理专业，获美国北卡罗莱纳大学药物临床开发硕士、流行病学博士学位。曾就职于原卫生部药政管理局、美国食品药品管理局药品评价与研究中心。在1996-2012 年间，历任美国默沙东公司默克研究所流行病学研究员、默沙东中国医学总监、默克研究所全球注册策略高级总监，上海罗氏制药医学及药品开发部总监，惠氏制药副总裁暨亚太区临床研究开发部负责人，诺华制药高级副总裁暨大中国区药品开发部负责人。2012-2016年在盛德国际律师事务所担任生命科学战略顾问。 2012-2013年获选任药物信息协会 (DIA) 全球理事会主席，现为DIA会士。目前他还担任中国药科大学国家药物政策与医药产业经济研究中心研究员，《药物流行病学杂志》、《中国新药杂志》、《中国药学杂志》编委等，并主持或参与亦弘商学院“临床研究管理”和“药品研发科学管理”等课程的设计和教学。其主要的研究和工作领域包括：药品法规及注册审评管理、新药研发策略和管理、药物临床试验、药物流行病学、药物安全和药物警戒等。

全体大会+特别论坛

朱立红

工商管理硕士，DIA中国董事总经理

朱立红女士现任DIA中国董事总经理， 负责DIA （药物信息协会） 的战略开发和商务拓展，发展会员等。 通过为政府，工业界，学术机构提供交流和学习的平台，促进知识更新和专业人才的培养。
朱女士于2013年-2016年任职比尔及梅琳达·盖茨基金会研发部的高级项目官， 负责基金会在中国的全球人类健康产品和解决方案的项目管理。 同时也帮助基金会了解中国的研发能力， 使得中国成为全球研发的一个有效的平台。
朱女士有着近二十年的国际研发型制药企业的临床研究及项目管理的经验。 她在美国默克公司 （即默沙东公司）和英国的葛兰素史克两家大型药企工作过。其中在默克公司工作了十二年，并在公司的美国总部的临床研究运营部门工作了五年。自2006年起， 朱女士在葛兰素中国研发部门任临床研究负责人，负责公司在中国的研发策略的制定和执行，以及所有治疗领域新产品的临床试验和外包服务的计划。随后她又参与了在中国上海的GSK研发中心的筹备和创立的全过程， 并为该中心的创新文化的建立做了大量贡献。自2010底，朱女士创立了始达上海医药科技有限公司并任其首席执行官， 致力于建立一家肿瘤药物早期临床研究的中心。
朱立红女士1990年毕业于北京大学医学健康部（北京医科大学）药学院，并于2006年获得美国新泽西州立大学的工商管理硕士学位。

Barbara Lopez KUNZ

全球首席执行官

本着改善全世界人民健康福祉的使命，昆茨女士专注于推动创新并制定和完善DIA战略。她负责领导DIA全球运营业务并向DIA的全球董事会汇报。昆茨女士曾在营利性和非营利机构担任管理职务。在加入DIA前，她在世界上规模最大，最受推崇的非营利的研发机构之一的Battelle 研究所，担任“健康和生命科学”部的总裁，该机构遍布100多个区域，研发经费高达65亿美金。她还曾担任Thermo Fisher Scientific的生物科学高级副总裁和总经理职位，建立了该组织的知名度，通过收购及战略联盟与生物制药领域，诊断领域和学术协会达成合作伙伴关系，并建立了14亿美金的投资战略组合。她还曾负责ICI/Uniqema’s的拉美区域业务，通过建立区域的贸易业务，提高了整个地区的成本效益，进而领导该公司在历史上最动荡的时期成功地实现了商业增长。

昆茨女士是一位科学家，拥有14项专利。她曾在美国俄亥俄州立大学的Wexner医学中心，BiOhio，国际科学标准（一家与韩方的合资企业），医疗器械公司Levitronix和POCARED等组织，担任不同的董事会职务。她积极支持儿童健康，在儿童联盟学校委员会任职，致力于解决俄亥俄州中部有发育障碍的儿童的需求，并成为全国儿童医院研究所和国家儿童研究所的受托人。昆茨女士持有阿克伦大学硕士、特尔大学学士学位，并获得欧洲工商管理学院（INSEAD）的国际管理项目的学位。

陆舜

上海市胸科医院肺部肿瘤临床医学中心主任；临床医学博士；主任医师
上海交通大学博士研究生导师
国务院特殊津贴获得者

陆舜教授，上海市胸科医院肺部肿瘤临床医学中心主任。主要从事胸部肿瘤的多学科综合治疗、靶向治疗以及免疫治疗方面的研究。2016年作为主要研究者之一参与或承担30余项国际国内多中心随机对照临床研究，其中参与的三项临床研究发表于Lancet Oncology杂志（IF 24.69），一项发表于JCO杂志（IF 18.428），参与发起成立中国胸部肿瘤研究组（C-TONG)，任副主席。主持多项C-TONG的临床研究。2016年作为发起者，建立了CTOP（中国胸部肿瘤合作平台），促进肺癌基础研究单位和临床单位间的交流与合作，并在全国开展多中心研究，建立完备的中国肺癌患者数据库与组织样本库。
目前承担国家和上海市科研基金项目9项。其中2016年作为项目首席专家承担科技部“重大慢性非传染性疾病防控研究”重点专项--基于组学特征的肺癌免疫治疗疗效预测指标的构建和验证；2016年作为第一负责人承担国家自然基金 “外泌体miRNAs介导FGFR/GLI2信号通路调控肺鳞癌干细胞表型及侵袭转移的分子机制”；2012年作为第一负责人承担科技部国际合作课题“中瑞合作肺癌临床医学中心肺癌诊治关键技术转化医学研究”。2007年与2012年均作为第1负责人承担国家863重大课题“肺癌的分子分型和个体化诊疗”的子课题；2007年参与承担国家十一五科技支撑计划课题，此外还承担上海市卫生局申康医院发展中心课题共3项。至2016年作为主要研究者之一参与或承担30余项国际国内多中心随机对照临床研究。2010年获得上海市医学领军人才。2013年获得上海市优秀学术带头人称号。2013年作为第1负责人获得上海市医学科技奖三等奖。

作为第一/通讯作者发表论文及论著100余篇，其中SCI收录45篇包括Chest、JTO、Plos One、Oncoltarget等知名杂志，总IF 121.8。参加多项专著的编写工作。曾担任美国临床肿瘤学会（ASCO）国际事务部委员，中华医学会肿瘤学会委员、上海市医学会肿瘤靶分子学会委员；目前担任ASCO多学科诊治小组（MCMC）成员，国际肺癌研究会（IASLC）组织委员会委员，国际肺癌研究会官方杂志Journal of Thoracic Oncology副主编，The Oncologist杂志编委，中国抗癌协会肺癌专业委员会候任主任委员，中华医学会肿瘤学会胸部肿瘤组组长，国家食品药品监督管理局新药评审专家，中国临床肿瘤学会（CSCO）常务理事、副秘书长，中国医药生物技术协会精准医疗分会副主任委员，中国医师协会临床精疗医学专业委员会委员，上海市医学会肿瘤学会候任主任委员兼胸部肿瘤组组长，上海市医师协会肿瘤科分会副会长，肿瘤内科规培组长，上海市抗癌协会姑息治疗委员会副主任委员，上海市抗癌协会理事，兼任多项国内外杂志的编委与特约审稿人。

苏岭

沈阳药科大学教授、药品监管科学研究所所长，礼来亚洲基金风险合伙人
沈阳药科大学亦弘商学院理事、研究员

毕业于上海医科大学药学院药理专业，获美国北卡罗莱纳大学药物临床开发硕士、流行病学博士学位。曾就职于原卫生部药政管理局、美国食品药品管理局药品评价与研究中心。在1996-2012 年间，历任美国默沙东公司默克研究所流行病学研究员、默沙东中国医学总监、默克研究所全球注册策略高级总监，上海罗氏制药医学及药品开发部总监，惠氏制药副总裁暨亚太区临床研究开发部负责人，诺华制药高级副总裁暨大中国区药品开发部负责人。2012-2016年在盛德国际律师事务所担任生命科学战略顾问。 2012-2013年获选任药物信息协会 (DIA) 全球理事会主席，现为DIA会士。目前他还担任中国药科大学国家药物政策与医药产业经济研究中心研究员，《药物流行病学杂志》、《中国新药杂志》、《中国药学杂志》编委等，并主持或参与亦弘商学院“临床研究管理”和“药品研发科学管理”等课程的设计和教学。其主要的研究和工作领域包括：药品法规及注册审评管理、新药研发策略和管理、药物临床试验、药物流行病学、药物安全和药物警戒等。

Theresa MULLIN

Office of Strategic Programs
FDA Center for Drug Evaluation and Research (CDER)

Dr. Mullin serves as Director of OSP, whose mission is to transform and modernize drug regulatory operations, playing a lead role in a number of CDER's strategic initiatives including the human drugs international program, data standardization, business informatics, lean management, development of benefit-risk and other decision support tools, program analysis, and major user fee negotiations. Having led successful negotiations for the previous 3 cycles of reauthorization, Dr. Mullin is currently serving as FDA's lead negotiator for the 2017 reauthorization of the Prescription Drug User Fee Act (PDUFA), a program that currently provides more than $800 million per year in fee funding for new drug review. She is also serving as FDA's lead negotiator for the 2017 reauthorization of the Biosimilar User Fee Act (BsUFA).
Dr. Mullin leads the FDA Patient Focused Drug Development Initiative, an effort begun in 2012 to better incorporate the patient's voice in drug development. She also heads the FDA delegation to the International Council on Harmonization, the primary venue for international harmonization of drug regulatory standards. Before joining CDER in September 2007, Dr. Mullin was Assistant Commissioner for Planning in the FDA Office of Commissioner, where she served as Director of the Office of Planning.
Since joining FDA Dr. Mullin has received numerous awards including the Senior Executive Service Presidential Rank Award for Distinguished Service in 2011, and the Presidential Rank Award for Meritorious Service in 2006. In addition, she has recently been named as one of the 2016/2017 recipients of the US Food and Drug Law Institute's Distinguished Service & Leadership Award. Before joining FDA, Dr. Mullin was a Senior Manager with The Lewin Group, specializing in health care consulting, and prior to that, Principal Scientist at Decision Science Consortium, specializing in decision research and analysis. Dr. Mullin received her B.A., magna cum laude, in Economics from Boston College, and Ph.D. in Public Policy Analysis from Carnegie-Mellon University.

专题1 监管科学

分会场 0101

Edward COX

Dr. Edward Cox is Director of the Office of Antimicrobial Products, where he has served since 2007. As Director for the Office of Antimicrobial Products, Dr. Cox oversees the review, approval and safety of antimicrobial (antibacterial, antiviral, antifungal, and antiparasitic)

drugs, ophthalmic drugs, and immunosuppressive agents for patients who have received solid organ transplants. Dr. Cox has worked extensively on the science and design of clinical trials for evaluating antimicrobial drugs.

Dr. Cox received his M.D. from the University of North Carolina School of Medicine. He completed an internship and residency in Internal Medicine at the Hospital of the University of Pennsylvania and an Infectious Disease fellowship at the National Institute of Allergy and Infectious Diseases of the National Institutes of Health. He also holds a Masters of Public Health Degree from the Johns Hopkins School of Hygiene and Public Health. He joined FDA in 1998.

Adam HACKER

Adam Hacker has twenty years of regulatory experience and has worked at Janssen Pharmaceuticals (a Johnson & Johnson company) since 2008 and was appointed Vice President and Head of Vaccines and subsequently head of Scientific Innovation Projects for the Global Regulatory Affairs (GRA) organization in June 2015.

Adam is responsible for coordinating regulatory activities for all disease interception related projects and establishing policy positions and working closely with the Janssen Disease Interception Accelerator.

Adam has a PhD in developmental molecular biology from the National Institute of Medical Research, Mill Hill, London.

胡劲捷

Dr. Jinjie Hu is the International Network Committee chair of the FDA Alumni Association and a senior consultant working at Biologics Consulting Group. She has almost 12 years of experience with the Food and Drug Administration, Center for Biologic Research and Review. She was a senior expert regulatory/scientific reviewer for multiple analytes In Vitro Diagnostic Devices (IVD) products. She lead and chaired many review committees for 510 (k), IDE, PMA, IND and BLA. Dr. Hu's responsibility included reviewing CMC, analytical and clinical study data, and labeling. She also has extensive experience working within the Center offices and other Centers of the FDA in reviewing companion diagnostic products, combination products, and applications for Clinical Laboratory Improvement Amendments (CLIA) waivers. As a trained manufacturer facility reviewer and CGMP inspector, she performed many pre-approval inspections of IVD manufacturing facilities. She also served CBER education planning committee and an instructor for CBER's Medical Device Training course for 4 years (2009-2012). She has been serving as scientific advisor, dossier reviewer and manufacturer facility inspector for the In Vitro Diagnostic Pre-Qualification Program at WHO since 2009. As

the chair for the International Network Committee of the FDA Alumni Association, she provides leadership to collaborate with developing and emerging regulatory agencies for regulatory capacity building and training.

Jinjie received her B.S. in Cell Biology from Beijing Normal University and her Ph.D. in Comparative Pathology from University of California, Davis, followed by postdoctoral fellowship at National Institute of Allergy and Infectious Diseases at the NIH.

分会场 0102

张象麟

现任沈阳药科大学亦弘商学院院长

此前，先后在国家药品监督管理局安全监管司，药品审评中心，国家药典委员会任职。曾任审评中心主任,药　典委副秘书长。
在任期间，组织实施了审评机制由外审向内审的转移，开启了由重临床前向重临床的转移，并组织建立了审评机构的组织架构、审评机制和完整的工作程序，并运用信息化方式，实现了审评流程的全过程管理和公开透明，推动了药品技术审评学科建设；参与了多版《药品注册管理办法》和药品研究、注册监管法规规章的制定和修订。
毕业于山东大学获化学理学学士，在中欧国际工商学院取得高级工商管理硕士学位。

Florence HOUN

Dr. Florence Houn is VP for Global Regulatory Science at Celgene Corporation. She is also a consultant to industry and health authorities regarding drug development programs and regulatory capacity building. She was Vice President, Global Regulatory Policy, Intelligence and Strategy from 2008-2015 at Celgene. Prior to this, she served 15 years in the US Food and Drug Administration (US FDA) as Division Director, Deputy Office Director and Office Director. In recognition of her contributions to public health, Dr. Houn received the US Department of Health and Human Services' (DHHS) Career Achievement Award in January 2009. In 2014, she received the FDA Distinguished Alumni Award from Commissioner Margaret Hamburg for contributions to global regulatory capacity building.
Prior to joining government, she served four years in the National Health Service Corps in a manpower health shortage area in Baltimore.
Dr. Houn was the founding co-chair of the FDA Alumni Association's (FDAAA) International Network (FDAAAIN) and is a member of the FDAAA Board of Directors since 2012. She is a member of the Centers for Medicare and Medicaid Services (CMS) Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), January 2017 to 2019. She served on the PDUFA V negotiating team representing the Biotechnology Industry Organization

(BIO) with FDA in 2010-2011. She serves on the Asia Pacific Economic Cooperation (APEC) Harmonization Center's Advisory Board (2013 to now) and is on the Board of Directors for the International Partnership for Microbicides (IPMglobal.org) (2016-now).
Dr. Houn received her Bachelor of Arts degree from Harvard University and her medical degree from the Albert Einstein College of Medicine. She completed her Cancer Prevention and Control Fellowship at the National Cancer Institute and obtained her MPH from the Johns Hopkins School of Hygiene and Public Health. She attended the Johns Hopkins Breast and Ovarian Surveillance Service as an Instructor in Oncology.

