

2015 SAPA-SDDA-SIMM-AZ Pharmaceutical R&D Symposium

2015美中医药开发协会(SAPA)-中国新药研发协会(SDDA)-中国科学院上海药物研究所(SIMM)-阿斯利康(AZ)新药创制高层
学术研讨会

Application of emerging technologies for the discovery and
development of better medicines

新药创制高层研讨会—研发策略与新技术应用



Application of emerging technologies for the discovery and development of better medicines



To meet the increasing demand for innovative drug discovery and development, Sino-American Pharmaceutical Professionals Association (SAPA), Sino Drug Discovery Association (SDDA), China Pharmaceutical Association, Shanghai Institute of Materia Medica (SIMM) CAS, AstraZeneca (AZ), and AZ-SIMM Drug Safety Evaluation Coalition will jointly organize the 2015 SAPA-SDDA-SIMM-AZ Pharmaceutical R&D Symposium **in Shanghai on September 21-22, 2015 and in Beijing on September 24, 2015.**

The symposium will focus on application of emerging technologies and strategies for innovative pharmaceutical R&D and overcoming hurdles at various stages of drug development. We are extremely honoured to have key opinion leaders and scientific experts from world's leading research institutions and multinational pharmaceutical companies to attend the meeting and give talks. They will present their latest work covering a wide range of topics including biomarker discovery and its clinical diagnostic applications, toxicity prediction and risk control in anticancer drugs development, cardiovascular safety assessment, regulatory requirements on safety pharmacology, clinical trial design, and state-of-the-art analytical technologies for pharmaceutical R&D. The symposium aims to promote scientific exchange among pharmaceutical scientists in China, US, and UK, and apply advanced technologies to accelerate the discovery of innovative and safer medicines.

Thanks to the generous sponsorship from Shimadzu (China) Co., Ltd., the symposium will be a free event to all invited guests in pharmaceutical R&D. Due to the limit of seats, please be aware of the confirmation e-mail after your registration, which assures your seat would be reserved.

Looking forward to meeting you at the symposium.

Sino-American Pharmaceutical Professionals Association (SAPA)
Shanghai Institute of Materia Medica (SIMM), CAS.
AstraZeneca-SIMM Drug Safety Evaluation Center
Sino Drug Discovery Association (SDDA)
Toxicological Pathology Chapter, Chinese Society of Toxicology
Shimadzu (China) Co., Ltd

July 31, 2015

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为适应我国创新药物研发不断增长的需求，美中药协（Sino-American Pharmaceutical Professionals Association, SAPA），中国新药研发协会（Sino Drug Discovery Association, SDDA），中国科学院上海药物研究所（SIMM），阿斯利康（AstraZeneca）与上海药物研究所－阿斯利康药物安全性评价联盟将于**2015年9月21日至22日在上海，9月24日在北京**联合举办2015 SAPA-SDDA-SIMM-AZ 药创制高层学术研讨会。本届研讨会以新药创制研发策略与新技术应用为主题，围绕着新药创制阶段中的热点和难点问题，从不同侧面进行广泛学术交流。

本届研讨会邀请了来自国际著名专业研究机构，跨国制药公司和国内知名的科研院所等多位具有丰富实践经验的专家作大会报告，内容涵盖人体临床试验设计，生物标志物（biomarker）发现和临床诊断应用，心血管毒性早期预测、风险控制和研发策略，包括抗肿瘤药物研发中出现的心脏毒性的特征、临床前研究数据如何外推于人等列举多个具体实例，以及研发中涉及的一些相关技术方法等多方面内容。大会旨在为推进以转化医学为核心的早期成药性评估理念和策略，促进我国创新药物的研发与国际接轨，为我国制药企业、研发机构及科研院所提供一个与世界知名药企与国内一流药物研究机构建立合作的桥梁和纽带。

感谢岛津企业管理（中国）有限公司的大力支持和赞助，本次研讨会将对受邀的新药研发工作同仁免费开放。鉴于人数限制，席位确认将以回复的电子邮件为准，敬请留意查收。

期待与您相聚！共同推动我国生物制药产业的创新和发展！

美中医药开发协会
中国科学院上海药物研究所（药物安全评价研究中心）
上海药物研究所-阿斯利康药物安全性评价联盟
中国新药研发协会
中国药学会毒性病理专委会
岛津企业管理（中国）有限公司

