2024 国际生物医药产业创新北京论坛
International Biomedical Industry Innovation Conference Beijing Forum

DIA 国际分论坛
International SubForum

从全球健康视角 看中国的药物创新 出海和国际合作

Beyond Borders: Connecting Drug Innovation in China with Global Health

2024年10月24–25日 中国北京
October 24-25, 2024, Beijing China

2024 International Biomedical Industry Innovation Conference Beijing Forum

DIA International SubForum

October 24-25, 2024, Beijing China

Beyond Borders: Connecting Drug Innovation in China with Global Health

The DIA International Sub-forum, organized by DIA China, is a premier event within the Beijing Forum, dedicated to exploring how advancements and innovations in biotechnology can be leveraged to benefit global health through international collaboration and regulatory innovation.

Venue: Beijing E-Town - Chaolin Songyuan Hotel - Juyuan Hall, 5th Floor, Block A
Address: Building 2, No.19 Ronghua Middle Road, Beijing Economic-Technological Development Area, Beijing, China

DIA International Sub-Forum Co-Chairs

Wei ZHANG
President of China Society for Drug Regulation
Former Director-General of Drug Registration at the NMPA
Former Secretary-General of Chinese Pharmacopoeia Commission

Zili LI
Special Advisor to CEO, Federal Agency for Medicines and Health Products, Belgium;
Board Member of DIA and US FDA Alumni Association

At the invitation of the Beijing Government and the Organizing Committee of the 2024 International Biomedical Industry Innovation Conference Beijing Forum, DIA China will host a two-day special sub-forum on October 24th and 25th, 2024, in Beijing, China. This forum will focus on drug innovation and global collaboration, providing a platform for participants to exchange perspectives on leveraging China's innovation for the advancement of global healthcare.

Highlights

Session I: Global Regulatory Session and Cell and Gene Therapy Session
This session comprises two sub-sessions: (1) policy presentations by heads of regulatory agencies from Belgium, Brazil, Saudi Arabia, and China, and (2) regulatory challenges and opportunities in the development of cell and gene therapy products, featuring insights from the U.S. FDA, PMDA, and NMPA.

Session 2: Meet with Expert Session
This session offers a personalized, interactive platform where participants can engage directly with a world-renowned regulatory expert and a panel of specialists. The discussion will focus on the critical topic of not only going global but also being global.

Session 3: Drug Innovation and Globalization
This session will explore strategies for building a robust global ecosystem that fosters drug innovation, with the goal of advancing global health and ensuring equitable access to groundbreaking therapies worldwide.

Session 4: Regulatory Round-*table Luncheon with the Head of Agencies* and DIA Exclusive Night.
Those are by-invitation-only networking and engagement opportunities with regulatory leaders, industry experts and academics.

Target attendees

- Leadership team member of MNC or innovative pharmaceutical companies
- Drug discovery scientists
- Drug regulators
- Regulatory affairs professionals
- Representatives of investors
- Executives from CRO and CDMO

Meeting inquiries: **Runsan Chen**
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Hugues MALONNE
Chief Executive Officer of the Federal Agency for Medicines and Health Products (FAMHP)
Belgium

Marwan FATHALLAH
CEO, DIA Global

Bin XUE
Executive Member of the Council
China Society for Drug Regulation
Director, Committee for International Exchange of China Society for Drug Regulation

Baoshi LAN
Secretary-General of the Chinese Peasants And Workers Democratic Party
Vice Chair, Primary Health Care Foundation of China
Chairman, Beijing Bio-Platform International Logistics Service Platform

Jing HE
Senior Vice President of AstraZeneca, Head of AstraZeneca Global R&D China Center Chair, Advisory Council of China, DIA

Ning LI
Vice President of Cancer Hospital Chinese Academy of Medical Sciences
Vice Chair, Advisory Council of China, DIA

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Head of International Innovation Parks and Innovation Centers, AstraZeneca China

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Director, Drug Clinical Trial Organization, Peking University Third Hospital

Member of the Program Committee

Nina LIU
Senior Director, Business Operation, Galapagos

Member of the Program Committee

Hualong SUN
Chief Strategy Officer
Clinical Service Center Co., Ltd.

Member of the Program Committee

Minmin SUN
Founder, Chairman and Chief Executive Officer, Shanghai EmuFon Biotechnology Co.

Member of the Program Committee

Tongyan WANG
Senior Vice President of DIA Global, Managing Director of China

Member of the Program Committee

Rebecca XU
Head of Commercial Excellence & Strategic Alliances, EMEA Emerging Markets
Johnson & Johnson Middle East FZ-LLC.