李自力

仿制药办公室全球事务副主任
医学博士、公共卫生硕士

李自力博士是美国FDA仿制药国际事务负责人。他肩负着建立一个以绩效为导向的仿制药国际事务工作模式的重任，从战略上有计划的应对美国仿制药项目所遇到的全球性挑战。
在2015年底重新回到FDA前，李自力博士曾担任比尔及梅琳达•盖茨基金会高级项目官及CFDA 项目负责人，基金会中国办公室副主任和研发部负责人。他还曾任美国默克公司中国医学部总监，亚太地区药品注册政策负责人，和全球新兴市场药品注册战略策划部执行总监等职位。2000-2005年期间，他在FDA新药办公室担任临床审评员和临床审评组负责人。
2009年，李自力博士和一些前美国FDA同事，成立了美国FDA同仁会国际部，致力于促进新兴市场药监机构的科学审评能力提高的培训工作。他于 2013 和 2014 年七月，分别获得中国国家食品药品管理总局药审中心颁发的"法规科学特别贡献奖"和美国FDA颁发的"特别贡献奖"。
李自力博士毕业于北京协和医学院八年制临床医学专业，在约翰•霍普金斯大学完 成了住院医师的培训，获得执业医师资格。他还取得了两个公共卫生硕士学位。

分会场 0105

苏岭

沈阳药科大学教授、药品监管科学研究所所长，礼来亚洲基金风险合伙人
沈阳药科大学亦弘商学院理事、研究员

毕业于上海医科大学药学院药理专业，获美国北卡罗莱纳大学药物临床开发硕士、流行病学博士学位。曾就职于原卫生部药政管理局、美国食品药品管理局药品评价与研究中心。在1996-2012 年间，历任美国默沙东公司默克研究所流行病学研究员、默沙东中国医学总监、默克研究所全球注册策略高级总监，上海罗氏制药医学及药品开发部总监，惠氏制药副总裁暨亚太区临床研究开发部负责人，诺华制药高级副总裁暨大中国区药品开发部负责人。2012-2016年在盛德国际律师事务所担任生命科学战略顾问。 2012-2013年获选任药物信息协会 (DIA) 全球理事会主席，现为DIA会士。目前他还担任中国药科大学国家药物政策与医药产业经济研究中心研究员，《药物流行病学杂志》、《中国新药杂志》、《中国药学杂志》编委等，并主持或参与亦弘商学院“临床研究管理”和“药品研发科学管理”等课程的设计和教学。其主要的研究和工作领域包括：药品法规及注册审评管理、新药研发策略和管理、药物临床试验、药物流行病学、药物安全和药物警戒等。

李寅

李寅，博士，英国皇家化学会会员。科睿唯安科学与解决方案顾问

曾就职于辉瑞公司欧洲研发中心，肺部给药部，担任高级科学家；参与多个药物研发过程及报批（包括临床I期/II期/III期）。现为科睿唯安（原汤森路透科技集团）资深顾问。负责生命科学领域企业、高校及研究单位信息咨询服务。就职期间，曾经为国内主要期刊撰写并多篇文章，阐述大数据在专业领域（医药）方面的应用与实践。并在国内外数十次会议中发表演讲交流相关内容。

杨悦

杨悦，女，博士，沈阳药科大学工商管理学院教授，博士生导师，沈阳药科大学国际食品药品政策与法律研究中心主任。是我国第一位药事管理方向药学博士学位获得者。主要从事药事法规与药品政策研究研究。国家食品药品监管总局《药品管理法》修订专家组成员，参与国家食品药品监督管理总局《药品管理法》修订研究工作，近年来的主持的课题主要涉及药品管理法修订、药品上市许可持有人制度、药物临床试验管理制度、药品风险管理、突发事件应急管理等领域。目

前为国家食品药品监督管理局高级研修学院专家；国家药品抽验评审专家；商务部中国医药保健品进出口商会专家，辽宁省食安办食品安全风险管理专业委会主任委员。

分会场 0106

王雅敏

Dr. Wang was born and raised in Nanjing, China. She obtained a BS degree from Nanjing University and a PhD in Chemistry from the University of Michigan in Ann Arbor, MI. She started her pharmaceutical career in 1998 by joining Bayer Pharmaceutical in the US. She led research project teams in metabolic diseases and oncology before transitioning into regulatory affairs.

Dr. Wang was a Global Regulatory Strategist at Bayer and then a Global Regulatory Team Leader at Bristol-Myers Squibb in the US. In 2010, she returned to Bayer US and held the position of Director and Senior Global Regulatory Strategist to oversee the integration of Asian regulatory strategies into global strategy for Therapeutic Area Specialty Medicine. From 2011 to 2014, Dr. Wang was Vice President, Head of Global Regulatory Affairs, Region Asia Pacific and was based in Singapore. From 2014-2016, she was Vice President, Head of Global Regulatory Affairs, Therapeutic Area General Medicine and was based in Berlin, Germany. In 2017, Dr. Wang became an independent consultant. Dr. Wang has a track record of successful global submissions and registrations, and interactions with US FDA, EMA, and other national authorities on diverse topics. Her therapeutic and technical knowledge and expertise range from small molecules to biologics, in the areas of oncology, hematology, metabolic disorders, cardiovascular, anti-infective, kidney diseases, women's health, rare diseases and medical device. She is excited and inspired by scientific innovations in healthcare, and is eager to support the advancement of these innovations to benefit people in need.

Mark GOLDBERGER

Dr. Goldberger received his MD degree from the Columbia University College of Physicians and Surgeons in New York and his MPH from George Washington University in Washington, DC. He completed his postgraduate training at the Presbyterian Hospital in New York and the Centers for Disease Control (CDC) in Atlanta. He is board certified in internal medicine and infectious disease and is a fellow of the Infectious Diseases Society of America. Dr. Goldberger was on the faculty of Columbia University for nine years.

Dr. Goldberger joined the Food and Drug Administration in 1989. At FDA he served as primary reviewer, medical team leader, Director of the Division of Special Pathogen and Immunologic Drug Products and Director of the Office of Antimicrobial Products within the Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration

(FDA). In addition to these positions he coordinated drug shortage activities within the CDER from 1990 -˘ 2006. Dr. Goldberger also was the FDA lead in an assessment of the readiness of the Pharmaceutical Industry for Y2K. In 2000 he spent 8 months as acting Associate Center Director for Quality Assurance in CDER during which time he developed the concept of the Regulatory Briefing. In 2003-˘2004 he was Acting Deputy Center Director of CDER. In 2006 he became Medical Director for Emerging and Pandemic Threat Preparedness within the Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration.

In October 2007 he joined Abbott as Divisional Vice President – Regulatory Policy and Intelligence. In this role he was involved in multiple areas of both product and policy development. He continued in this position when AbbVie separated from Abbott until May 2013 when he became VP Regulatory Affairs and Senior Advisor. In this position he provided regulatory and scientific input both into multiple development programs and in the preparation of marketing applications. In September 2014 he retired from AbbVie and opened his own consulting practice as Mark Goldberger MD MPH LLC.

While at Abbott and AbbVie he participated in PhRMA and efpia working groups on antibiotic resistance and twice presented on this subject to the European Medicines Agency as well as to the FDA. As a member of the FDA Alumni Association he has participated in several training sessions for staff from CDE/CFDA as well as for CDE/TFDA. He has presented multiple times at DIA China as well as at APEC 2012 and 2016 in Taiwan.

分会场 0107

邵颖

理学博士
上海复星医药（集团）股份有限公司副总裁兼研发中心主任，北京大学药物信息与工程研究中心资深研究员
华中科技大学、沈阳药科大学兼职教授

曾任中国药科大学副教授，国家食品药品监督管理局药品审评中心原审评部副部长、部长，研究与评价部部长，高级审评员。
长期从事药物研发、药品注册管理及相关法规研究、技术评价与管理，以及药物化学的教学工作。
《中国新药杂志》、《中国临床药理学杂志》、《药学进展》、《现代药物与临床》杂志编委。

Lane CHRISTENSEN

Assistant Country Director, FDA China Office

Dr. Lane Christensen is an Assistant Country Director of the China Office in the Office of International Programs (OIP) at the US Food and Drug Administration (FDA) where he serves as the International Program and Policy Analyst (IPPA) for Drugs. Before joining the FDA China Office, he was a Branch Chief in the Office of Process and Facilities (OPF), in the Office of Pharmaceutical Quality (OPQ), CDER, FDA which is tasked with the review of manufacturing process and established facility inspections for abbreviated and new drug applications (A/NDAs).
Previously he was with the Office of Generic Drugs (OGD) as a Team Leader in a review division and as a Chemist with the Immediate Office having various responsibilities related to Chemistry Manufacturing Control activities such as ANDA review, Control Correspondences, Citizen Petitions, and policy development. Lane was extensively involved in various initiatives related to OPQ reorganization and new user fee implementation under GDUFA including the lead for hiring efforts and involvement with risk-based review efforts. He received his Ph.D. in Pharmaceutics and Pharmaceutical Chemistry from the University of Utah followed by a post-doctoral fellowship within the pharmaceutical industry. Lane began his FDA career with the CDRH Office of Compliance.

张庆

Dr. Andrew Chang has more than twenty years of experience in the development, regulation and quality of biologics and pharmaceuticals. At his current capacity as a Vice President, Quality and Regulatory Compliance, Product Supply Quality, Novo Nordisk, he is responsible for providing strategic advice and solutions for quality and regulatory related issues and expert support to inspection preparation. Since 2013, Andrew has represented Novo Nordisk at the Global Quality and Manufacturing Committee, PhRMA to advocate patient and industry's interests by developing position papers and participating liaison meetings with the FDA. He is also a member of PhRMA's ICH Coordinating Work Group, and representing PhRMA as an expert to ICH Q12 Expert Working Group for developing guideline on Pharmaceutical Products Lifecycle Management.

Prior to Novo Nordisk, Andrew served more than eleven years at US FDA, most recently as an Associate Director for Policy and Regulation, Acting Deputy Director and Senior Regulatory Scientist in the Division of Hematology, Center for Biologics Evaluation and Research (CBER). During his tenure, Andrew received numerus high level FDA awards for his exceptional and outstanding performance on regulatory review and management, GMP inspection, and policy development. These include, but are not limited to FDA Commissioner's Special Citation for successfully completing FDA's initiative on product quality regulation and CBER's Public Health Achievement Award for outstanding regulatory review performance that resulted in averting a crisis in product availability. In 2002, the FDA recognized Andrew as the FDA regulatory expert in the regulation of new and novel recombinant products as well as naturally - derived biological products. Andrew's formal scientific training includes post - doctor in immunology from the National Institutes of Health, Ph.D. in Biochemistry from the State University of New York, and B.S. in Pharmaceutical Chemistry from the China Pharmaceutical University. He has published numerus peer reviewed scientific papers in JAMA, J.Exp.Med., Blood, J.Immunol., Dev. Immunol. Thromb Haemost., Haemophilia, Pharmaceutical Engineering etc., and has been a frequent speaker at national and international conferences.

分会场 0108

李自力

仿制药办公室全球事务副主任
医学博士、公共卫生硕士

李自力博士是美国FDA仿制药国际事务负责人。他肩负着建立一个以绩效为导向的仿制药国际事务工作模式的重任，从战略上有计划的应对美国仿制药项目所遇到的全球性挑战。
在2015年底重新回到FDA前，李自力博士曾担任比尔及梅琳达•盖茨基金会高级项目官及CFDA 项目负责人，基金会中国办公室副主任和研发部负责人。他还曾任美国默克公司中国医学部总监，亚太地区药品注册政策负责人，和全球新兴市场药品注册战略策划部执行总监等职位。2000-2005年期间，他在FDA新药办公室担任临床审评员和临床审评组负责人。
2009年，李自力博士和一些前美国FDA同事，成立了美国FDA同仁会国际部，致力于促进新兴市场药监机构的科学审评能力提高的培训工作。他于 2013 和 2014 年七月，分别获得中国国家食品药品管理总局药审中心颁发的“法规科学特别贡献奖”和美国FDA颁发的“特别贡献奖”。
李自力博士毕业于北京协和医学院八年制临床医学专业，在约翰•霍普金斯大学完 成了住院医师的培训，获得执业医师资格。他还取得了两个公共卫生硕士学位。

黄琴嘵

Section Chief, Division of Medicinal Products, Taiwan Food and Drug Administration

Ms. Chyn-Liang (Cindy) Huang has been serving as the Section Chief of Division of Medicinal Products of Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare since 2015. Her primary duties are to supervise the affairs of international cooperation, pharmaceutical care, etc. Prior to joining Medicinal Products Division, she worked as Chief Inspector of the GMP Inspectorate of Division of Risk Management, TFDA.
In recent years, she was invited as a speaker to present in several international conferences, such as 2013 Joint Conference of Taiwan-Japan on Medical Products Regulation, 2015 Asia Regulatory Conference, 2015 DIA Risk-based inspection and compliance section, 2015 APEC LSIF Training Program on Global Medical Product Integrity and Supply Chain Security-detection technology working group and GMP working group, and 2016 FAPA Congress. In addition, she attended meetings of international harmonization initiatives, such as ICH and APEC LSIF-RHSC, and successfully leads the organization of the 3rd PIC/S GDP Expert Circle and the International Good Submission Practice Workshop on Pharmaceuticals in 2015, and the APEC Good Registration Management Center of Excellence Pilot Workshop in 2016.

Shinji HATAKEYAMA

Director
Asia Regulatory Affairs, Japan/Asia Regulatory & Asia Clinical Operations Department, GRA CFU, Medicine Development Center, Eisai Co., Ltd., Japan

Education
2002
Ph.D. of Medical Sciences, University of Tsukuba, Japan
1990
Master of Pharmaceutical Sciences, Toyama Medical and Pharmaceutical University, Japan
1988
Pharmacist and Bachelor of Pharmaceutical Sciences, Toyama Medical and Pharmaceutical University, Japan

Work Experiences
2012 -
Asia Regulatory Affairs, Eisai Co., Ltd., Japan
2005 - 2012
Project Management, Planning & Coordination for Medicine Development (CMC, Nonclinical & Clinical), Eisai Co., Ltd., Japan
1991 - 2005
Discovery Research in Neuroscience Area (Biology & Pharmacology), Eisai Co., Ltd., Japan

Membership
2014 -
Asia Partnership Conference of Pharmaceutical Associations, Regulations and Approvals Expert Working Group (APAC, RA-EWG)

蒲绘华

Associate Director, Regulatory
Roche Pharma Product Development
Roche (China) Holding Ltd.

Ms. Huihua PU is the Associate Director of Regulatory Affairs, Roche (China) Holding Ltd. She has served for 6 years in Roche Pharma Product Development from 2011.

Ms. Pu had over 15 years' experience of Regulatory and R&D in Pharmaceutical industries.
Ms. Pu earned her Master of Public Health and Bachelor of Pharmaceutical Science from Health Science Center of Peking University.

专题3 多方合作，共同打造高质量临床研究

分会场 0301

Peter SCHIEMANN

Peter Schiemann, PhD, MBA, is a renowned expert in R&D Strategy, Clinical Development, Risk-, Quality- and Project Management.
He is Managing Partner at Widler & Schiemann Ltd, a consulting firm focusing on all aspects of clinical development from Protocol Quality by Design to Study set-up, Project Management and Risk-based oversight of Clinical Trials such as Risk-based Monitoring. Before founding Widler & Schiemann Ltd., he worked at Roche in several functions, at PricewaterhouseCoopers in R&D Strategy Consulting and in Academic Research (Endocrinology).
Dr. Schiemann is member of EFGCP (European Forum for Good Clinical Practice) and their working parties "Patient's roadmap to Treatment" and "Medical Technology" and RQA (The Research Quality Association).

Alexander HONEL

Quality By Experts, The Inspectors Network. Consulting and Training Services

- Audits in GCP, GMP, GLP, Blood, Tissue and Medical Devices, and Trainings (since 2014)

10 years Head Inspectorate & Enforcement, Federal Office for Safety in Health Care, Austria, Europe (2004-2014)

- Responsible as inspector, Areas of Expertise GMP, GLP, GCP, Blood and Tissues, Advanced Therapies, Medical Devices, Hemo- and Tissue Vigilance, Quality Defects and Drug Shortages, Pharmacovigilance, Narcotics (for OECD), Import of Medicines to Austria, Enforcement, Specialty GCP inspections / audits around the world. Several hundred inspections in the mentioned fields during these years, main areas Quality Management Systems in Hospitals, functioning of Quality Assurance and Management Oversight, companies, special areas under the mentioned laws and guidelines
- As head of Enforcement link to police and border police, speeches at congresses of the WGEO, Working Group of European Enforcement Officers. EMA Expert (PHV and GCP), Medical Devices, and PIC/S Executive Committee member.
- Several years in Industry, Clinical Liaison Manager and Senior Medical Manager

- Clinical Trials Management, Project Management, Quality Assurance and Quality Control for Clinical Development, Opinion Leader Contact Point
- Background: Medical Law (Lawyer), Veterinary Medicine: Dr. med. Vet, Master of Business Administration, MBA, Master of Laws, LL.M, Master of Science, MSc, PharmaManagement, ISO Quality Manager and Quality Auditor

沈一峰

医学博士
美国Association of Clinical Research Professionals认证研究医生（CPI®）
上海市精神卫生中心副主任医师、临床试验机构办公室主任

第二军医大学本科（1996），复旦大学上海医学院硕士（2002）、博士（2011），Vienna School of Clinical Research接受Scientific aspects of clinical trials in psychiatry培训（2005），Rutgers New Jersey Medical School高级访问学者（2015-2016）。
曾任CFDA药审中心外聘审评员（External Reviewer，2012.1-6）。国家十一五和十二五"重大新药创制"精神药物GCP平台课题副组长（2008-2015）。
兼职：中国GCP联盟副秘书长，CFDA药品审评专家和GCP检查员，China QA Forum会员，世中联伦理审查委员会理事，WHO-TDR SIDCER/FERCAP检查员（Surveyor），MedDRA中国工作小组成员，American Society of Clinical Psychopharmacology会员。

分会场 0302

周立萍

默沙东研发（中国）有限公司亚太区质量保证总监

周立萍有15年的跨国制药企业工作经验，曾先后就职于Novartis, Quintiles, Bayer Healthcare.
加入默沙东（研发）有限公司前，立萍服务于拜耳医药保健有限公司全球研发质量保证部门（2009.6-2017.2），曾先后从事GCP/GPvP (Good Pharmacovigillance Practice) 稽查 和 药监部门检查的管理工作, 足迹遍及亚太及欧、美地区，曾协调管理来自US FDA, EMA, PMDA, CFDA 等国家和地区的药监部门检查。
从事质量保证工作以来，立萍作为中国质量保证论坛(CQAF)的核心成员与联席主席，积极参与论坛的建设及质量保证活动, 致力于与业内同仁及专业人士合作共同推动中国药物临床试验的质量。
周立萍毕业于北京医科大学（现北京大学医学部）。

陈华

西安杨森公司药物研发质量和合规部 亚太区质量计划和策略总监

陈华于2012年9月加入强生中国公司药物研发质量和合规部，现任亚太质量计划和策略总监，负责制定亚太区质量监督管理的策略和应对药监部门检查的策略。
2012.9 - 2016.9: JNJ 任亚太区及中国研发中心的质量保证总监，领导公司亚太区稽查员团队对非临床研究，临床研究，药物安全警戒系统以及研究合同组织进行稽查;
1997.5 – 2012.9: GSK，拥有5年临床试验监查经验和10年的稽查经验，主要负责GCP相关的稽查以及应对法规部门的检查。多次作为申办者的代表协调和出席了美国FDA，欧盟及韩国药监部门对研究中心的检查;
2010-2012 期间多次参与美国FDA，WHO 对国家药监局检查员的培训。并于2010年创建了中国质量保证论坛(CQAF)，并从2015年开始领导论坛的讲师团队与CFDA高级研修学院合作设计和实施对临床稽查员的培训.
陈华毕业于首都医科大学儿科系，在加入制药企业前有数年临床医生的工作经验.