2015年7月31日

Application of emerging technologies for the discovery and development of better medicines



Day 1 Shanghai Parkyard Hotel

Time	Speakers	Topics
09:00-09:30		Registration
09:30-09:45	Dr. Charles Wang, GSK R&D Shanghai (RDS)	Opening Remarks
09:45-10:30	Dr. Charles Xie, Boehringer Ingelheim	Optimal First in Human Study Design.
10:30-10:45	Coffee Break	
10:45-11:30	Dr. Kevin A. Schug, University of Texas	Multipath Liquid Chromatography - Tandem Mass Spectrometry for Simultaneous Analysis of Small Molecules and Proteins.
11:30-12:15	Dr. Jingkang Shen, SIMM	Molecular Targeted Anticancer Drugs Development: Project Case Studies.
12:15-14:00	Lunch	
14:00-14:45	Dr. Eric Sun, Yangtze River & BioDuro Joint Drug Discovery Center	Systematic Approaches to Quality by Design (QbD) Analytical Methods for Pharmaceutical Developments.
14:45-15:30	Dr. Masayuki Nishimura, Shimadzu	Opening a New Chapter in Analytical Science Using Online SFE-SFC-MS/MS.
15:30-15:45	Coffee Break	
15:45-16:45	Dr. Daniel W. Chan Johns Hopkins Medical Institutions	Translation of Biomarker Discovery into Clinical Diagnostics: Opportunities, Challenges and Solutions.
16:45-17:00	Closing	

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Day 2 Shanghai Parkyard Hotel

Time	Speakers	Topics
09:00-09:30		Registration
09:30-09:45	Dr. Charles Xie, Boehringer Ingelheim	Opening Remarks
09:45-10:30	Dr. Mark Anderton, AstraZeneca	The Fundamentals of Cardiovascular Safety Assessment.
10:30-10:45	Coffee Break	
10:45-11:30	Dr. Chris Pollard, AstraZeneca	Cardiotoxicity of Cancer Therapeutics - Case Studies on Electrophysiology & Inotropy.
11:30-12:15	Dr. Chris Pollard, AstraZeneca	The Evolution of AZ's Non-clinical Cardiovascular Safety Strategy - Case Studies on Blood Pressure & Structural Cardiac Toxicity.
12:15-14:00	Lunch	
14:00-14:45	Dr. Likun Gong, SIMM	Safety Pharmacology Core Battery and Regulatory Requirements: Case Studies.
14:45-15:30	Dr. Jerome Mettetal, AstraZeneca	Modelling and Simulation of In vivo Cardiovascular Endpoints and Their Application for Human Risk Assessment.
15:30-15:45	Coffee Break	
15:45-16:45	Dr. Jerome Mettetal, AstraZeneca	The Future of Non-clinical Cardiovascular Safety Risk Assessment.
16:45-17:00	Closing	

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Sept.24 Beijing IHG Crowne Plaza Hotel U-Town

Time	Speakers	Topics
09:00-09:20		Registration
09:20-09:30	Dr. Charles Xie, Boehringer Ingelheim	Opening Remarks
09:30-10:15	Dr. Charles Xie, Boehringer Ingelheim	Optimal First in Human Study Design.
10:15-10:30	Coffee Break	
10:30-11:15	Dr. Kevin A. Schug, University of Texas	Multipath Liquid Chromatography - Tandem Mass Spectrometry for Simultaneous Analysis of Small Molecules and Proteins.
11:15-12:00	Dr. Likun Gong, SIMM	Safety Pharmacology Core Battery and Regulatory Requirements: Case Studies.
12:00-13:30	Lunch	
13:30-14:15	Dr. Eric Sun, Yangtze River & BioDuro Joint Drug Discovery Center	Systematic Approaches to Quality by Design (QbD) Analytical Methods for Pharmaceutical Developments.
14:15-15:00	Dr. Masayuki Nishimura, Shimadzu	Opening a New Chapter in Analytical Science Using Online SFE-SFC-MS/MS.
15:00-15:15	Coffee Break	
15:15-16:00	Dr. Jingkan Shen, SIMM	Molecular Targeted Anticancer Drugs Development: Project Case Studies.
16:00-16:55	Dr. Daniel W. Chan Johns Hopkins Medical Institutions	Translation of Biomarker Discovery into Clinical Diagnostics: Opportunities, Challenges and Solutions.
16:55-17:00	Closing	



Biography



Charles Ying Wang, Ph.D., DABT

Head of Safety Assessment, GSK R&D Shanghai (RDS).