Agenda | October 24th

9:00-12:00
Juyuan Hall
5th Floor
Block A

Session I Strengthening International Cooperation to Promote Drug Innovation and Regulatory Modernization

Session Co-chair

Wei ZHANG
President of China Society for Drug Regulation
Former Director-General of Drug Registration at the NMPA
Former Secretary-General of Chinese Pharmacopoeia Commission

Zili LI
Special Advisor to CEO, Federal Agency for Medicines and Health Products, Belgium
Board Member of DIA and US FDA Alumni Association

9:00-9:10	**Opening Remarks**
9:00-9:05	**Marwan FATHALLAH** CEO, DIA Global
9:05-9:10	Opening Remarks by the People's Government of Beijing Municipality

Executive Forum for Heads of Regulatory Authorities

Session Chair

Li HE
Deputy Director General of Department of Science, Technology and International Cooperation, National Medical Products Administration (NMPA)

9:10-9:30	Report I Promoting and Protecting Public Health Through Regulatory Innovation and International Cooperation-Belgium Perspective
	Hugues MALONNE Chief Executive Officer, Federal Agency for Medicines and Health Products (FAMHP), Belgium
9:30-9:50	Report 2 Promoting and Protecting Public Health Through Regulatory Innovation and International Cooperation-Brazil Perspective
	Antonio BARRA TORRES President-Director, Brazilian Health Regulatory Agency (Anvisa), Brazil
9:50-10:10	Report 3 Promoting and Protecting Public Health Through Regulatory Innovation and International Cooperation-Saudi Arabia Perspective
	Adel AL-HARF | Video Vice President for Drug Sector, Food and Drug Administration, Saudi Arabia
10:10-10:30	Report 4 Promoting and Protecting Public Health Through Regulatory Innovation and International Cooperation- China Perspective
	Junning ZHAO Deputy Commissioner, National Medical Products Administration (NMPA)
10:30-11:00	Break

Cell and Gene Therapy Session

Session Chair
Zili LI
Special Advisor to CEO, Federal Agency for Medicines and Health Products, Belgium
Board Member of DIA and US FDA Alumni Association

11:00-11:20 Report 5 The Future of Cell and Gene Therapy - An US FDA Perspective

Peter MARKS | Video
Director, Center for Biologics Review and Research (CBER), U.S. Food and Drug Administration (FDA)

11:20-11:40 Report 6 Regulatory Considerations for Development and Approval of Cell and Gene Therapy Products in Japan

Yoshiaki MARUYAMA
Director of the Office of Cellular and Tissue-based Products at the Pharmaceuticals and Medical Devices Agency (PMDA), Japan

11:40-12:00 Report 7 Challenges and Reflections on the Development and Regulation of Cell and Gene Therapy - A NMPA Perspective

Tao WANG
Deputy Director, Center for Drug Evaluation (CDE), National Medical Products Administration (NMPA)

12:00-12:10 **Closing Remarks**

Wei ZHANG
President of China Society for Drug Regulation
Former Director-General of Drug Registration at the NMPA
Former Secretary-General of Chinese Pharmacopoeia Commission

12:10-14:00 Lunch Juyuan Hall

14:00-16:00
Juhui Hall
2nd Floor, Block B

Session 2 DIA The Insider's Insights (Meet with Expert)

With the changing of geopolitics, many Chinese pharmaceutical companies are increasing or starting to pay more attention to EU countries and markets. For Chinese companies that already have or will have drug exports to EU countries, no regulatory document has had a deeper and greater impact than the EU GMP Annex 1 (revised edition) issued by the EMA two years ago.

The updated EU GMP Annex 1 focuses on asepsis production, contamination control, and quality risk management (QRM). The guidelines of Annex 1 are mandatory for all pharmaceutical companies that produce or distribute sterile drugs in the EU. It requires companies to improve their systems to meet EU GMP standards better.

While the overall response from EU-based companies and industry associations has been positive, there are challenges in implementing the requirements, particularly in terms of the cost and operational challenges of complying with the new standards. Upgrading plant facilities, especially for older factories, will consume significant resources.

Many Chinese companies are relatively new and have advantages in plant design and equipment. However, there are still many areas that need further improvement in terms of interpreting and implementing the new GMP mindset and understanding the quality culture behind it.

In this forum, we are fortunate to have Aurelie Poll, a senior GMP inspector at the Belgian Federal Agency for Medicines and Health Products, as our speaker. She directly participated in the discussions and formulation of EU GMP Annex 1. She will explain not only the standards and requirements but also the background and considerations behind Annex 1. At the same time, she will analyze the challenges confronted by the industry in implementing practices.

We hope that by communicating with international regulatory experts, we can help the industry better understand the regulations and considerations behind it, and support companies in achieving their globalization.

Target audience: GMP quality management and other quality managers in enterprises.