黎婉珊

默沙东（研发）有限公司 全球临床数据管理中心亚太区总监

Joyce具有18年专业临床数据管理工作经验。她生於香港，曾在香港、比利时、波兰等地工作过，并于2007年移居北京。Joyce毕业于药学专业，毕业后加入默沙东香港，曾参与默沙东全球临床数据管理中心多个重大项目。

沈一峰

博士，副主任医师，ACRP认证研究医生（CPI），上海市精神卫生中心机构办公室主任

“重大新药创制”精神药物GCP平台课题副组长，CFDA药品审评专家和GCP检查员。
沈博士毕业于复旦大学上海医学院，Rutgers New Jersey Medical School高级访问学者

孙晔

中国百时美施贵宝质量保证亚太区

孙晔在跨国药企历炼多年，在GCP/GPvP稽查核查领域有10年相关经验，专注亚太并涉足美欧。有FDA，EMA以及亚太地区主要药政当局的成功核查管理经验。加入药企前在大学医学院从事科研与教学。
孙晔先后于上海交通大学医学院临床医学和复旦大学取得MD和MPH学位。

王方敏

上海药品审评核查中心副主任

王方敏主任为国家GCP和GLP资深检查员、国家药品注册批准前生产现场检查员。1995年毕业于上海医科大学药学院药理专业，进入上海市药品检验所从事药品研究检验、药理毒理和临床试验技术审评。2001年起进入新组建的上海药品审评部门从事技术审评和现场核查，2005年起担任上海药品审评部门负责人。2009年获英国Cardiff大学MBA，成为英国志奋领学者。

汪秀琴

博士，副主任医师，江苏省人民医院科技处副处长，伦理总监

汪博士目前为中国药物临床试验机构联盟副秘书长，江苏省药学会药物临床评价研究专业委员会秘书长，美国AAHRPP认证现场检查员，亚太地区伦理审查论坛检查员。她曾于2005年和2007-2008年美国哈佛大学公共卫生学院以及日内瓦全球生命伦理学论坛访问学习并发表了相关论文数十篇，主编出版《临床试验机构伦理委员会操作规程》与《医学研究受试者的权益保护》，为《医学伦理学》副主编、《伦理委员会制度与操作规程》执行主编。

夏文璐

Vice President，QuintilesIMS

文璐于2010年加入Quintiles IMS，负责临床研究运营管理。自2013负责该Quintiles IMS在中国的全资子公司（昆拓）的整体运营，为国内外制药企业和医疗器械公司提供全方位的专业临床研究服务。
在加入昆泰之前，夏文璐自2001年起曾先后在Roche，Sanofi、Eli Lilly的医学部工作，涉及职能包括临床研究运营管理、项目管理、质量控制和医学信息等。
夏文璐毕业于上海交通大学医学院临床医学系，之后在上海财经大学获得MBA学位。

阎昭

天津医科大学肿瘤医院 主任药师，博士，硕士生导师，药物临床试验机构办公室主任

阎博士同时兼任国家肿瘤临床医学研究中心 GCP平台负责人临床药理研究室主任，国家食品药品监督管理局 GCP检查组专家，国家科技部“重大新药创制重大专项”十一·五、十二·五GCP平台课题 主要承担人，
中国抗癌协会 继教与科技服务部 常务副部长，肿瘤药物临床研究专业委员会 常委 兼 秘书长，中国肿瘤临床试验稽查协作组 主任委员，中国GCP联盟 青年委员会 副主任委员 伦理学部 副秘书长，天津市医院协会 临床试验管理专业委员会 副主任委员，天津市市场和质量监督管理委员会（原天津市食药监局）药品/医疗器械审评专家

分会场 0305

陈睿

Rui Chen is Team leader of CTOM (Clinical Trial Operations Managers) in Sanofi based in BJ with successful experience in leading APAC and global diabetes studies in Sanofi. Rui was trained as Risk management champion in Sanofi for APAC region to provide study risk management training and help study team to develop study specific risk management plan. From 2014, Rui had delivered 7 study risk management workshops in this region.

许文成

目前在药明康德的全资子公司临床研究CRO康德弘翼中当担任项目发展整合管理总监，负责优化临床研究流程，建立临床研究系统、项目管理系统和文档管理系统。另外一项工作是管理治疗领域的重要研究者和公司大客户，促进肿瘤等治疗领域的管理。
之前担任项目管理总监，负责所有国际多中心项目和中国地区项目的整体管理，保证I期、II期、III期和IV药物临床研究的按计划实施，以及器械、诊断试剂和非干预研究项目的按期高质量完成。也负责所有项目经理的人员管理和职业发展和成长。

曾经担任昆泰中国高级项目经理（2010-2015年）负责在中国大陆、台湾、泰国和韩国等地实施的国际多中心临床研究；在此之前，服务过德国默克、阿斯利康、勃林格殷格翰和北京甘李等国内外知名医药企业，在肿瘤、心血管和内分泌领域等领域负责过多个重磅药物的临床研究。
2002年毕业于武汉大学临床医学系，目前在北京大学医学部公共卫生专业师从胡永华教授和姚晨教师，钻研临床研究的学术研究。同时服务于DIA中国的项目管理组，致力于在中国推进项目管理的发展。
工作和学习之余，亦组织超过400个项目经理参加的项目管理讨论沙龙，并发表一系列关于临床研究和项目管理的文章。
从2002年从武汉大学临床医学系毕业以来，一直以极高的热忱和兴趣投身于中国临床研究事业，在不断学习、钻研和精进自己的临床研究的运营和管理水平的同时，不断分享自己的心得、注重帮助和培养临床研究的专业人才，期待中国临床研究不断超越现有水平，吸收国外先进的管理方式，创造出更多的优良药物帮助提高人们的健康。

分会场 0307

顾哲明

顾哲明博士于2011年创办并连续7年组织南京国际药代会，力图为推动中国新药研发的药代动力学研究做点工作。他于1986年获得北京医科大学生药学博士，曾任日本富山医科药科大学WHO客座研究员（1989）、成都中医药大学教授(1992)等。现任中国药理学会药物代谢专业委员会委员、中国药科大学生科基地校外客座教授、江西中医药大学客座教授、四川省中医药科学院客座研究员等，为CFDA 2015年药物非临床药代动力学研究技术指导原则和2015中国药典生物样品定量分析方法验证指导原则的主要攥写人之一。1991年赴美国普渡大学进行了3年博士研究，于1994年受聘于美国XenoBiotic Laboratories, Inc. (XBL)公司，成功地将该公司的主业务由农药代谢转为药物DMPK研究服务，并在1997年创建XBL生物分析部门。顾哲明领导的XBL代谢和生物分析团队在美国药界享有盛誉，完成了数百个新药代谢、PK和仿制药BE项目，迄今为止在FDA通过率为100%。2008年帮助XBL建立中国分部XBL-China并任总经理，创建了国内独树一帜的以放射性药代为特色全方位DMPK研究平台，完成了国内70多个新药的DMPK研究，多数已通过CDDA的IND申请，并有约10个获FDA批准临床试验。他领导的团队在7.22前完成的BE生物分析和新药DMPK研究，到目前还没有任何项目因分析部门的原因撤回。顾博士发表论文70余篇，为美国药学科学家协会（AAPS）、药物代谢研究国际学会(ISSX)、美国化学会（ACS）、美国质谱学会（ASMS）、及美国生药学会（ASP）的专业会员；曾获1989- 1990年度世界卫生组织(WHO)研究奖，1990年霍

英东中国优秀青年教师奖，1994年委内瑞拉中央大学研究奖。现任江苏万略医药科技有限公司总经理（gu-zheming@walueps.com，手机18705196650）。

张玥

北京博纳西亚医药科技有限公司 数据统计分公司 总裁

曾多年就职默沙东全球数据管理中心并任亚太区负责人。在加拿大蒙特利尔大学医学生物信息中心、MDS Pharma Services 中心实验室、中国疾病预防控制中心、默沙东研发等国际、国内和跨国公司从事了近22年的临床研究数据管理和运营工作。对国际国内临床试验数据管理法规及专业知识有着深入的理解和丰富的经验。现为中国临床试验数据管理学组核心成员、中国药监局数据管理咨询顾问、美国临床数据管理协会中国区核心委员，多次在DIA、中国制药工业协会、北京药理学会等国际国内的重要业界年会、年度培训上受邀为会议主席或演讲嘉宾。

分会场 0308

包文俊

美国SAS软件研究所JMP生命科学的首席科学家和高级研发经理

包文俊博士是美国SAS软件研究所JMP生命科学的首席科学家和高级研发经理。她从美国俄勒冈健康和科学大学获得博士学位。在加入SAS之前，她是美国国家卫生研究所的IRTA研究员，杜克大学的教授和美国国家环保署的科学家。她在生物信息学，生物化学，分子生物学的研究拥有丰富的经验，善长各种尤其是临床实验，基因组学等的数据分析。包博士自2005年以来一直是美国国家卫生研究所的研究资助审查委员会成员，也是多个大学和政府机构科学家的研究顾问。她在同行评议的期刊上有多篇文章发表。包博士是临床数据交换标准委员会（CDISC）中国协调委员会成员，国际MAQC组学质量控制联盟的组织委员会成员和地方组织主席,以及复旦大学的兼职教授

Eric HERBEL

Eric S. Herbel is President, Integrated Clinical Systems, Inc. He is principal architect of Integrated Review™ and a developer on the JReview® product. Before forming Integrated Clinical Systems, Inc. in 1994, he was with Hoechst Roussel Pharmaceuticals (which is now sanofi) for 17 years, responsible for Clinical Systems – supporting clinical research in the areas of data management, in-house systems development, and SAS programming in support of regulatory submissions. During that period, he was directly involved in systems development in support of clinical research activities. Eric holds a BS and MS from Rutgers University in physiology and nutrition research, with extensive graduate work in computer science.

卢宝蓝

卢宝蓝 (Lobo Loo), 现任默沙东研发（中国）有限公司全球临床数据管理中心副总监，全球临床数据运营部亚太区负责人。
在临床研究数据管理及运营工作有逾16年的經驗，对临床数据管理、医学编码、流程设计和优化擁有丰富的经验；并通过SCDM 临床数据管理学会获得CCDM™临床数据管理专业认证。

专题4 肿瘤药物开发

分会场 0401

宁志强

共同创始人/执行副总裁
深圳微芯生物科技有限责任公司

1978年入承德医学院医疗系学习，1988获中国军事医学科学院实验血液学硕士学位，1996年获英国伦敦大学免疫学博士学位。1996~2001年在美国辛辛那提大学（University of Cincinnati）医学院任博士后研究员、研究助理教授。2001年作为深圳微芯生物科技有限责任公司创始人之一，参与公司的发起和创建，负责企业的新药研发工作，带领团队完成一个抗肿瘤原创新药从发现到上市的全程研发和注册工作，以及一个糖尿病原创新药从发现到III期临床试验研究。对在中国开展原创性新药研发具有深刻的体验，对自主原创新药的国际联合开发具有成功的实践经历。作为课题负责人和主要参加者，承担多项国家和地方重大科技项目。作为合作单位和个人，获得2013年国家科学技术进步一等奖。在国际期刊上发表论文40余篇。

鲁先平

Xian-Ping Lu, Ph.D., CEO & CSO, Chipscreen Biosciences Ltd., Shenzhen, China

Dr. Xian-Ping Lu founded Chipscreen Biosciences, the leading drug discovery and development company in China focusing on innovative small molecular therapeutics, 13 years ago with a group of US-trained professionals. Previously he was Director of Research at Galderma R&D (subsidiary of L'Oreal and Nestle) in Princeton until 2000, the year he became visiting professor at China's State Key Laboratory for Biomembrane and Membrane Biotechnology in Tsinghua University. He also participated in founding Galderma Research Inc. and Maxia Pharmaceuticals.

Dr. Lu came to the US in 1989 for postgraduate fellowship study at the Department of Pharmacology, University of California in San Diego, followed by research at La Jolla Cancer Research Foundation (Burnham Institute). He obtained his Ph.D. in Molecular Biology and M.S. in Biochemistry from Peking Union Medical College, Chinese Academy of Medical Sciences, and his B.S. degree in Biochemistry from Sichuan University.

With over 20 years of biomedical research and biotech/pharmaceutical experiences in various therapeutic areas, Dr. Lu is a skilled leader of diverse groups in global operating settings. He has published more than 60 peer-reviewed papers in prestigious journals including *Nature* and *Science*. He is the lead inventor of over 60 patented inventions in areas of small molecule therapeutics.

谢雨礼

谢雨礼，毕业于南开大学化学系,获得中国科学院上海药物研究所博士,曾在美国哥仑比亚大学化学系从事博士后研究。美国期间，在哥仑比亚大学医学院与Merck合作的孵化中心担任项目主管，从事立项和新药研发工作。回国后，先后在制药公司担任多个职务，包括扬子江药业集团上海研究所所长，日本大冢上海药物研发中心副总监，和药明康德CMC办公室主任和制剂部运营主管。现担任苏州偶领生物医药有限公司总经理。从事运营,新药立项，项目管理以及市场研究等工作。曾发表学术论文30余篇，获国际专利5项和中国发明专利3项。有15年新药和仿制药开发经验，熟悉治疗领域和新靶点,以及法规，政策和市场.

沈月雷

沈月雷，博士，教授级高级工程师，百奥赛图基因生物技术有限公司董事长兼总经理，国家“千人计划”专家。

1992年本科毕业于武汉大学病毒学及分子生物学系，1995年硕士毕业于中国食品药品检定研究院，2003年博士毕业于美国麻萨诸塞大学医学院， 2003-2008于纽约大学医学院进行博士后研究。 期间主要是从事利用模式小鼠进行自身免疫性疾病致病机理的基础研究。 2008成立百奥赛图（Biocytogen）基因生物技术有限公司。公司主要从事基因敲除模式动物的开发、规模化生产、以及利用模式动物进行药物研发服务。
沈月雷博士先后入选“北京市海聚工程”、“国家千人计划”、“科技北京百名领军人才”和“全国优秀科技工作者”等。

分会场 0402

刘晓曦

Dr. George Liu is the Head of Early Development at Harbour BioMed (HBM). Before joining HBM, he was Director of Clinical Pharmacology for Novartis Oncology, where he was responsible for all aspects of clinical pharmacology for oncology product development in China. Prior to joining Novartis, Dr. Liu worked at Sanofi, GSK, and Guilford Pharmaceuticals where he held positions with increasing responsibilities for both nonclinical and clinical pharmacokinetics and contributed to the discovery and/or development, including regulatory approval, of Lusedra®, Insuman, Mozobil, LEE011, LDK378, and LCI699.
Dr. Liu obtained his BS in Biology from Nanjing University in 1990 and PhD in Medicinal Chemistry and Molecular Pharmacology from the School of Pharmacy and Pharmaceutical Sciences of Purdue University in 1999.

Mithat Gönen

Dr. Gönen has been at MSK since 1999 and he has been serving as the Chief of Biostatistics Service since 2015. His translational and clinical collaborations focus on genomic profiling of hematologic malignancies, surgical treatment of gastrointestinal and hepatobiliary cancers and development and evaluation of novel molecular imaging technologies. Most of Dr Gönen’s methodological research originates from these collaborations, including building, assessing and comparing prognostic and predictive models; design and analysis of clinical trials and imaging studies; as well as Bayesian methods. He was the principal investigator of a 2012 Geoffrey Beene Grant Award on Integrated Genetic Profiling to Predict Response to Therapy in Acute Myeloid Leukemia, a recent awardee of the Foundation for NIH to study alternative response

metrics in cancer clinical trials and the author of a book on the use of receiver operating characteristic (ROC) curves using SAS®.
Dr. Gönen served a co-director of the AACR/ASCO Vail Workshop on Methods in Clinical Cancer Research from 2011 to 2013 and a member of ASCO's Cancer Research Committee from 2012 to 2014. He has been serving the Society for Clinical Trials in various roles: Program Chair for the 2012 Annual Meeting, deputy editor of Clinical Trials: Journal of the Society for Clinical Trials and member of the board of directors. Dr. Gönen is a fellow the American Statistical Association (ASA) and is an associate editor of Statistics in Biopharmaceutical Research, an ASA journal. He served the International Biometric Society as the Program Chair for its North America (ENAR) meeting in 2015.