Dr. Wang is the current Head of Safety Assessment at GSK R&D Shanghai (RDS). Before he joined GSK, Dr. Wang was the Vice President of Drug Safety and Regulatory Affairs at Hua Medicine, Ltd., Director of Toxicology at Johnson & Johnson PRD, and Senior Scientist at Novartis Pharmaceutical Corp. Before he joined the pharma industry, Dr. Wang worked as a Study Director in a couple of US CROs. He has more than 18 years of working experience in drug safety evaluation and led preparation of non-clinical safety sections for IND/CTA filing to US, EU and Chinese Regulatory Authorities. Dr. Wang received his Ph.D. in Toxicology from University of Illinois at Chicago, M.S. in Pharmacology from Peking Union Medical College/CAMS, and B.S. in Pharmacy from Beijing Medical College (the current College of Pharmacy of Beijing University Medical Center). He is a board certified toxicologist in US and the current Council member of Drug Safety Evaluation Section, Chinese Society of Toxicology. Dr. Wang was a board member and Treasurer of American Association of Chinese in Toxicology (AACT), a special interest group of US Society of Toxicology, and the former President and the current Board member of Sino-American Pharmaceutical Professionals Association (SAPA), and President of SAPA China.



Charles Xie, M.D., Ph.D.

Head of Clinical Development, Boehringer Ingelheim (China) Investment Co., Ltd.

Dr. Charles Xie was trained as a scientist in toxicology (PhD) and a medical professional with 15-year medical practice (MD). Dr. Xie has 20-year experiences in pharmaceutical industry, working at several major international pharmaceutical companies in US, such as Johnson & Johnson, Pfizer, and Sanofi. Dr. Xie's expertise is specialized in clinical pharmacology, in all types of early phase clinical drug trials in various therapeutic areas. He is experienced in clinical drug development in US and China, and knowledgeable of ICH, FDA and CFDA guidance. Dr. Xie currently is the Head of Clinical Development, Boehringer Ingelheim (China) Investment Co., Ltd.

Speakers Biography



Prof. Daniel W. Chan, Ph.D., DABCC, FACB Johns Hopkins Medical Institutions.

Dr. Daniel W. Chan is Professor of Pathology, Oncology, Radiology and Urology at the Johns Hopkins University, Baltimore, Maryland. He is a diplomat of the American Board of Clinical Chemistry and a fellow of the National Academy of Clinical Biochemistry. At the Johns Hopkins Hospital, he is the Director of Clinical Chemistry Division and the Co-Director of Pathology Core Laboratories. In 2000, he founded the Centre for Biomarker Discovery and Translation at the Johns Hopkins University where he has been the Director. The focus of the Centre is to discover and translate proteomics cancer biomarkers using mass spectrometry, protein microarrays and immunoassays. Dr. Chan developed the test OVA1 which is based on 5 proteomic biomarkers for ovarian cancer. In 2009, this test became the 1st FDA cleared proteomic in vitro diagnostic multivariate index assay (IVDMIA). He is also the principal investigator (PI) of the Biomarker Reference Laboratory (BRL) for the National Cancer Institute (NCI) Early Detection Research Network (EDRN) and the NCI Clinical Proteomic Tumor Analysis Consortium (CPTAC). He was instrumental in the development of public-private partnerships leading to the clinical study, publication and FDA approval in 2012 of two new prostate cancer tests. Dr. Chan was a founder and served as the Chair of the American Association for Clinical Chemistry (AACC) Proteomics Division. He was also one of founders of the USHUPO (Human Proteomics Organization) and has been serving on the Board of Directors since 2005. He is the Editor-in-Chief of Clinical Proteomics, an open access journal (BioMed Central) focusing on translational proteomics. He has written 5 books, 40 book chapters and about 300 scientific articles. He received >20 awards from many scientific organizations. At this year's HUPO world congress in Madrid, Spain, he was awarded the inaugural "Translational Proteomics Award" for his outstanding life time achievement in proteomics.



Prof. Jingkang Shen, Ph.D.

Professor of Shanghai Institute of Materia Medica(SIMM), Chinese Academy of Sciences(CAS).Dean of R&D Centre, Chief Scientist of Shanghai Pharma.