分会场 0405

申华琼

科学博士，临床医学博士，
强生医药公司中国开发中心总负责，副总裁

申华琼先后在东南大学临床医学专业及四川大学华西医学院获医学学士及硕士学位 ，并曾担任外科医生。后赴美深造获得印第安纳大学(Indiana University)生命科学博士学位。经过住院医生资格论证及培训成为美国有处方权的执照医生并通过了美国精神心理学和神经病学委员会专科认证。作为印第安纳大学临床兼职教授在附属医院做临床医生的同时在礼来公司从事临床药物研发。她还获得国际糖尿病基金会专项研究基金进行内分泌与代谢学博士后研究，在糖尿病及肥胖学的研究方面取得显著成就。此后还从事了精神病药物学和临床药理学的博士后研究。2009及2010年，她连续两年被授予"美国最佳精神心理医生"的荣誉称号，还发表了20多篇学术论文。
申华琼博士曾在美国礼来，惠氏，辉瑞担任全球临床研发高管10 多年，回国后又加入恒瑞医药并帮助建立了创新药临床团队，成功开拓了在澳洲及美国的临床试验。这些经历让她获得了丰富的新药研发专业知识及创建管理多元化团队的经验并与全球的专家和医生们建立了广泛的联系。
此外，她还致力于中美文化和学术方面的合作交流，她曾是印第安纳中华医学会的主席，礼来制药公司中华文化网的理事，惠氏公司亚洲员工协会的创始人之一；中美医药协会(SAPA)的副总裁，

她也多次在CDE或CFDA举行演讲或培训，她的贡献为她赢得多项荣誉，包括惠氏的卓越领导奖，辉瑞的优秀员工奖，SAPA优秀服务奖等。她被选为2014“国家千人计划创新人才”并当选中国药物临床评价研究专业委员会第二届委员.她2015 年作为副总裁及中国开发中心总负责加入强生医药。新近更是当选RDPAC研发核心工作组的预备主席.

邹建军

Dr. JIANJUN(Jessie Zou) was trained by medical oncology in China and got her medical doctor degree in the second military medical university. She had been working in the level 3 A hospital as a medical oncologist for 10 years from 1995 – 2005. Then she joined Bayer Healthcare pharmaceutical company in China. She had been leading the clinical development programs of Sorafenib in China as the clinical trial physician, head of oncology therapeutic team in Bayer China. Then she moved to NJ, USA and worked as the global medical lead of Xofigo in the global medical affairs team in BayerhealtherCare Headquarter. In 2012, she moved back to China as the director, head of the medical department in Celgene China. Starting from Oct 2015, she has been the Vice president, Clinical Research and Development - Oncology in JIANGSU HENGRUI MEDICINE, CO. LTD.

王丽霞

Recognized Leader Who Developed and Led Successful Global and Regional Biometrics Organizations within Leading Pharmaceutical & Biotech

Twenty four years' of hands-on leadership and experience in all phases of drug development. Seventeen years' building and leading best-in-class global and regional biometrics organizations supporting all aspects of drug development and worldwide registrations. Demonstrated leadership and performance excellence by proactively collaborating with all key stakeholders to ensure alignment and outstanding results.

Select Highlights:

Created and executed compelling vision and strategy for multiple statistical organizations across big and Biotech. Built high performing teams (up to 100 people globally) by creating synergy among different locations and collaborating with all internal and external stakeholders. Established and implemented best practices and set company benchmarks to ensure quality statistical design, analyses, and data interpretation.
Consistently recognized by upper management for developing and energizing teams, driving for innovation, making change happen, and attracting and retaining top talent.
Drug Development Expertise / Strategy & Execution /Innovative/ Well Connected with Thought Leaders /Committed to Excellence / Team Leadership & Development

分会场 0406

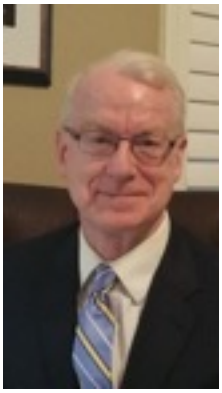
董晨

董晨教授1989年武汉大学本科毕业后赴美留学，1996年获美国阿拉巴马大学伯明翰分校博士学位，1997至2000年在美国耶鲁大学免疫学系从事博士后工作。而后曾任美国得克萨斯大学MD Anderson癌症中心免疫学系终身讲席教授、炎症与肿瘤中心主任。2013年获千人计划回国工作，现任清华大学医学院教授，医学院院长，清华大学免疫学研究所所长，清华大学生命科学与医学研究院副院长，清华大学生命联合中心副主任。
董教授主要致力于免疫学的研究，应用小鼠遗传学手段重点探讨免疫应答的分子调控机制以及免疫疾病的发病机理。董晨教授是Th17细胞分化、调节和功能研究领域的奠基者和研究权威之一，并在Tfh和Tfr细胞的发现和研究中，做出了开创性贡献。董晨教授目前已发表论文近200余篇，总被引用次数达20000次，2014、2015、2016年连续被汤森路透评选为“高被引科学家”，是全球最具影响力的科学家之一。董晨曾获美国免疫学家协会BD Bioscience研究员奖，是首个获得该协会奖项的华裔科学家，他是美国科学促进会会士、曾被授予教育部长江讲座教授、国家基金委海外合作基金B类杰出青年、国家中组部千人计划创新A类。他是国家重点研发精准医学计划的项目负责人。

张连山

1982年毕业于南京药学院，现中国药科大学，1992年在德国Tubingen大学获有化学博士。先后在Tubingen大学和美国Vanderbilt大学医学中心从事博士后研究。
1998年，受聘于美国礼来公司，从事糖尿病和肥胖症新药研发，是礼来GLP-1激动剂和长效胰岛素的发明者，并分别于2003和2007年两次荣获公司研发最高总裁奖。
2008年，加盟Marcadia生物制药，任高级化学总监，成功研发五个临床化合物。
现任江苏恒瑞医药股份董事、高级副总经理兼全球研发总裁。
张连山博士从事多肽蛋白药研究二十多年，在新药研发方面取得了重大成绩，在糖尿病、肥胖症领域尤有建树，在国际学术刊物上发表论文62篇，专利申请46项。
张连山博士亦是国家重大新药创制总体组审评专家，2010年入选国家千人计划创新人才。
目前，张连山博士致力于将国外新药开发经验及管理理念与恒瑞现有的系统相结合，强化肿瘤、糖尿病及心血管的新药研究开发，拓展蛋白、抗体生物药领域，并加大引进多方位人才力度，使恒瑞的团队管理更有效、更科学，打造具有持续发展力的中国制药模式。

Forrest ANTHONY



Senior Director
Head - Oncology Center of Excellence - North America
QuintilesIMS.

Dr. Anthony has more than 25 years' experience in the biopharmaceutical industry. He conducts early engagement with innovative immuno-oncology companies, offering QuintilesIMS resources and insights for global oncology clinical development projects. Previously a biotech entrepreneur, he founded several companies, serving as CEO, CMO, or VP of oncology clinical development. He was the CEO and founder of Quality Biotech Inc, a contract biosafety testing lab for biotherapeutics, and created affiliated companies in Glasgow and Belgium. He was on the founding Executive Committee of the Biotechnology Industry Organization (BIO) trade association Board after serving as President (1991-92) of the

Association of Biotechnology Companies (ABC) one of the two precursor trade associations that merged to form BIO. He started his career as a researcher at J & J and Rorer Group (now Sanofi). Education: BA from Dartmouth College, MS from Dartmouth Medical School, MD from Oregon Health Sciences University, PhD in Biomedical Engineering from University of Virginia.

分会场 0407

刘颢

刘颢，医学硕士，现任燃石医学首席医学官。拥有14年外资药企肿瘤，免疫，泌尿，感染，神经等多个疾病领域的临床研发经验，参与的工作涉及从临床产品开发策略到临床科学和临床操作多个方面。对于药物注册临床研究的设计，管理，操作，结果分析,研究报告和药监当局报批递交等都具有丰富和深刻的认识。先后主持过克唑替尼，ceritinib等多种肿瘤药物在中国注册上市前研发。进入企业界之前在中国医学科学院肿瘤医院学习和工作了5 年。分别毕业于上海医科大学和中国协和医科大学。

胡劲捷

Dr. Jinjie Hu is the International Network Committee chair of the FDA Alumni Association and a senior consultant working at Biologics Consulting Group. She has almost 12 years of experience with the Food and Drug Administration, Center for Biologic Research and Review. She was a senior expert regulatory/scientific reviewer for multiple analytes In Vitro Diagnostic Devices (IVD) products. She lead and chaired many review committees for 510 (k), IDE, PMA, IND and BLA. Dr. Hu's responsibility included reviewing CMC, analytical and clinical study data, and labeling. She also has extensive experience working within the Center offices and other Centers of the FDA in reviewing companion diagnostic products, combination products, and applications for Clinical Laboratory Improvement Amendments (CLIA) waivers. As a trained manufacturer facility reviewer and CGMP inspector, she performed many pre-approval inspections of IVD manufacturing facilities. She also served CBER education planning committee and an instructor for CBER's Medical Device Training course for 4 years (2009-2012). She has been serving as scientific advisor, dossier reviewer and manufacturer facility inspector for the In Vitro Diagnostic Pre-Qualification Program at WHO since 2009. As the chair for the International Network Committee of the FDA Alumni Association, she provides leadership to collaborate with developing and emerging regulatory agencies for regulatory capacity building and training.

Jinjie received her B.S. in Cell Biology from Beijing Normal University and her Ph.D. in Comparative Pathology from University of California, Davis, followed by postdoctoral fellowship at National Institute of Allergy and Infectious Diseases at the NIH.

分会场 0408

张磊

执业资格： 执业药师
工作经历：从事药品注册领域工作20余年，现任西安杨森制药有限公司注册事务部负责人。此前在国家食品药品监督管理局工作十余年。
教育背景：毕业于沈阳药科大学药学专业，先后获得中国政法大学法律硕士以及伦敦政治经济学院(LSE)国际卫生政策理学硕士学位。

陈之健

SrVP and Head of China Development Unit
Global Medicines Development
AstraZeneca
george.chen@astrazeneca.com

Dr. George Chen currently serves aSrVP and Head of China Development Unit at AstraZeneca's Global Medicines Development. Dr. George Chen is an accomplished pharmaceutical R&D executive with over 15 years of industry experience in clinical

development, medical affairs, strategic planning and business development. Prior to joining AstraZeneca, Dr. Chen was the Chief Medical Officer at BeiGene, a China based biotech focusing on oncology drug research and development.

Dr. Chen started his pharmaceutical industry career with Eli Lilly, where he served as a Strategy Advisor for Corporate Strategic Assets Management and Business Development and as a Global Medical Advisor for Global Oncology Platform Team. After his tenure at Eli Lilly, Dr. Chen joined GSK as the Chief Medical Officer and Head of Development for GSK's Great China Area responsible for clinical development, medical affairs and China portfolio management, and then as a Global Medicine Development Leader (MDL) with GSK's Global Oncology in Collegeville ofPennsylvania, USA. Later on, he joined JnJPharmaceutical R&D (JJPRD) as a VP/Head of Compound Development Teams for Asia.Dr. Chen has deep experience and knowledge in drug development with a proven track record of building and leading high performance development teams and getting INDand NDA approvals.

Prior to his career in pharmaceutical industry, Dr. Chen was a Senior Staff Scientist and Investigator at NIH in Bethesda of Maryland, USA. Dr Chen received his medical degree from Shanghai Medical College of FudanUniversity and his MBA from the Wharton School of University of Pennsylvania. He had his post graduate medical training in oncology at Shanghai Cancer Hospital and New York Medical College, respectively. Dr. Chen is also well published in oncology and immunology on international peer reviewed journals.

申华琼

科学博士，临床医学博士，
强生医药公司中国开发中心总负责，副总裁

申华琼先后在东南大学临床医学专业及四川大学华西医学院获医学学士及硕士学位 ，并曾担任外科医生。后赴美深造获得印第安纳大学(Indiana University)生命科学博士学位。经过住院医生资格论证及培训成为美国有处方权的执照医生并通过了美国精神心理学和神经病学委员会专科认证。作为印第安纳大学临床兼职教授在附属医院做临床医生的同时在礼来公司从事临床药物研发。她还获得国际糖尿病基金会专项研究基金进行内分泌与代谢学博士后研究，在糖尿病及肥胖学的研

究方面取得显著成就。此后还从事了精神病药物学和临床药理学的博士后研究。2009及2010年，她连续两年被授予“美国最佳精神心理医生”的荣誉称号，还发表了20多篇学术论文。
申华琼博士曾在美国礼来，惠氏，辉瑞担任全球临床研发高管10 多年，回国后又加入恒瑞医药并帮助建立了创新药临床团队，成功开拓了在澳洲及美国的临床试验。这些经历让她获得了丰富的新药研发专业知识及创建管理多元化团队的经验并与全球的专家和医生们建立了广泛的联系。
此外，她还致力于中美文化和学术方面的合作交流，她曾是印第安纳中华医学会的主席，礼来制药公司中华文化网的理事，惠氏公司亚洲员工协会的创始人之一；中美医药协会(SAPA)的副总裁，她也多次在CDE或CFDA举行演讲或培训，她的贡献为她赢得多项荣誉，包括惠氏的卓越领导奖，辉瑞的优秀员工奖，SAPA优秀服务奖等。她被选为2014“国家千人计划创新人才”并当选中国药物临床评价研究专业委员会第二届委员.她2015 年作为副总裁及中国开发中心总负责加入强生医药。新近更是当选RDPAC研发核心工作组的预备主席.

牟骅

先声药业首席科学官

牟骅博士于2016年8加入先声药业，负责主持和领导公司研发战略的制定、优化和实施，以及国际研发合作业务。加入先声药业之前，牟博士担任药明康德公司高级副总裁和产品开发服务与合作事业部全球负责人，负责公司的药物开发一体化服务和战略合作，建立并领导了药明康德与美国礼来和MedImmune/阿斯利康等跨国公司在共同开发创新药物方面的新型战略合作。此前牟博士任职于和记黄埔医药公司，担任执行副总裁及首席医学官，建立了和记黄埔医药的临床和注册团队，领导推进6个候选化合物进入了中国和全球I期到III期的临床试验，领导建立与推进和黄与阿斯利康、雀巢和礼来等跨国公司的多个战略合作项目并且实现了多项重要里程碑。牟博士20多年来致力于临床研究及新药开发，曾在多个著名跨国药企和生物科技公司如罗氏制药、Abraxis Bioscience（现属赛尔基因Celgene)、百健艾迪、基因泰克公司担任领导职位。他先后参与和领导了近20个小分子化学药和大分子生物药的研发，包括重要抗癌药物希罗达(Xeloda®)、白蛋白结合型紫杉醇和贝伐单抗(Avastin®)的全球开发与上市。

宁志强

共同创始人/执行副总裁

深圳微芯生物科技有限责任公司

1978年入承德医学院医疗系学习，1988获中国军事医学科学院实验血液学硕士学位，1996年获英国伦敦大学免疫学博士学位。1996~2001年在美国辛辛那提大学（University of Cincinnati）医学院任博士后研究员、研究助理教授。2001年作为深圳微芯生物科技有限责任公司创始人之一，参与公司的发起和创建，负责企业的新药研发工作，带领团队完成一个抗肿瘤原创新药从发现到上市的全程研发和注册工作，以及一个糖尿病原创新药从发现到III期临床试验研究。对在中国开展原创性新药研发具有深刻的体验，对自主原创新药的国际联合开发具有成功的实践经历。作为课题负责人和主要参加者，承担多项国家和地方重大科技项目。作为合作单位和个人，获得2013年国家科学技术进步一等奖。在国际期刊上发表论文40余篇。

专题5 变革中的定量科学

分会场 0501

王勇

Dr. Yong Wang has more than 20 years of experience with clinical development in both pharmaceutical and medical device industries.

He has extensive experience in regulatory submissions and interactions with regulatory agencies

He had worked for a cardiovascular medical device company (St. Jude Medical, 圣犹达医疗公司) for 9 years, then followed by working for pharmaceutical companies (mostly with former Forest Labs --- now Allergan) for more than 10 years as a clinical statistician in the United States.

Starting from late 2015, he works for his current company PAREXEL (精鼎医药), a global CRO company as the head of biostatistics of Asia-Pacific Region. He is currently based in Shanghai

Dr. Yong Wang holds a Ph.D. in mathematics and had his postdoc fellowship in biostatistics and epidemiology.

陈峰

南京医科大学公共卫生学院 教授、博士生导师。现任中国卫生信息学会（原中国卫生统计学会）统计理论与方法专业委员会主任委员，中国临床试验统计学组(CCTS working group)组长，《中国卫生统计》杂志副主编，我国临床试验生物统计学指导原则主要起草人之一，江苏省卫生统计学会主任委员，ICSA会员。曾留学英国伦敦大学和美国哈佛大学。江苏省有突出贡献的中青年专家，江苏省优秀教育工作者，江苏省第八、九、十届政协委员。主要从事非独立数据、生物医学高维数据、临床试验评价和分析中的统计理论与方法。主持过国家自然科学基金项目4项，负责973、863、国家九五、十五攻关项目、十一五支撑项目、国家自然科学基金重大项目等课题的统计设计和分析，承担30多项新药临床试验的统计设计和分析。发表和联合发表论文240多篇，教材和学术

专著20余部。

郭翔

Dr. Guo currently is a Senior Director of MSD R&D China, head of the Asia-Pacific Statistic Group of Merck Research Laboratories. Before joining Merck, Dr. Guo started his industrial career with Sanofi in 2005 in Bridgewater, New Jersey. He was the lead statistician for Sanofi's bestselling drug Lantus.