Dr. Jingkang Shen is professor and Principal Investigator of Shanghai Institute of Materia Medica, CAS. He is Vice Director of Medicinal Chemistry committee of Chinese Pharmaceutical Association; Vice Chairman of Shanghai Pharmaceutical Association. He graduated from School of Pharmacy at Shanghai Medical University in 1975 and obtained his Ph. D degree at Kyoto University in 1993. His current research focus in discovery and development of molecular targeted anti-tumour drugs, protein tyrosine kinase inhibitors, epigenetic-related protein modulators and monoclonal antibody drug conjugates; Studies on synthetic methods and compound library construction for drug discovery.



Prof. Kevin A. Schug, Ph.D.

Department of Chemistry & Biochemistry, University of Texas.

Prof. Kevin A. Schug is the Shimadzu Distinguished Professor of Analytical Chemistry in the Department of Chemistry and Biochemistry at The University of Texas at Arlington (UTA). He received his B.S. degree in Chemistry in 1998 from the College of William and Mary, and his Ph.D. degree in Chemistry from Virginia Tech in 2002 under the supervision of Prof. Harold M. McNair. From 2003-2005, he performed post-doctoral research in the laboratory of Prof. Dr. Wolfgang Lindner at the University of Vienna in Austria. Since joining UTA in 2005, his research has been focused on the theory and application of separation science and mass spectrometry for solving a variety of analytical and physical chemistry problems. He has 95 peer-reviewed publications and 350 presentations, posters, and invited talks to his group's credit. Dr. Schug has received the 2009 Emerging Leader in Chromatography award given by LCGC magazine, an NSF CAREER award, the 2009 Eli Lilly and Company ACACC Young Investigator Award in Analytical Chemistry, and the 2013 American Chemical Society Division of Analytical Chemistry Young Investigator in Separation Science Award. For his teaching, he received the 2014 University of Texas System Regents' Outstanding Teaching Award. He is a member of the Editorial Advisory Board of LCGC Magazine (Advanstar) and Analytica Chimica Acta (Elsevier). He is a Senior Editor for Journal of Separation Science (Wiley).

Speakers Biography



Eric Sun, Ph.D.

Sr. Director & Head of Analytical Chemistry Yangtze River & BioDuro Joint Drug Discovery Centre Nanjing.

Dr. Eric Sun received his Ph.D. from College of Pharmacy, University of Florida and has since then played significant roles in R&D organizations of various US pharmaceutical companies including Amgen, Barr Pharmaceuticals, and Emisphere Technologies for over 14 years. Inspired by the vast potential of China new and generic drug markets, he left Amgen Thousand Oaks as Principal Scientist after the 10-year services on a number of new chemical entity (NCE) programs and was appointed Senior Director and Head of Analytical Chemistry at Yangtze River & BioDuro Joint Drug Discovery Centre. His research interest has been focused on innovative analytical technologies and pioneering applications that powers drug development and improves product quality. His recent works including the separation and detection of Biogenic Amines by LC - Chemiluminescent Nitrogen Detector (CLND); the determination of method design spaces aided by HPLC automation and statistics design software; and the GMP qualification of Analytical SFC had drawn broad attentions through scientific publications, presentations at scientific gatherings, and research articles of pharmaceutical magazines.



Chris Pollard, Ph.D.

Principal Scientist, Drug Safety and Metabolism Department, AstraZeneca.

Chris is a Principal Scientist in the Translational Safety section of Drug Safety & Metabolism. He received a 1st Class honours degree in Physiology followed by a PhD in Neuroscience, both from the University of Sheffield (UK). He then did post-doctoral ion channel research at the universities of London and Newcastle-upon-Tyne. In 1990 he joined Fisons Pharmaceuticals (which became AstraZeneca) where he worked as the lead biologist on projects seeking to modulate ion channels to treat respiratory diseases. In 2001 Chris moved into drug safety to set-up and led a team responsible for cardiac ion channel screening for all AstraZeneca projects and is recognised as a leader in cardiac electrophysiology. He has published over 30 articles in this field. His role has gradually broadened to cover all aspects of cardiovascular safety such that he now leads the non-clinical cardiovascular safety strategy at AstraZeneca.



Jerome Mettetal, Ph.D.

Leader of Translational Safety Department, AstraZeneca.