Dr. Guo received his Ph.D. degree in Statistics from North Carolina State University. His research interests focus on statistical inference in Multi-regional Clinical Trial, benefit risk assessment, missing data analysis and adaptive design. Besides his industrial position, Dr. Guo also holds adjunct teaching positions in Peking University and Beijing Normal University. Dr. Guo is the chair of DIA China statistical community, a member of DIA Advisory Committee of China, a member of China Clinical Trial Statistics Working Group (CCTS) and the secretary general of Beijing Biometrics Association.

汪涛

Tao Wang, graduated from School of Public Health, Fudan University in 1994 and got his PhD in Biostat and Epidemiology at the University of Tokyo, Japan in 2003. He joined in Pfizer in 2006 and Hengrui in 2015. Now he is the Head of Dept. of Biostat and Programming.

分会场 0502

Jim STREETER

Global Vice President, Life Sciences Product Strategy
Oracle Health Sciences

As the global head of life sciences product strategy for Oracle, James Streeter collaborates closely with Oracle customers, regulatory agencies, analysts, and industry thought leaders to develop and help execute the overall business and product strategy for Oracle Health Sciences. He previously held leadership roles at PPD in both operations, as the Global Head of Global Clinical Technical Operations and EDC and recently in IT, as Global Head of Systems Development, Business Operations Teams, and eClinical Strategy and Innovation.

James has 25 years of data acquisition and analysis experience utilizing computerized systems and has focused on eClinical systems and processes for trials for the last 15 years. James' experience includes implementing end to end eClinical Solutions and processes across all therapeutic areas and all phases of studies.

James' early experience in eClinical was gained at Pfizer Inc., where he was Senior Director of Global Clinical Data Services, heading the global data acquisition department for the company's global research and development organization. Prior to joining Pfizer, he was a Senior Hardware, Software and Systems Engineer for the U.S. Navy Underwater Sound Laboratory with a focus in data acquisition and analysis.

分会场 0505

易秉明

易秉明博士目前就任葛兰素史克（上海）中国研发有限公司统计，流行病学，和数据管理部门总监。他毕业于北京大学，获得学士和硕士学位，后来又获得美国北卡罗莱纳州立大学统计学博士学位。

易博士在国际制药行业工作十六年，拥有丰富的经验，包括非临床，动物试验和人体临床方面的产品研究和发展，工作领域涉及很多不同种类的适应症。他曾经在美国默沙东工作过三年半，其中他参与研发的一个糖尿病产品（Januvia）成功上市，2013年销售额达40多亿美元，目前也已经在中国市场销售（捷诺维）。

易博士在葛兰素史克工作共十二年时间。2011年初，他从美国公司回到上海，组建了一支富有经验的统计，流行病学，和数据管理团队。团队成员平均拥有五年多的工作经验，其中一半为从美国回来的海归。

易博士的研究兴趣包括贝叶斯统计，适应性设计（Adaptive Designs）。

王勇

Dr. Yong Wang has more than 20 years of experience with clinical development in both pharmaceutical and medical device industries.

He has extensive experience in regulatory submissions and interactions with regulatory agencies He had worked for a cardiovascular medical device company (St. Jude Medical, 圣犹达医疗公司) for 9 years, then followed by working for pharmaceutical companies (mostly with former

Forest Labs --- now Allergan) for more than 10 years as a clinical statistician in the United States.
Starting from late 2015, he works for his current company PAREXEL (精鼎医药), a global CRO company as the head of biostatistics of Asia-Pacific Region. He is currently based in Shanghai
Dr. Yong Wang holds a Ph.D. in mathematics and had his postdoc fellowship in biostatistics and epidemiology.

分会场 0506

郭翔

Dr. Guo currently is a Senior Director of MSD R&D China, head of the Asia-Pacific Statistic Group of Merck Research Laboratories. Before joining Merck, Dr. Guo started his industrial career with Sanofi in 2005 in Bridgewater, New Jersey. He was the lead statistician for Sanofi's bestselling drug Lantus.
Dr. Guo received his Ph.D. degree in Statistics from North Carolina State University. His research interests focus on statistical inference in Multi-regional Clinical Trial, benefit risk assessment, missing data analysis and adaptive design. Besides his industrial position, Dr. Guo also holds adjunct teaching positions in Peking University and Beijing Normal University. Dr. Guo is the chair of DIA China statistical community, a member of DIA Advisory Committee of China, a member of China Clinical Trial Statistics Working Group (CCTS) and the secretary general of Beijing Biometrics Association.

分会场 0507

朱连升

Aileen Zhu got her PhD in statistical bioinformatics from Hasselt University, Belgium. Afterwards, she worked as a post-doctoral researcher in statistical signal processing at Catholic University of Leuven, Belgium. She later on moved to pharma industry with her first job as a biostatistician at Merck, Sharp & Dohme, the Netherlands, and joined Novartis China in 2014. She had worked on various therapeutic areas, such as women's health, antipsychotics, and ophthalmology. Her research interests include Bayesian analysis, joint models, missing data, and competing risk analysis.

廖珊妹

Shanmei Liao graduated from University of California at Davis, with a Ph.D. in statistics. After graduation, she worked in BMS for three years and then moved back to China and started to

work in Pfizer. Her current interested areas include biosimilar development, multi-regional clinical study design, meta-analysis and bootstrap.

MaryAnn Morgan-COX

Principal Research Scientist, Statistics & Advanced Analytics, Eli Lilly, United States

Speaker Bio: MaryAnn Morgan-Cox is a Principal Research Scientist in the Strategy & Decision Sciences group at Eli Lilly and Company. She is based in Indianapolis at Lilly's global headquarters, but is working in Shanghai until July. MaryAnn is originally from Texas, where she received Bachelors degrees in Education and History from the University of North Texas, and earned Masters and PhD degrees in Statistical Science from Baylor University. Her dissertation and research specialties are Bayesian in nature, focusing on modeling & prediction of rare events and probabilistic criteria for decision-making.
MaryAnn joined Lilly in 2010, where she has focused her efforts on clinical development in Immunology over the last 7 years. MaryAnn has worked or consulted on assets prior to first human dose, all the way through approval and line extension planning. In addition to her work as a clinical statistician and group leader for late phase assets, she also served as the Hub Leader for Lilly's analytics-driven corporate initiative to increase the speed, quality, and flexibility in all development plans.
She is a member of the DIA Bayesian Statistics Working Group, and has served as an invited speaker at industry, academic, and regulatory sessions, with an emphasis on improving evidence-assessment & decision-making approaches. It is through this lens that she offers Using Critical Success Factors to Facilitate Decision-Making in Drug Development for your consideration.

分会场 0508

王钧源

默克雪兰诺全球生物统计,流行病学和医学写作部中国负责人

王钧源博士在默克雪兰诺、百时美施贵宝、惠氏/辉瑞等公司担任重要的领导职务。他在众多治疗领域拥有广泛的研发经验，例如肿瘤学，心血管，神经科学，免疫学和血液学; 并在两款新药在美国和全球市场新药上市和扩展适应症的审批申请当中起到了至关重要的作用。他曾带领超过20人的团队成功的支持一个CV药物的全球新药上市申请。这个药物在2016销售额已达到34亿美金。 他不仅在与FDA，EMA，PMDA和CFDA等部门互动方面有很多良好的互动，也在与KOL和供应商合作推动基于数据的决策方面也有丰富经验。他在诸多顶级期刊上发表文章，并在众多的专业协会和学术会议的委员会中担任领导职务。

蒋志伟

默沙东研发（中国）有限公司高级科学家

蒋志伟，博士，毕业于第四军医大学，默沙东中国联合博士后项目第一批成员，现为默沙东高级统计师。研究兴趣包括适应性与成组序贯设计、MRCT设计、替代终点的应用等，在Statistics in Medicine, JBS, Contemporary Clinical Trial, Trial等期刊发表多篇统计学术论文。

唐雄文

罗氏（中国）投资有限公司统计科学家

唐博士是来自罗氏中国的统计科学家。在罗氏他主要从事肿瘤临床试验的设计与分析，包括中国还有全球的临床实验。加入罗氏之前，唐博士在位于美国新泽西州的Forest Labs工作了近3年，主要从事心理疾病药物的研发。通过在制药行业5年的研究工作，唐博士在晚期临床实验的设计与分析方面累计了丰富而深入的知识经验，尤其是适用于在中国开展临床研究的桥接和扩展实验设计方面。

俞章盛

上海交通大学-耶鲁大学, 生物统计学联合研究中心副主任

俞博士现为上海交通大学-耶鲁大学联合生物统计中心教授。他于2006年毕业于密歇根大学生物统计系。曾任印第安纳大学生物统计系副教授（终身教职）。作为一个生物（临床医学）统计领域的工作者，广泛地与临床医学专家合作（包括呼吸，心律，疼痛，重症，癌症），为提高医学研究的效率，研究方法的适用性，研究结果的正确理解作出了显著的贡献。在过去的六年中在统计和生物医学期刊中发表了五十余篇的论文，其中包括发表在Biomtrika, Biometrics, JAMA， JAMA（Internal Medicine）论文。作为一个应用科学领域的专家，通过和和医学专家紧密合作，促进临床医学研究。由于在统计方法和应用上的贡献，还被Statistics in Medicine, Joural of System Science and Complexity聘为副主编， 被Heart Rhythm(影响因子5.0)和pediatric pulmonology(2.7)聘为统计副主编或编委。2009-2013年分别担任中印第安纳统计协会的副会长和会长, 现当然世界中医药联合会临床统计学会副会长。2014年获得上海市“东方学者“特聘教授，2016年获聘上海“千人计划”。

专题6 恪守临床价值，满足患者需求

分会场 0601

张芳宁

全球董事合伙人
麦肯锡公司
大中华区, 上海办公室

张芳宁于2007年加入麦肯锡， 现为麦肯锡中国医疗健康行业咨询业务联席领导人，为制药和医疗器械企业客户提供范围广泛的咨询服务，包括商业战略、创新、业务拓展和组织转型等等。
张芳宁女士同时主导中国医学事务相关咨询工作。她组织过多次行业领袖参与的麦肯锡医学事务圆桌会议，发表多篇医疗行业的文章及报告（如：IN VIVO 题为“打造卓越的中国医学事务组织”等文章）。
加盟麦肯锡前，张芳宁女士曾在辉瑞美国总部从事新药研发工作。她持有美国西北大学凯洛格管理学院工商管理硕士学位和纽约州立大学石溪分校化学硕士学位。
麦肯锡公司是一家全球性管理咨询公司，为企业和公共机构提供有关战略、组织、运营和技术方面的咨询。目前我们在北京、上海、深圳、香港和台北开设了五家分公司，全球合伙人、咨询师和业务支持专家总共超过了七百名。

分会场 0602

陶立波

陶立波，北京大学卫生经济学博士，英国剑桥大学博士后研究员，专注于卫生政策、卫生技术评估、医药经济学等领域的研究，曾在日本第一制药、瑞士诺华制药、美国BD医疗、美国GE医疗等公司。现为中山大学医药经济研究所特聘研究员，中国卫生经济学会专业委员会委员。

分会场 0605

康志清

东南大学医学院 医学学士
爱尔兰赫伯纳学院 制药医学硕士
中欧国际商学院 高级管理人员工商管理硕士

2014年3月加入阿斯利康，出任阿斯利康中国医学事务部副总裁。
拥有31年的医学领域从业经验，包括11年的临床医生经验以及在跨国药企担任医学领导职务20年之久。拥有丰富的医学事务、临床研究、药物注册、药物安全、医学信息、药物经济学以及对外医学事务的工作经验。
曾在辉瑞美国全球总部担任新兴市场医学总监；曾出任辉瑞中国基础医疗事业部总经理，领导商业运营工作长达3.5年。

毛京梅

李健

医学总监，阿斯利康中国

李健于2012年加入阿斯利康中国医学部，目前担任医学信息和医学合规团队负责人。阿斯利康中国医学合规团队承担着预防公司在医学合规领域发生违规行为的职责。为此，医学合规团队针对公司发起或支持的所有项目、从合规策略角度予以前期指导，针对所有由公司制作的、与公司产品和/或治疗领域有关的材料进行审核和批准，通过政策制定和政策培训、优化阿斯利康中国医学合规管控体系，同时积极参与阿斯利康全球医学标准的制定和修订。
在加入阿斯利康中国之前，李健曾在艾伯维、雅培和勃林格殷格翰中国医学部担任医学顾问、医学事务经理和医学经理。李健还拥有两年的医药广告和PR行业经验，曾就职于Havas集团。在此之前，李健在上海新华医院担任呼吸内科医师，拥有九年临床工作经验。
李健毕业于上海第二医科大学（临床医学本科）和上海交通大学（内科学硕士）。

周苏

医学事务负责人，专科产品中国/辅助体外生殖全球，法国博福-益普生公司
公共卫生硕士，悉尼大学；外科学硕士，北京大学医学部

他在跨国药企拥有10年的医学事务经验，涉及10个不同的治疗领域。岗位跨越中国、亚太以及全球。他在辉瑞中国工作期间，在医学部建立了健康教育职能团队。

分会场 0608

贺李敬

诺华中国医学事务副总裁

贺李镜博士于2014年6月16日加入诺华制药（中国），任职首席科学官及医学事务部负责人；同时，担任诺华制药（中国）管委会成员。
加入诺华前，贺李镜博士服务于勃林格殷格翰，担任医学事务及临床发展总监。他具有二十年在医学事务及临床研究领域的管理经验，先后服务于北美及亚洲多家大型跨国制药企业，包括安进、和记黄浦医药、辉瑞美国等。加入制药行业前，他从事临床和科研工作十余年。贺李镜博士获有加拿大滑铁卢大学理学硕士及首都医学院医学博士学位。

专题6-2 临床申报文件-如何应对新的监管要求

分会场 0607-2

冀呈雪

冀呈雪，医学博士，波士顿科学，医学与法规事务部，临床评价经理，负责新产品医疗器械的临床评价工作。
主要学习和经历：
2006年本科毕业于青岛大学临床医学专业，
2011年博士毕业于清华大学医学部&北京协和医学院，药物研究所药理学专业，

毕业后留药物所担任助理研究员从事科研工作，后在昆拓担任高级医学顾问和医学事务经理。近两年主要从事医疗器械的临床评价工作，已先后组织完成20余个产品的临床评价报告，现已成功获批10个产品，其余产品产品均在审评和发补阶段。

分会场 0608-2

Andrea HENNIG

Since 2015, Andrea Hennig acts as Medical Writing TA Head, General Medicine at Bayer AG, Pharmaceuticals. She steers a global group of medical writers and is based in Berlin, Germany. With her staff she is responsible for the authoring, alignment and consistent quality of global clinical study protocols and reports, clinical submission documents and responses to Authorities in the USA, EU and China.

From 2006 to 2014, Andrea headed the global R&D Project and Portfolio Management Office at Bayer (Schering) Pharma, being responsible to enforce unified standards and tools, provide assistance and training, foster a learning organization, increase transparency, and implement quality control and continuous improvement measures to assure best project management practice. During this time she also implemented project risk management, risk/value based project evaluation methods, promoted master data management and introduced an IT tool for project management.

Between 2004 and 2006 Andrea worked as scientific and business assistant for the Global Development Board Member at Schering AG.

From 1998 to 2004 she was project leader for a variety of research and development projects at Schering AG. She coordinated the development strategy and steered projects with diligent adherence to target product profile, budget and timelines. Dealt with patent assessments, contract interpretations and evaluated in-licensing opportunities.

Andrea is veterinary surgeon with board certification for pharmacology and toxicology and more than seven years working experience as general toxicologist and reproduction toxicologist in pharmaceutical industry (Schering AG and Bristol-Myers Squibb) and federal (German) institutes.

张磊

Leo Zhang, MSc, has been an Associate Manager, Medical Writing Services, at PAREXEL International since 2015. From 2013 to 2015, he was a Clinical Pharmacology Scientist at Novo Nordisk (China) Pharmaceuticals Co., Ltd. He has more than 5 years' experience in developing a wide range of clinical regulatory documents, including protocols, CSRs, clinical overviews and summaries for efficacy and clinical pharmacology, and the Integrated Summary of Safety for NDA submission in the USA. From 2008 to 2012, Leo was a Project Manager for early phase studies at Fountain Medical Development Company. Over the last 10 years, he has developed

strong expertise in Phase 1 clinical research through the design and protocol preparation of more than 20 clinical pharmacology studies including FIH, PK/PD, and BE studies, across multiple therapeutic areas. His experience in project management for early phase clinical studies further includes bid support, resource planning, project tracking and management, and achieving project targets.

王楠

From 2012 till now, Nan Wang has served as the head of medical writing at Bayer Health Care. Prior to joining Bayer, Nan Wang worked as a medical writer for Novo Nordisk.

郑凝

Ning ZHENG is a senior medical writer at Sanofi since 2013. Before joining Sanofi, she got her PhD at the University of Chicago on cell biology and neuroscience, and worked at Takeda North America as a medical writing intern.