Dr. Jerome graduated with BS degrees in mathematics and in physics from Virginia Tech before earning a PhD in physics at MIT. His work there on biophysics and systems biology led him to work in the newly formed systems biology group at Pfizer where he studied network biology of the PI3k/AKT pathway activity in cancer. He later moved into the Pfizer Biologics unit at Rinat, where he supported antibody discovery and development through mechanism based modeling approaches. In 2011, Jay joined the drug metabolism and pharmacokinetics department at Millennium Pharmaceuticals where he led a small research team and worked to establish the Modeling & Simulation (M&S) as a support function for oncology projects. In 2013, Jay joined AstraZeneca to build and lead an M&S function within the newly formed Translational Safety department. Jay is passionate about using M&S approaches to enhance decision making in drug discovery and development, with particular focus on cardiovascular safety and oncology.



Mark Anderton, Ph.D.

Discovery Toxicologist, Drug Safety and Metabolism Department, AstraZeneca.

Mark received his 1st Class honours degree in Pharmacology from University of Leeds (UK) followed by a PhD in Cancer Pharmacology from the Medical Research Council Toxicology Unit (Leicester, UK). After his PhD, Mark joined Vertex Pharmaceuticals (UK) where he worked as the lead Project Pharmacologist within drug discovery teams. In 2008, Mark joined AstraZeneca where he is now a Principal Scientist within the Drug Safety and Metabolism Department. Mark's current role is a Discovery Toxicologist where he works with drug discovery research teams to identify and mitigate safety liabilities with the aim of influencing the selection of candidate drugs with the right safety profile. Mark's main area of expertise is the safety of oncology therapeutics where he has over 10 years' experience. As a discovery toxicologist Mark has experience in identifying, mitigating and providing solutions to cardiovascular safety liabilities within the drug discovery phase.

Speakers Biography



Prof. Likun Gong, M.D., Ph.D.

Associate Director of Centre for Drug Safety Evaluation and Research (CDSER), SIMM, CAS.

Dr. Likun Gong has 20 years of experience in non-clinical drug safety evaluation and toxicological research. Currently she directs the development of key technologies for non-clinical evaluation of biotech drugs and establishment of advanced toxicity screening methods in the early development stage of innovative drugs in the CDSER, SIMM.



Masayuki Nishimura, Ph.D.

Senior Global Marketing Manager, Liquid Phase Separation Sciences, Shimadzu Marketing Centre.

Dr. Masayuki Nishimura is the Senior Global Marketing Manager for LC and MS related business at Analytical and Measuring Instruments Division, Shimadzu Corporation. He graduated from the Faculty of Engineering of Kyoto University in 1983 and immediately joined Shimadzu. He started his career at Shimadzu as an analytical applications chemist in the HPLC/IC group at the Analytical Applications Laboratory, located at Shimadzu's headquarters in Kyoto, Japan. He was the group leader of the lab from 1990 until being relocated to the United States in 1996 as a member of the newly established Shimadzu Marketing Centre (SMC), which he is currently supervising as the Senior Manager. While working for Shimadzu in Japan, he studied retention mechanism of small anions on ion exchange chromatography and obtained a doctoral degree in Chemistry at Kanazawa University. He is the recipient of the Young Researcher Award from Japan Chromatography Society in 1996. As a member of SMC, he has been working on helping increase Shimadzu's HPLC and MS related business in the USA and worldwide by 1) performing collaborations and establishing partnerships with international companies, universities, hospitals and governmental research institutes, 2) gathering and summarizing customers' requirements for new product development, 3) promoting Shimadzu's solutions for unmet needs in the most advanced markets and regulatory compliance, and 4) working with other vendors for jointly providing better solutions for mutual customers.