专题7 生物制品与生物类似物的开发与监管专题

分会场 0701

王俭

加拿大卫生部, 生物药品及基因治疗局, 放射及生物治疗评审中心, 临床评估部主管

1996年加入加拿大卫生部, 历经临床前期，仿制药，临床试验，上市前评估等各个阶段的药物监管及审评过程。其所在部门负责肿瘤, 传染病, 心血管和肾脏疾病相关的生物药的非临床和临床评审. 生物类似药, 放射性药品, 基因治疗和免疫治疗也在其部门的监管评审范围之内.
专业活动:
加拿大卫生部 临床安全与疗效委员会（CSEC）成员
加拿大卫生部 人用药品注册技术要求国际协调会议（ICH）专家组成员 (ICH S6, S9 and E3)
WHO“生物类似药指导原则”作者之一
WHO“重组DNA技术制备的生物医药质量，安全和疗效指导原则”起草小组成员
WHO Guidelines on evaluation of monoclonal antibodies as similar biotherapeutic products (SBPs) 起草小组成员
药物信息协会 (DIA) 生物类似药年会组委会成员(2013 – 2017)
APEC协调中心: 生物治疗研讨会组委会成员 (2014 & 2015年).
教育
PhD, May 1989
加拿大不列颠哥伦比亚大学生理学
MD, July 1982

哈尔滨医科大学医学系

Nick CECIL

副总裁（技术）

Cecil在30多年前从开普敦大学以生物化学荣誉学士毕业后就开始了法规和临床开发方面漫长的职业生涯；在最近的25年里，他工作的领域集中在了生物药的开发，尤其是单克隆抗体和生物类似药上；他参与了十多个这类产品的开发并在多个工业界的国际会议上研讨相关问题。
从2001年2月起他加入了PAREXEL并负责或参与这类产品的临床研发，法规申报，生物类似药，孤儿药以及提供培训。在最近的5年里，他主要负责整合药理学家，统计专家，治疗领域专家以及可行性分析等意见后制定最优化的临床开发计划，尤其是在炎性疾病领域产品的开发计划。
1987 – 2000年期间他担任诺和诺德的法规经理，负责生物制品和创新产品的注册和研发；在此之前，曾在Farmitalia Carlo Erba, May and Baker, London International Group， Lundbeck等企业任职。因此，他还有药物经济学分析，质量保证，供应链以及临场研发的相关经验。
他还曾担任卡迪夫大学和格林威治大学硕士课程，药物科学专业的客座教授；并且还领导过TOPRA硕士课程，生物技术模块的课程。他还是SCRIP Clinical Research杂志的编辑，并在法规和临床开发领域发表过多篇文章。
Ceicil的专业经验集中在法规，生物制品和临床开发上，并且是生物类似药和可比性方面的知名专家。近期他积极参与了很多单克隆抗体生物类似药的开发及上市申请；并受邀在多个国际会议上就生物类似药和可比性做专题演讲。

分会场 0702

王亚宁

Dr. Yaning Wang is currently the Director (acting) and Deputy Director in the Division of Pharmacometrics in the Office of Clinical Pharmacology at FDA. Before joining FDA, Dr. Wang received his Ph.D. in Pharmaceutics and master's degree in Statistics from the University of Florida from 1999 to 2003. He also obtained a master's degree in Biochemistry (1999) from National Doping Control Center and a bachelor's degree in Pharmacy (1996) from Peking University in China. At his current position, Dr. Wang oversees reviews, research projects, and policy development within the Division of Pharmacometrics for all disease areas. During his thirteen years of service at FDA, Dr. Wang received numerous awards, including Award of Merit (the most prestigious honor awarded at FDA) and FDA Outstanding Service Award. Dr. Wang is an Adjunct Professor in the Department of Pharmaceutics at the University of Florida and an invited lecturer in the College of Engineering and College of Pharmacy at the University of Michigan. Dr. Wang is a regulatory expert lecturer for American Course on Drug Development and Regulatory Sciences (ACDRS) organized by University of California at San

Francisco (UCSF), European Course in Pharmaceutical Medicine (ECPM) organized by University of Basel, and Chinese Course on Drug Development and Regulatory Sciences (CCDRS) organized by Peking University Clinical Research Institute in collaboration with University of Basel and UCSF. Dr. Wang is the chair of the FDA working group to draft a new guidance for the industry to optimize dose selection during the clinical development stage. Dr. Wang served as a committee member for multiple Ph.D. candidates from various universities. He mentored more than thirty former research fellows (visiting scholars, post-doctoral scholars, and Ph.D. candidates) at FDA. Dr. Wang is an invited manuscript reviewer for eighteen scientific journals in the medical, pharmaceutical and statistical areas. He has published 53 papers and given 130 presentations at various national and international meetings. He is a member of the Advisory Committee for Chinese Pharmacometrics Society and a member of the Editorial Advisory Board for the Journal of Pharmacokinetics and Pharmacodynamics.

分会场 0705

王俭

加拿大卫生部, 生物药品及基因治疗局, 放射及生物治疗评审中心, 临床评估部主管

1996年加入加拿大卫生部, 历经临床前期，仿制药，临床试验，上市前评估等各个阶段的药物监管及审评过程。其所在部门负责肿瘤, 传染病, 心血管和肾脏疾病相关的生物药的非临床和临床评审. 生物类似药, 放射性药品, 基因治疗和免疫治疗也在其部门的监管评审范围之内.
专业活动:
加拿大卫生部 临床安全与疗效委员会（CSEC）成员
加拿大卫生部 人用药品注册技术要求国际协调会议（ICH）专家组成员 (ICH S6, S9 and E3)
WHO“生物类似药指导原则”作者之一
WHO“重组DNA技术制备的生物医药质量，安全和疗效指导原则”起草小组成员
WHO Guidelines on evaluation of monoclonal antibodies as similar biotherapeutic products (SBPs) 起草小组成员
药物信息协会 (DIA) 生物类似药年会组委会成员(2013 – 2017)
APEC协调中心: 生物治疗研讨会组委会成员 (2014 & 2015年).
教育
PhD, May 1989
加拿大不列颠哥伦比亚大学生理学
MD, July 1982
哈尔滨医科大学医学系

王亚宁

Dr. Yaning Wang is currently the Director (acting) and Deputy Director in the Division of Pharmacometrics in the Office of Clinical Pharmacology at FDA. Before joining FDA, Dr. Wang received his Ph.D. in Pharmaceutics and master's degree in Statistics from the University of Florida from 1999 to 2003. He also obtained a master's degree in Biochemistry (1999) from National Doping Control Center and a bachelor's degree in Pharmacy (1996) from Peking University in China. At his current position, Dr. Wang oversees reviews, research projects, and policy development within the Division of Pharmacometrics for all disease areas. During his thirteen years of service at FDA, Dr. Wang received numerous awards, including Award of Merit (the most prestigious honor awarded at FDA) and FDA Outstanding Service Award. Dr. Wang is an Adjunct Professor in the Department of Pharmaceutics at the University of Florida and an invited lecturer in the College of Engineering and College of Pharmacy at the University of Michigan. Dr. Wang is a regulatory expert lecturer for American Course on Drug Development and Regulatory Sciences (ACDRS) organized by University of California at San Francisco (UCSF), European Course in Pharmaceutical Medicine (ECPM) organized by University of Basel, and Chinese Course on Drug Development and Regulatory Sciences (CCDRS) organized by Peking University Clinical Research Institute in collaboration with University of Basel and UCSF. Dr. Wang is the chair of the FDA working group to draft a new guidance for the industry to optimize dose selection during the clinical development stage. Dr. Wang served as a committee member for multiple Ph.D. candidates from various universities. He mentored more than thirty former research fellows (visiting scholars, post-doctoral scholars, and Ph.D. candidates) at FDA. Dr. Wang is an invited manuscript reviewer for eighteen scientific journals in the medical, pharmaceutical and statistical areas. He has published 53 papers and given 130 presentations at various national and international meetings. He is a member of the Advisory Committee for Chinese Pharmacometrics Society and a member of the Editorial Advisory Board for the Journal of Pharmacokinetics and Pharmacodynamics.

分会场 0706

张庆

Dr. Andrew Chang has more than twenty years of experience in the development, regulation and quality of biologics and pharmaceuticals. At his current capacity as a Vice President, Quality and Regulatory Compliance, Product Supply Quality, Novo Nordisk, he is responsible for providing strategic advice and solutions for quality and regulatory related issues and expert support to inspection preparation. Since 2013, Andrew has represented Novo Nordisk at the Global Quality and Manufacturing Committee, PhRMA to advocate patient and industry's interests by developing position papers and participating liaison meetings with the FDA. He is also a member of PhRMA's ICH Coordinating Work Group, and representing PhRMA as an expert to ICH Q12 Expert Working Group for developing guideline on Pharmaceutical Products Lifecycle Management.

Prior to Novo Nordisk, Andrew served more than eleven years at US FDA, most recently as an Associate Director for Policy and Regulation, Acting Deputy Director and Senior Regulatory Scientist in the Division of Hematology, Center for Biologics Evaluation and Research (CBER). During his tenure, Andrew received numerus high level FDA awards for his exceptional and outstanding performance on regulatory review and management, GMP inspection, and policy development. These include, but are not limited to FDA Commissioner's Special Citation for successfully completing FDA's initiative on product quality regulation and CBER's Public Health Achievement Award for outstanding regulatory review performance that resulted in averting a crisis in product availability. In 2002, the FDA recognized Andrew as the FDA regulatory expert in the regulation of new and novel recombinant products as well as naturally - derived biological products. Andrew's formal scientific training includes post - doctor in immunology from the National Institutes of Health, Ph.D. in Biochemistry from the State University of New York, and B.S. in Pharmaceutical Chemistry from the China Pharmaceutical University. He has published numerus peer reviewed scientific papers in JAMA,

J.Exp.Med., Blood, J.Immunol., Dev. Immunol. Thromb Haemost., Haemophilia, Pharmaceutical Engineering etc., and has been a frequent speaker at national and international conferences.

分会场 0707

王亚宁

Dr. Yaning Wang is currently the Director (acting) and Deputy Director in the Division of Pharmacometrics in the Office of Clinical Pharmacology at FDA. Before joining FDA, Dr. Wang received his Ph.D. in Pharmaceutics and master's degree in Statistics from the University of Florida from 1999 to 2003. He also obtained a master's degree in Biochemistry (1999) from National Doping Control Center and a bachelor's degree in Pharmacy (1996) from Peking University in China. At his current position, Dr. Wang oversees reviews, research projects, and policy development within the Division of Pharmacometrics for all disease areas. During his thirteen years of service at FDA, Dr. Wang received numerous awards, including Award of Merit (the most prestigious honor awarded at FDA) and FDA Outstanding Service Award. Dr. Wang is an Adjunct Professor in the Department of Pharmaceutics at the University of Florida and an invited lecturer in the College of Engineering and College of Pharmacy at the University of Michigan. Dr. Wang is a regulatory expert lecturer for American Course on Drug Development and Regulatory Sciences (ACDRS) organized by University of California at San Francisco (UCSF), European Course in Pharmaceutical Medicine (ECPM) organized by University of Basel, and Chinese Course on Drug Development and Regulatory Sciences (CCDRS) organized by Peking University Clinical Research Institute in collaboration with University of Basel and UCSF. Dr. Wang is the chair of the FDA working group to draft a new guidance for the industry to optimize dose selection during the clinical development stage. Dr. Wang served as a committee member for multiple Ph.D. candidates from various universities. He mentored more than thirty former research fellows (visiting scholars, post-doctoral scholars, and Ph.D. candidates) at FDA. Dr. Wang is an invited manuscript reviewer for eighteen scientific journals in the medical, pharmaceutical and statistical areas. He has published 53 papers and given 130 presentations at various national and international meetings. He is a member of the Advisory Committee for Chinese Pharmacometrics Society and a member of the Editorial Advisory Board for the Journal of Pharmacokinetics and Pharmacodynamics.

严瑾

Associate Director and Principal Scientist, Global Head of Modeling and Simulation, Clinical Pharmacology

Dr. Jin Yan Jin is Associate Director and Principal Scientist, Global Head of Modeling and Simulation (M&S) in Clinical Pharmacology at Genentech, and oversees clinical M&S and data programming activities for all molecule types in various therapeutic areas. She also acts as Group Leader for OMNI Clin Pharm Group 3 – Neuroscience and oversees overall clinical pharmacology support for all neuroscience molecules in Genentech portfolio. She has been actively involved in development and/or registration for many molecules, including Atezolizumab, Avastin Pediatric, Cobimetinib, Herceptin SC, Pertuzumab, T-DM1, Vismodegib, and Xolair in CIU. Before joining Genentech in 2009, she worked at Eli Lilly in metabolism and neuroscience areas after Ph.D. and post-doc in Pharmaceutical Sciences from the State University of New York at Buffalo. Dr. Jin is a strong advocate for M&S application in drug development. Her scientific areas of expertise include mechanistic Pharmacokinetics/ Pharmacodynamics (PK/PD), Physiologically Based Pharmacokinetics (PBPK), population analysis, trial simulation, disease modeling, literature meta-analysis.

Dr. Jin is a recognized leader in the scientific community. She serves on the Board of Directors for International Society of Pharmacometrics (ISoP) and will be the President for ISoP 2017-2018. She is also on the Editorial Board for Clinical Pharmacology and Therapeutics: Pharmacometrics and System Pharmacology (CPT:PSP), and involved in various Task Forces and activities for American Society for Clinical Pharmacology and Therapeutics (ASCPT) such as the Scientific Programming Committee. She chaired the 2015 American Conference on Pharmacometrics annual meeting (ACoP6). Dr. Jin has nearly 50 publications, gave over 25 invited talks, and moderated many scientific workshops and sessions.

分会场 0708

Yow-Ming Chen WANG

Dr. Yow-Ming Wang is the biologics team leader in Division III of the Office of Clinical Pharmacology at FDA. The biologics team at DCP III is responsible for reviewing submissions of biologic products in three clinical divisions. Dr. Wang joined FDA in March 2011 and has been an active contributor at national conferences where she presented on various topics related to clinical pharmacology of protein therapeutics. Prior to the FDA, she spent many years in the pharmaceutical industry with experience in the discovery research, preclinical development, and clinical development of small molecules and large molecules. From 2004 to 2011, she worked at Amgen where she supported multiple biologic products in clinical development, in registration phase, and in post-marketing phase. Prior to that, she supported small molecule drug discovery and development for 11 years at Vertex Pharmaceuticals and at Parke-Davis Pharmaceutical Research. She received her PhD degree from The Ohio State University College of Pharmacy with a research focus on Pharmacokinetics and Biopharmaceutics.

专题8 患者安全-持续关注的焦点

分会场 0801

周晓枫

Dr. Xiaofeng Zhou is a Senior Director in Epidemiology, World Safety and Regulatory at Pfizer Inc, New York, USA. She has 20 years of professional experience with Pfizer across a wide spectrum of pharmaceutical science including the clinical development operation, post marketing drug safety and pharmacovigilance, clinical safety and risk management, and epidemiology. Xiaofeng has led Pfizer's drug safety active surveillance methodological research, signal detection in clinical development in addition to multiple responsibilities in the

design and conduct of epidemiological studies and analyses over 20 drug products. She is an adjunct professor at Fudan University, China. Xiaofeng earned her doctoral degree in Epidemiology from University of Michigan, USA and holds Masters Degrees in Statistics and Applied Economics from Virginia Tech, USA, and Food and Nutrition Planning from University of Philippines, Philippines.

Jae-Gook SHIN

Dr. Jae-Gook Shin is a Professor of Pharmacology and Clinical Pharmacology, and Director of Inje University Busan Paik Hospital's Global Center of Excellence in Clinical trials. He is also the Chair of the Department of Pharmacology and Clinical Pharmacology and Director of the Pharmacogenomics Research Center at Inje University College of Medicine.
Dr. Shin founded the Clinical Trial Center at Busan Paik Hospital in 1997 and the Korean Ministry of Health and Welfare funded Global Center of Excellence in Clinical Trials in 2013. Dr. Shin has also served for many Academic Societies, Editorial Boards and National/Regional Committees. He has been served for the Korean Association of Clinical Trial Centers and the Institutional Review Board of South-Eastern Regional Clinical Trial Organization as a Vice President and Chair. He has been also served as the Board of director for the Korean National Enterprise for Clinical trials, and the Council member of International Union of Basic and Clinical Pharmacology. He has been honored as a member of the National Academy of Medicine of Korea.
Dr. Shin has published over 270 papers in clinical pharmacology including pharmacogenomics, clinical PK/PD, DM/PK and drug interaction, Clinical trial in drug development and more.

Brian EDWARDS

Director of ISoP Secretariat Ltd and Advisory Board Member of ISoP
Vice President Pharmacovigilance & Drug Safety in the Alliance Clinical Research Excellence and Safety (ACRES) and Chair of UK Pharmaceutical Human Factors & Ergonomics group

1980 - 1994 Guy's Hospital Medical School followed by hospital medicine and clinical research in London, Birmingham, and Manchester
1994 -1999 Senior Medical Assessor Pharmacovigilance Assessment Group UK Medicines Control Agency
1999 - 2005 Senior Medical Director – Parexel Scientific and Medical Services
2005 - 2007 Deputy Qualified Person for pharmacovigilance for Janssen Cilag
Since July 2007 Principal Consultant in Pharmacovigilance and Drug Safety with NDA Regulatory Science Ltd.

分会场 0802

顾芸

Dr Yun Gu currently works as a Director in Epidemiology at Pfizer. She earned her PhD degree from the University of Texas - School of Public Health at Houston, Texas. Before she joined Pfizer in 2005, she has worked in the Department of Epidemiology at the University of Texas - M. D. Anderson Cancer Center for more than 4 years.
At Pfizer she proposes and carries out various components of Epidemiology deliverables for development and product teams, including epidemiology research strategy, Risk Management Plan and other regulatory documents, background epidemiology studies, natural history of disease studies, and post-approval safety studies. In addition, she also designs and implements database and de novo epidemiological studies to estimate risks potentially associated with the products.