Hotel Info & Reservation

上海博雅酒店 < Shanghai Parkyard Hotel >

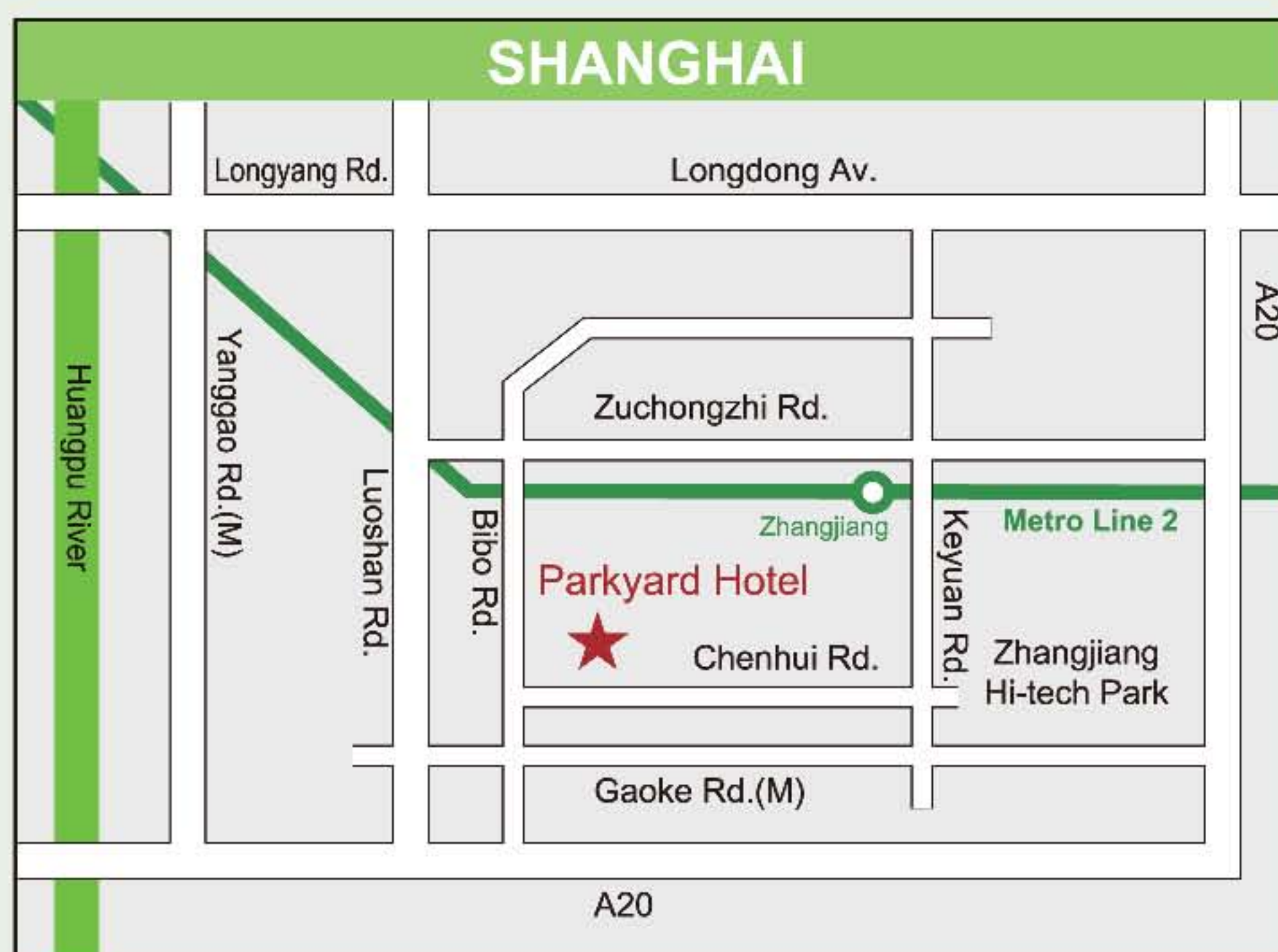
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Locations



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<http://cn.ihg.com/crowneplaza>

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Registration

2015 SAPA-SDDA-SIMM-AZ Pharmaceutical R&D Symposium

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报名和注册请登录以下任一页面：

Please register at ONE of the following webpages:

<http://sapa2015.shimadzu.com.cn/2015SAPA-register>

<http://www.sapaweb.org>

<http://www.sddaweb.org/>

<http://www.simm.ac.cn/>

Or please send your information to e-mail: sapa@shimadzu.com.cn

或请将您的信息直接发送到电子邮件：sapa@shimadzu.com.cn

*PLEASE BEWARE OF THE CONFIRMATION E-MAIL
WHICH ASSURES YOUR SEAT WOULD BE RESERVED

*鉴于人数限制，席位确认将以回复的电子邮件为准，敬请留意查收。

2015 SAPA-SDDA-SIMM-AZ Pharmaceutical R&D Symposium

September 21st - 22nd, 2015,
Parkyard Hotel, Pudong District, Shanghai
(博雅酒店)

September 24th, 2015
Crowne Plaza Hotel U-Town
(北京朝阳悠唐皇冠假日酒店)

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