分会场 0805

纪立伟

主任药师,医学硕士，硕士生导师，执业药师。就职于北京医院药学部。北京市医学会医疗事故鉴定聘任专家。
长期从事临床药学工作。对内分泌药物使用有丰富的临床经验。已带教了24名内分泌专业临床药师学员及10名师资学员。与带教的临床药师学员完成了4000余人的内分泌科住院患者药学监护及用药教育工作。
2004年开始负责北京医院药品安全监测及管理工作。任职期间所在医院曾多次获得北京市ADR监测先进集体称号。主要从事医院用药安全与药物警戒方面的研究。作为主要研究者承担和参与了北京市食品药品监督管理局药品安全性评价课题及国家科技重大专项等多项科研课题。
已在国家核心期刊上发表相关论文二十余篇，主编学术专著三部，参编学术专著十部。中国科技核心期刊《中国药物应用与监测》与《中国药物警戒》编委。
2011年获中国药学会医院药学专业委员会青年药师优秀奖。

2016年4月获得中华医学会临床药学分会“优秀临床药师”称号。

王玉红

拜耳国际药品安全行政总监，拜耳医药保健MA&PV获益-风险管理

目前在拜耳公司主要负责抗糖尿病药及一些普药的药品安全性评价及获益-风险管理的工作。在加入拜耳公司前，于罗氏公司任职9年，曾先后担任药品安全科学主管参与肿瘤药物上市前的临床安全性数据评估，以及罗氏亚太区药品安全执行负责人和罗氏在中国的药物警戒负责人。此前，曾在诺华公司国际临床研究执行部任职4年。
首都医科大学老年医学专业硕士研究生毕业，曾在北京宣武医院老年科工作9年。

Carol KORO

Carol E. Koro is an Executive Director at MSD, Center for Observational and Real-World Evidence. Dr. Koro has over 15 years of experience in Pharmacoepidemiology, focusing primarily on drug safety related issues utilizing real-world data. She is a Pennsylvania registered pharmacist and holds a PhD and a M.S. degree in Pharmaceutical Health Services Research from the University of Maryland. She is an Affiliate Assistant Professor, School of Pharmacy, Department of Pharmaceutical Health Services Research, University of Maryland.

分会场 0806

黄健

Sr. Safety Science Leader, Genentech Early Development Safety Science

Jack joined the Genentech Early Development Safety Science team in 2010, and since then he has actively involved in many oncology projects in the early clinical development stage, including PI3K-Akt-mTOR pathway inhibitors, selective estrogen receptor degraders, and biologics/bispecific antibodies targeting immuno-oncology targets. Jack has about 20-year industrial experience in drug safety/risk management as well as translational medicine covering all phases of clinical development and post-approval products with focus on oncology therapeutic area. Prior to Genentech, he worked at Bayer (both Japan and US), Millennium Pharmaceuticals, and Bristol-Myers Squib where he was the clinical safety lead involving multiple NDA/BLA filings and approvals, including ipilimumab, cetuximab and ixapepilone.
Prior to coming to the pharmaceutical industry, Jack had spent about 7 years working as an occupational medicine physician and a research scientist in multiple academic institutions in both Japan and US. Jack obtained his MD in China (Peking University Health Sciences Center), his Ph.D in Japan (Nagoya University School of Medicine), and his postdoctoral training in the

US (Rutgers University and UC Berkeley). He has extensively published his research and clinical works in the areas of occupational medicine, epidemiology, toxicology/pharmacology, neuroscience, and cancer research.

黄葵

Kui Huang is a Senior Director, Epidemiology in Worldwide Safety, part of Research and Development at Pfizer in USA. She is responsible for developing epidemiologic research strategies throughout a product's lifecycle in several therapeutic areas. Her work has primarily been involved in designing and implementing observational peri- and post-approval safety studies. Kui has extensive experiences in designing and conducting pharmocoepidemologic studies involving primary data collection as well as various electronic health care databases in the US, Europe and Asia. She has published in the area of cancer research, genetic epidemiology, women's health, and drug safety. She holds a B.S. from Winona State University, a MPH in Epidemiology & Biostatistics from Boston University and a Ph.D. in Epidemiology from University of North Carolina-Chapel Hill.

Stephen KNOWLES

Dr Knowles is currently Senior Medical Director, Global Patient Safety Medical and Benefit Risk Management at Eli Lilly & Company.
Steve received his MD from the University of Newcastle Upon Tyne, UK in 1984 and worked in the UK National Health Service for 17 yrs, initially in Internal Medicine, Radiation Oncology and subsequently in General Practice.
He joined Eli Lilly in 2001 and has worked in pharmacovigilance since 2005 in various roles in both the UK and USA. In his current role, Steve has management responsibility for the Senior Directors, physicians and scientists in all therapeutic areas (across all phases of clinical development and post-approval medicines,) who are responsible for safety surveillance activities, benefit risk assessments, labelling and risk management/ risk minimization activities.

专题9 创新药物早期研发战略和战术

分会场 0901

Dennis BASHAW

Director, Division of Clinical Pharmacology-3, Food and Drug Administration, Silver Spring, MD

Captain Bashaw's involvement with ASCPT goes back almost 25 years. CAPT Bashaw joined the US Public Health Service Commissioned Corps in 1987 and was assigned as a pharmacokineticist in the Division of Biopharmaceutics at the FDA. In 1992, he was selected to be one of the founding members of the Pilot Drug Evaluation Staff (PDES) in the FDA. This was a new group in the FDA that was formed by the then Center of Drug Evaluation and Research Director, Dr. Carl Peck.

分会场 0902

王敏

Adam COHEN

Health Council of the Netherlands (Independent Advisory Body to the Minister of Health)
Member of the Council for Medical Sciences of the Royal Netherlands Academy of Science
Member of the board of the Alumni Association of Leiden University Medical School
Chairman and founder of the LeidenFutureLab a new school for scientific entrepeneurs established by the Ministry of Health of the Netherlands in association with Leiden University
Editor-in-Chief of the British Journal of Clinical Pharmacology
Member of the scientific advisory board of the Netherlands Diabates Patients Association

JuAn WANG

王博士现任美国礼来总部全球患者安全药物效益风险管理研究员. 王博士毕业于中国苏州大学苏州医学院医学专业，美国北德克萨斯大学藥理學专业 并获得美国医药项目管理证书药物效益风险评

估管理证书. 王博士在肿瘤和糖尿病领域的药物早期研究和晚期开发以及药物效益风险管理有豐富的經驗. 她是礼来创新藥 效益风险评估和上市后产品的效益风险评估专家. 并在药物效益风险评估领域多次发表文章.

分会场 0905

Dennis BASHAW

Director, Division of Clinical Pharmacology-3, Food and Drug Administration, Silver Spring, MD

Captain Bashaw's involvement with ASCPT goes back almost 25 years. CAPT Bashaw joined the US Public Health Service Commissioned Corps in 1987 and was assigned as a pharmacokineticist in the Division of Biopharmaceutics at the FDA. In 1992, he was selected to be one of the founding members of the Pilot Drug Evaluation Staff (PDES) in the FDA. This was a new group in the FDA that was formed by the then Center of Drug Evaluation and Research Director, Dr. Carl Peck.

John LAMBERT

VP, Chief Medical Officer,Global Head of Early Phase Medical Sciences and Consulting

Dr Lambert provides a broad range of expert consulting services to clients for early drug development. This includes the development of a clinical development plan with focus on time and cost savings; selection of compound specific biomarkers for early proofofmechanism; selection of compound specific safety parameters and preparation of relevant documents including the protocol and Investigator's Brochure.
Dr Lambert is Vice President, Chief Medical Officer and heads the global Early Phase Medical Sciences and Consulting group. Prior to his current role, he worked as Senior Director and then

Vice President PAREXEL Early Phase, London, United Kingdom (UK), for 8 years. He has been with the company since 2001. Dr Lambert is based in the London Early Phase Clinical Unit and provides additional medical and scientific oversight of studies including overseeing the safety of the study participants.

With 40 years' medical experience, Dr Lambert has worked in Australia, Canada and the UK, and he has over 13 years' experience working at three CROs, holding positions including director of clinical studies, director of medical affairs, vice president and chief medical officer. He has extensive clinical experience and is trained and certified in gastroenterology, pharmaceutical medicine and clinical pharmacology. He has worked as Principal Investigator on over 70 clinical studies including new biologicals and biosimilars.

Among various industry affiliations, Dr Lambert is a member of the British Association of Pharmaceutical Physicians, American Gastroenterology Association, fellow of the Faculty of Pharmaceutical Medicine, member of the American College of Clinical Pharmacology and on the specialist register of the Royal College of Physicians, in addition to being a member of other international associations.

He holds a MBBS and a MMed from the University of Melbourne, Australia; a PhD from Monash University, Melbourne; and a Dip Pharm Med from the University of Wales, UK.

Dr Lambert has published extensively, including peer reviewed articles, abstracts, and book chapters.

专题10 立足中国的新药开发和创业论坛

分会场 1005

Florence HOUN

Dr. Florence Houn is VP for Global Regulatory Science at Celgene Corporation. She is also a consultant to industry and health authorities regarding drug development programs and regulatory capacity building. She was Vice President, Global Regulatory Policy, Intelligence and Strategy from 2008-2015 at Celgene. Prior to this, she served 15 years in the US Food and Drug Administration (US FDA) as Division Director, Deputy Office Director and Office Director. In recognition of her contributions to public health, Dr. Houn received the US Department of Health and Human Services' (DHHS) Career Achievement Award in January 2009. In 2014, she received the FDA Distinguished Alumni Award from Commissioner Margaret Hamburg for contributions to global regulatory capacity building.

Prior to joining government, she served four years in the National Health Service Corps in a manpower health shortage area in Baltimore.

Dr. Houn was the founding co-chair of the FDA Alumni Association's (FDAAA) International Network (FDAAAIN) and is a member of the FDAAA Board of Directors since 2012. She is a member of the Centers for Medicare and Medicaid Services (CMS) Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), January 2017 to 2019 and was a member of the PDUFA V negotiating team representing the Biotechnology Industry Organization (BIO) with FDA in 2010-2011. She serves on the Asia Pacific Economic Cooperation (APEC) Harmonization Center's Advisory Board and is on the Board of Directors for the International Partnership for Microbicides (IPMglobal.org).

Dr. Houn received her Bachelor of Arts degree from Harvard University and her medical degree from the Albert Einstein College of Medicine. She completed her Cancer Prevention and Control Fellowship at the National Cancer Institute and obtained her MPH from the Johns Hopkins School of Hygiene and Public Health. She attended the Johns Hopkins Breast and Ovarian Surveillance Service as an Instructor in Oncology.

Mark GOLDBERGER

Dr. Goldberger received his MD degree from the Columbia University College of Physicians and Surgeons in New York and his MPH from George Washington University in Washington, DC. He completed his postgraduate training at the Presbyterian Hospital in New York and the Centers for Disease Control (CDC) in Atlanta. He is board certified in internal medicine and infectious disease and is a fellow of the Infectious Diseases Society of America. Dr. Goldberger was on the faculty of Columbia University for nine years.

Dr. Goldberger joined the Food and Drug Administration in 1989. At FDA he served as primary reviewer, medical team leader, Director of the Division of Special Pathogen and Immunologic Drug Products and Director of the Office of Antimicrobial Products within the Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA). In addition to these positions he coordinated drug shortage activities within the CDER from 1990 -˘ 2006. Dr. Goldberger also was the FDA lead in an assessment of the readiness of the Pharmaceutical Industry for Y2K. In 2000 he spent 8 months as acting Associate Center Director for Quality Assurance in CDER during which time he developed the concept of the Regulatory Briefing. In 2003-˘2004 he was Acting Deputy Center Director of CDER. In 2006 he became Medical Director for Emerging and Pandemic Threat Preparedness within the Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration.

In October 2007 he joined Abbott as Divisional Vice President – Regulatory Policy and Intelligence. In this role he was involved in multiple areas of both product and policy development. He continued in this position when AbbVie separated from Abbott until May 2013 when he became VP Regulatory Affairs and Senior Advisor. In this position he provided regulatory and scientific input both into multiple development programs and in the preparation

of marketing applications. In September 2014 he retired from AbbVie and opened his own consulting practice as Mark Goldberger MD MPH LLC.
While at Abbott and AbbVie he participated in PhRMA and efpia working groups on antibiotic resistance and twice presented on this subject to the European Medicines Agency as well as to the FDA. As a member of the FDA Alumni Association he has participated in several training sessions for staff from CDE/CFDA as well as for CDE/TFDA. He has presented multiple times at DIA China as well as at APEC 2012 and 2016 in Taiwan.

分会场 1006

Yang CHEN

盛德国际律师事务所合伙人

杨晨律师是盛德国际律师事务所的合伙人，也是本所中国生命科学业务的负责人。杨律师主要提供公司法、商法和行业监管领域的法律服务，常年代理跨国药品、医疗器械和食品公司处理市场准入、产品本土化、市场推广、产品召回、临床试验及美国海外反腐败法及反贿赂等方面的事务，并就行业特有的监管、合规及稽查方面的问题提供法律咨询。杨律师的业务范围还包括生命科学领域的合资企业、公司并购、许可、知识产权及反垄断法律事务。
杨律师获得《亚洲律师》（The Asian Lawyer）评选的生命科学"All-Star"律师，并且在《PLC律师年鉴》（PLC's Which Lawyer）评选的"中国/香港地区公司法/商法杰出律师"以及"全球杰出生命科学律师"中均名列前茅。她曾被《国际金融法评论》（IFLR 1000）评为"中国杰出并购律师"以及被《钱伯斯（亚太区）》（Chambers Asia Pacific）评为"中国/香港地区生命科学领域杰出律师"。她亦被《法律名人录》（Who's Who Legal）评为领先的生命科学律师。杨律师还获得2016年《钱伯斯中国》生命科学（国际律师事务所）类别"第一等级"排名并获得2016年《钱伯斯亚太》生命科学类别"杰出律师"荣誉。
杨律师于1991年从北京大学获得法学学士学位，同时被授予"年度最佳毕业生"殊荣，之后于1997年从美国乔治亚大学获得法学硕士学位，并取得美国纽约州执业资格。杨律师经常在全国和国际性行业大会及研讨会上发表演讲。
杨律师的母语为中文，并通晓英语。

邹建军

Dr. JIANJUN(Jessie Zou) was trained by medical oncology in China and got her medical doctor degree in the second military medical university. She had been working in the level 3 A hospital as a medical oncologist for 10 years from 1995 – 2005. Then she joined Bayer Healthcare pharmaceutical company in China. She had been leading the clinical development programs of Sorafenib in China as the clinical trial physician, head of oncology therapeutic team in Bayer China. Then she moved to NJ, USA and worked as the global medical lead of Xofigo in the global medical affairs team in BayerhealtherCare Headquarter. In 2012, she moved back to China as the director, head of the medical department in Celgene China. Starting from Oct 2015, she has been the Vice president, Clinical Research and Development - Oncology in JIANGSU HENGRUI MEDICINE, CO. LTD.

分会场 1007

杨建新

杨建新博士现任基石药业首席医学官及国家“千人计划” 特聘专家，在抗肿瘤新药研发策略，临床开发计划、方案设计、医学和安全监察、结果的分析、风险的评估和控制等方面拥有丰富全面的经验和突出的专业水准。
在加入基石药业前杨建新博士担任百济神州高级副总裁和临床开发部负责人，建立并全面领导百济神州的临床开发团队，在中国及海外多个国家开展了多个创新性抗肿瘤药物，包括PD-1单抗（第一个进入临床试验的源于中国的PD-1单抗），BTK抑制剂，PARP抑制剂及BRAF抑制剂的临床试验并取得显著成效，为百济神州两轮融资(2015)以及在NASDAQ的成功上市（2016）提供了关键的安全性与有效性临床数据。
在2014年回国前，杨建新博士已拥有在海外大型跨国药企、科研院所等机构逾23年的学术科研与新药研发经验，曾担任美国科文斯公司肿瘤医学总监, 辉瑞肿瘤生物标记及精准医学资深首席科学家，及美国安进公司肿瘤基因组学科学家。他在肿瘤新药的临床试验, 以及肿瘤生物标记和精准医学方面获得了丰富的经验，对多个抗肿瘤新药的成功研发作出了重大贡献，并在国内外学术刊物上发表了30多篇学术论文及摘要并拥有9项专利。
杨建新博士于湖北医学院与南京医科大学接受医学教育，获医学学士及硕士学位，随后他在美国德克萨斯大学西南医学中心诺贝尔奖获得者Michael Brown和Joseph Goldstein教授的实验室获得分子遗传学博士学位，并在哈佛大学Stuart Schreiber教授的实验室完成博士后研究工作

刘冀

上海张江生物医药基地开发有限公司 营销部（孵化器）部门负责人。自2004年加入张江药谷后，主要负责企业孵化、服务；产业合作、宣传等工作。

专题11 热点话题

分会场 1101

郭彤

昆泰非洲亚洲地区生物统计负责人

郭彤博士现任昆泰艾美仕公司亚太及非洲生物统计执行总监，负责昆泰公司生物统计全球欧美以外的离岸团队及交付业务。郭彤博士曾获加拿大麦吉尔大学生物统计学硕士及博士学位。具有近二十年的国际大制药公司新药研发经验。曾任拜耳医药保健有限公司北京国际研发中心，数据科学与分析亚太总监；上海康德保瑞医学临床研究有限公司副总裁，临床信息及FSP业务部门负责人；高知特信息技术(上海)有限公司生物统计及生命科学BPS部门主管；美国百时美施贵宝主任生物统计师及美国强生研发总部生物统计师；并在加拿大麦科马思特大学心血管项目中心及兰州生物制品研究所从事过研究工作。主持过多个全球多中心临床试验的统计设计及分析。特别是对生物统计及大数据分析在生命科学及新药研发上的应用方面颇具建树。

朱立红

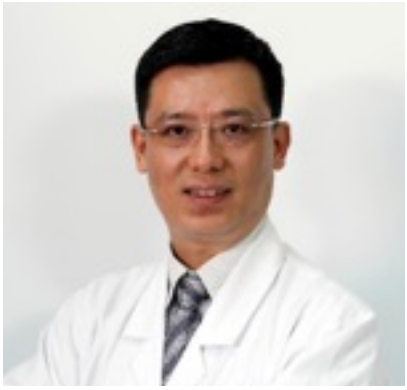
工商管理硕士，DIA中国董事总经理

朱立红女士现任DIA中国董事总经理， 负责DIA （药物信息协会） 的战略开发和商务拓展，发展会员等。 通过为政府，工业界，学术机构提供交流和学习的平台，促进知识更新和专业人才的培养。
朱女士于2013年-2016年任职比尔及梅琳达·盖茨基金会研发部的高级项目官， 负责基金会在中国的全球人类健康产品和解决方案的项目管理。 同时也帮助基金会了解中国的研发能力， 使得中国成为全球研发的一个有效的平台。
朱女士有着近二十年的国际研发型制药企业的临床研究及项目管理的经验。 她在美国默克公司 （即默沙东公司）和英国的葛兰素史克两家大型药企工作过。其中在默克公司工作了十二年，并在公司的美国总部的临床研究运营部门工作了五年。自2006年起， 朱女士在葛兰素中国研发部门任临床研究负责人，负责公司在中国的研发策略的制定和执行，以及所有治疗领域新产品的临床试验和外包服务的计划。随后她又参与了在中国上海的GSK研发中心的筹备和创立的全过程， 并为该中心的创新文化的建立做了大量贡献。自2010底，朱女士创立了始达上海医药科技有限公司并任其首席执行官， 致力于建立一家肿瘤药物早期临床研究的中心。
朱立红女士1990年毕业于北京大学医学健康部（北京医科大学）药学院，并于2006年获得美国新泽西州立大学的工商管理硕士学位。

Sebastien BOHN

Part of the IBM Lifesciences pillar within Watson Health, Sébastien is the Offering Manager Lead for the IBM Clinical Development platform. IBM Clinical Development is a robust electronic data capture (EDC) system and a unified, cloud-based data management platform that lets you design and manage clinical trials with unparalleled control, convenience and confidence.
In charge of the entire platform roadmap, responsible for the product enhancement and innovation, Sébastien has been working in the Clinical Trial Field for 15+ years.

阴忆青



医学博士，上海中山医疗科技发展公司总经理

毕业于原上海医科大学。后进入复旦大学附属中山医院普外科工作。外科专业方向为乳腺肿瘤、胃肠道肿瘤的诊治和腹腔镜手术等。
2007年2月起，任复旦大学附属中山医院计算机网络中心主任。先后组织自行开发、部署了一系列信息系统，包括结构化电子病历（EMR）、医生录入医嘱（CPOE）、临床路径（Clinical Pathway）、手术麻醉（OTS）、患者主索引（EMPI）、统一影像流程管理系统（UIW）、营养配餐、输血全流程管理系统等医院核心业务系统。完成了医院自主开发的影像管理系统和多家国内外厂商的PACS系统的集成。在全院部署了基于WIFI技术的医生移动查房推车和护士手持设备移动护理系统、基于广域网和安卓操作系统的移动电子病历，实现了临床医生在院外实时查看患者电子病历，完成了医院系统和多家银行、上海申康一卡通系统和银联系统的对接，完成了与江苏盐城等地区的医保实施结算的对接。在上海CA的支持下，部署了全院级的电子认证和时间戳系统。配合多个临床科室建立了符合专科特色的临床数据仓库（CDR）持续地进行数据分析和挖掘，建立了初步的临床决策支持系统（CDSS），并在不断完善之中。
长期努力改善信息基础架构支持医院信息化持续发展，2010年起在软件开发、测试和新开发的系统中，大量使用服务器虚拟化技术。主持更新了全院的骨干网络，升级到万兆骨干千兆到桌面。并且部署了相对独立的无线网络支撑在全院范围内开展包括医生用推车和护理用手持设备等无线业务。借助在运营商端的核心设备，在全院部署了统一通讯系统，实现了IP电话的覆盖，并和电子病历系统进行了呼叫和视频流的集成，以便支持远程会诊和院内的视频和电话会议。
因为在医院信息系统的建设中，不断涉及流程的优化和改善，对精益流程改善怀有浓厚的兴趣，并在信息系统的设计和实施中贯彻精益的思想和做法。
2015年9月起，任上海中山医疗科技发展公司总经理。上海中山医疗科技发展公司成立于1990年，是复旦大学附属中山医院全额投资的企业， 2003年起被上海市政府认定为市高新技术企业。主要从事医疗技术与产品的研发、生产，健康领域的咨询与服务，健康体检管理和生物技术、医院管理和临床业务软件的研发等业务。

分会场 1106

朱立红

工商管理硕士，DIA中国董事总经理

朱立红女士现任DIA中国董事总经理， 负责DIA （药物信息协会） 的战略开发和商务拓展，发展会员等。 通过为政府，工业界，学术机构提供交流和学习的平台，促进知识更新和专业人才的培养。
朱女士于2013年-2016年任职比尔及梅琳达·盖茨基金会研发部的高级项目官， 负责基金会在中国的全球人类健康产品和解决方案的项目管理。 同时也帮助基金会了解中国的研发能力， 使得中国成为全球研发的一个有效的平台。
朱女士有着近二十年的国际研发型制药企业的临床研究及项目管理的经验。 她在美国默克公司 （即默沙东公司）和英国的葛兰素史克两家大型药企工作过。其中在默克公司工作了十二年，并在公司的美国总部的临床研究运营部门工作了五年。自2006年起， 朱女士在葛兰素中国研发部门任临床研究负责人，负责公司在中国的研发策略的制定和执行，以及所有治疗领域新产品的临床试验和外包服务的计划。随后她又参与了在中国上海的GSK研发中心的筹备和创立的全过程， 并为该中心的创新文化的建立做了大量贡献。自2010底，朱女士创立了始达上海医药科技有限公司并任其首席执行官， 致力于建立一家肿瘤药物早期临床研究的中心。
朱立红女士1990年毕业于北京大学医学健康部（北京医科大学）药学院，并于2006年获得美国新泽西州立大学的工商管理硕士学位。

鲁先平

Ph.D., CEO & CSO, Chipscreen Biosciences Ltd., Shenzhen, China

Dr. Xian-Ping Lu founded Chipscreen Biosciences, the leading drug discovery and development company in China focusing on innovative small molecular therapeutics, 15 years ago with a group of US-trained professionals. Previously he was Director of Research at Galderma R&D (subsidiary of L'Oreal and Nestle) in Princeton until 2000, the year he became visiting professor at China's State Key Laboratory for Biomembrane and Membrane Biotechnology in Tsinghua University. He also participated in founding Galderma Research Inc. and Maxia Pharmaceuticals in San Diego.

Dr. Lu came to the US in 1989 for postgraduate fellowship study at the Department of Pharmacology, University of California in San Diego, followed by research at La Jolla Cancer Research Foundation (Burnham Institute). He obtained his Ph.D. in Molecular Biology and M.S. in Biochemistry from Peking Union Medical College, Chinese Academy of Medical Sciences, and his B.S. degree in Biochemistry from Sichuan University.

With over 20 years of biomedical research and biotech/pharmaceutical experiences in various therapeutic areas, Dr. Lu is a skilled leader of diverse groups in global operating settings. He has published more than 80 peer-reviewed papers in prestigious journals including Nature and Science. He is the lead inventor of over 80 patented inventions in areas of small molecule therapeutics.

林亮

礼来亚洲基金 合伙人

专注于医疗领域的风险投资，负责投资项目的考察筛选，尽职调查，和被投资公司的管理；目前担任多家公司董事，包括兴齐眼药、康希诺生物、北京凯因、迈博斯生物和艾森生物。此前他先后在葛兰素史克（中国）负责企业收购兼并以及产品的引进和对外授权，在默克-雪兰诺（中国）负责核心产品的市场营销，在三九医药创建了战略规划部并领导公司战略规划与业务拓展方面的工作。拥有中国药科大学药物化学硕士学位、中欧国际工商学院MBA学位及执业药师资格。

邵颖

理学博士；上海复星医药（集团）股份有限公司副总裁兼研发中心主任，北京大学药物信息与工程研究中心资深研究员,华中科技大学、沈阳药科大学兼职教授。
曾任中国药科大学副教授，国家食品药品监督管理局药品审评中心原审评部副部长、部长，研究与评价部部长，高级审评员。
长期从事药物研发、药品注册管理及相关法规研究、技术评价与管理，以及药物化学的教学工作。
《中国新药杂志》、《中国临床药理学杂志》、《药学进展》、《现代药物与临床》杂志编委。

张丹

“千人计划”专家联谊会秘书长
方恩医药发展公司董事长兼首席执行官

方恩医药发展公司是一个能够全方位提供临床新药开发服务的外包服务组织（CRO）。目前在北京、天津、南京、上海、广州，成都，台北、汉城、香港,亚美尼亚，日本，印度，英国，菲律宾及美国均建有其分支机构，提供临床I，II，III及IV期药物临床开发服务。现有员工1200人.
之前张丹在意大利Sigma-Tau 公司全面负责其北美市场的临床开发及药物安全性评价。Sigma-Tau公司是意大利本土最大的制药公司之一。在此之前，张丹为美国昆泰集团公司（Quintiles Transnational Corp.）开创了大中国区市场，任其第一任大中国区董事长，并在1995-2000年期间任总公司副总裁兼执行委员会成员。Quintiles Transnational是世界上最大的药物研发外包服务公司。
张丹先后在中国科技部，卫计委，北京市政府，中国医学科学院/协和医科大学、清华大学，北京大学、复旦大学医学院（前上海医科大学），南开大学药学院、华南理工大学及哈尔滨医科大学等做顾问，客座教授或特邀授课专家。他亲自参于了两个新药在美国的报批（NDA），十个在美国上临床证书（IND）的报批。
张丹于1981-1984年在北京大学生物系医预科就读，并在1984-1989年在北京协和医科大学学习临床医学并获医学博士学位，然后先后在哈佛大学公共卫生学院，宾州大学沃顿商学院等院校进修医院管理，经济学及金融学等，获公卫硕士、医院管理硕士及在读金融学博士。
张丹任百华协会（Bayhelix）董事。曾任美国华人生物医药科技协会会长（Chinese Biopharmaceutical Association-USA）及美中药协（Sino-American Pharmaceutical Association）执行董事。曾任科技部新药研发海外专家委员。目前是中组部“千人计划”生物医药国家特聘专家,并任“千人计划”专家联谊会秘书长(第一及第二)及欧美同学会理事。中国医药创新促进会药物研发专业委员会主任委员。同时任国家”十二五”重大新药创制计划责任专家,参加医药项目申请的评审工作,并参与国家食品药品监督管理总局药审中心的技术指南制订,新药临床评审及药审人员培训工作。

专题12 罕见病，未被满足的市场需求

分会场 1207

鲁先平

Ph.D., CEO & CSO, Chipscreen Biosciences Ltd., Shenzhen, China

Dr. Xian-Ping Lu founded Chipscreen Biosciences, the leading drug discovery and development company in China focusing on innovative small molecular therapeutics, 15 years ago with a group of US-trained professionals. Previously he was Director of Research at Galderma R&D (subsidiary of L'Oreal and Nestle) in Princeton until 2000, the year he became visiting professor at China's State Key Laboratory for Biomembrane and Membrane Biotechnology in Tsinghua University. He also participated in founding Galderma Research Inc. and Maxia Pharmaceuticals in San Diego.

Dr. Lu came to the US in 1989 for postgraduate fellowship study at the Department of Pharmacology, University of California in San Diego, followed by research at La Jolla Cancer Research Foundation (Burnham Institute). He obtained his Ph.D. in Molecular Biology and M.S. in Biochemistry from Peking Union Medical College, Chinese Academy of Medical Sciences, and his B.S. degree in Biochemistry from Sichuan University.

With over 20 years of biomedical research and biotech/pharmaceutical experiences in various therapeutic areas, Dr. Lu is a skilled leader of diverse groups in global operating settings. He has published more than 80 peer-reviewed papers in prestigious journals including Nature and Science. He is the lead inventor of over 80 patented inventions in areas of small molecule therapeutics.

David TSUI

Regulatory Affairs Regional Lead

Mr. David Tsui is currently the Regulatory Affairs Regional Lead at Shire, a biopharmaceutical company focusing on developing medicines for patients with rare diseases. He is currently responsible for developing and implementing regulatory strategy in the Australia and New Zealand. David received a Bachelor of Pharmacy from University of Sydney and Master of Biomedical Engineering degree from University of NSW in Australia. Prior to joining Shire, David worked in a leadership role covering Health Economics, Regulatory Affairs and Medical Affairs function in Australia for a number of multinational pharmaceutical companies including Bayer and Janssen.

分会场 1208

刘秀凤

Phoenix has been in the drug regulatory affairs for about 20 years, covering areas for both small molecules and biologics regulatory activities in China. Phoenix started her regulatory affairs career in Boehringer Ingelheim and had worked for US biotech companies of Biogen

Idec and Amgen China. Since March 2015, Phoenix joins Shire China as regulatory affairs country lead.

Hae-Young AHN

Dr. Ahn is currently the deputy director in Division of Clinical Pharmacology 3, Office of Clinical Pharmacology, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). She received her B.S. in pharmacy from Ewha Women's University, M.S. in pharmaceutics from Seoul National University, and Ph.D. in pharmaceutics from West Virginia University. She also received a postdoctoral training in pharmaceutics at the University of Michigan.

Since joining the FDA in 1990 as a research scientist, she has held several positions in the Office of Clinical Pharmacology including a clinical pharmacology and biopharmaceutic reviewer, the metabolic and endocrine clinical pharmacology team leader and deputy division director. As a deputy division director, she has been leading the efforts to apply scientific tools in drug development and regulatory decision-making process in the therapeutic areas of Bone, Reproductive/Urology products, Gastroenterology/Inborn Errors products and Dermatology/ Dental products. She is active in biologics and biosimilar development and regulations. She has recently completed her detail with Office of New Drugs, Therapeutic Biologics and Biosimilar Staff. During her detail, she served as a senior advisor to the Office of New Drugs (OND) Associate Director for Therapeutic Biologics on broad policy and strategic initiatives related to follow-on products, follow-on protein products, and other related complex products. She has been interested in international collaborations for drug development and approval, and organized and participated at several international conferences. She has participated in many important CDER coordinating committees and working groups such as Complex Drug Substance Coordinating Committee, Biopharmaceutical Coordinating Committee, Non-glycosylated peptide working group, Biosimilar Implement Committee, Biologic Oversight Board, and Hepatic Impairment working group.

刘宏宇

德益阳光生物技术（北京）有限责任公司首席执行官
在蛋白质药物的前期研发、工艺开发、和文件报批等方面有多年经验
十五年在国内外蛋白质药物开发行业的经验
三年管理国内药物开发公司的经验
三年管理国际药企中试生产部门的经验
二年管理国际药企蛋白质研发部门的经验
合著65项国际专利
北京市“海聚人才”
河北省“百人计划”

专题13 展商学术交流会

分会场 1305

Peter SCHIEMANN

Peter Schiemann, PhD, MBA, is a renowned expert in R&D Strategy, Clinical Development, Risk-, Quality- and Project Management.
He is Managing Partner at Widler & Schiemann Ltd, a consulting firm focusing on all aspects of clinical development from Protocol Quality by Design to Study set-up, Project Management and Risk-based oversight of Clinical Trials such as Risk-based Monitoring. Before founding Widler & Schiemann Ltd., he worked at Roche in several functions, at PricewaterhouseCoopers in R&D Strategy Consulting and in Academic Research (Endocrinology).
Dr. Schiemann is member of EFGCP (European Forum for Good Clinical Practice) and their working parties “Patient’s roadmap to Treatment” and “Medical Technology” and RQA (The Research Quality Association).

邵颖

理学博士
上海复星医药（集团）股份有限公司副总裁兼研发中心主任
北京大学药物信息与工程研究中心资深研究员
华中科技大学、沈阳药科大学兼职教授。

曾任中国药科大学副教授，国家食品药品监督管理局药品审评中心原审评部副部长、部长，研究与评价部部长，高级审评员。
长期从事药物研发、药品注册管理及相关法规研究、技术评价与管理，以及药物化学的教学工作。
《中国新药杂志》、《中国临床药理学杂志》、《药学进展》、《现代药物与临床》杂志编委。