Session Chair
Guiliang CHEN
Director, Shanghai Center for Drug Evaluation and Inspection, Shanghai Municipal Medical Products Administration

Speaker
Aurélie POLL
Senior GMP Inspector, Federal Agency for Medicines and Health Products (FAMHP), Belgium

17:30-18:30
Juyuan Hall
5th Floor
Block A

DIA Night - Networking Reception
(Invite-Only)

Agenda | October 25th

9:00-17:00
Juyuan Hall
5th Floor
Block A

Session 3 Drug Innovation and International Collaboration Session

The session will focus on the global public health impacts of drug innovations in China.

9:00-9:10 Opening Remarks

9:00-9:05 **Session Co-Chairs**

9:05-9:10 **Xiangyu WANG**
Deputy Director General, Center for Food and Drug International Exchange, National Medical Products Administration (NMPA)

9:10-12:00 Sub-session 1

Building Healthy Ecosystem for Drug Innovation

Session Co-Chair
Jing HE
Senior Vice President of AstraZeneca, Head of AstraZeneca Global R&D China Center
Chair, DIA Advisory Committee of China

Shun LU
Director, Center for Clinical Medicine of Lung Cancer, Shanghai Chest Hospital
Shanghai Jiaotong University, China

9:10-9:30 Report I Promoting Global Simultaneous Drug Development through Regulatory Innovation and Reform

Zhimin YANG
Deputy Director, Center for Drug Evaluation (CDE), National Medical Products Administration (NMPA)

9:30-9:50 Report 2 Understanding and Working with ANVISA

Ana CAROLINA MARINO
Head of the International Affairs Office, Brazilian Health Regulatory Agency (Anvisa), Brazil

9:50-10:10 Report 3 Developing the New Generation of Principal Investigator (PI) as the Core of Building Clinical Trial Ecosystems in China

Shun LU
Director, Center for Clinical Medicine of Lung Cancer, Shanghai Chest Hospital, Shanghai Jiaotong University, China

10:10-10:30 Report 4 Economic Considerations for Promoting Pharmaceutical Innovation

Gordon LIU
Dean, Institute for Global Health and Development, Peking University

10:30-11:00 Break

11:00-12:00 Panel Discussion: Building a Healthy Ecosystem for Drug Innovation - Next Steps?

Moderator
Jing HE
Senior Vice President of AstraZeneca, Head of AstraZeneca Global R&D China Center
Chair, DIA Advisory Committee of China

Panelist
Session Speakers and
Baoshi LAN
Chairman, Beijing Bio-Platform International Logistics Service Platform

Sizhen WANG
Co-Founder, Chairman and CEO of Genetron Health

12:00-13:30 Lunch

13:30-17:00
Juyuan Hall
5th Floor
Block A

Sub-session 2

Meeting Global Health - Products Are the Key

Session Co-Chair

Ning LI
Vice President of Cancer Hospital Chinese Academy of Medical Sciences
Vice Chair, Advisory Council of China, DIA

Janet LYU
Senior Advisor, Roche Pharma Product Development China

13:30-13:40	Co-chair Opening Remarks
13:40-14:00	Report 1 The Strength and Uniqueness of Universities in Promoting Drug Innovation – An Insights and Experience from Capital Medical University **Lin MEI** Distinguished Investigator & Director, Chinese Institutes for Medical Research, Beijing Chair Professor, Capital Medical University
14:00-14:20	Report 2 Meeting Global Health - Products Are the Key **Weiwu HE** Founder, Chairman and CEO, CASI Pharmaceuticals Inc.
14:20-14:40	Report 3 Partnering with China: A Commitment to Innovation and Global Healthcare Solutions **Thad HUSTON** CFO and COO of Galapagos, Belgium
14:40-15:00	Report 4 The Rise and Challenges of China Pharmaceutical Industry from Global Perspective **Jingyu CAI** Partner, China/HK Pharma & Life Sciences Industry Sector, PwC
15:00-15:20	Break
15:20-16:10	Panel Discussion China Cell and Gene Therapy for Global Health: Next Steps? Moderator **Minmin SUN** Founder, Chairman and Chief Executive Officer, Shanghai EmuFon Biotechnology Co Panelist Session Speakers and **Bing CHEN** Vice President, AstraZeneca International Business Development and Venture Fund Managing Director and Co-founder of AZ-CICC Healthcare Investment Fund **Dongyao NI** Senior Vice President, Global BD Head & General Affairs, AbelZeta Inc. **Helen YANG** Co-founder/Chairperson/CEO, Oricell Therapeutics **Jinhua ZHANG** Founder/ Chairwoman/ CEO, IASO Bio

16:10-17:00 Panel Discussion Drug Innovation: Addressing Unmet Medical Needs Globally

Moderator
Hualong SUN
Chief Strategy Officer, Clinical Service Center Co., Ltd

Panelist
Session Speakers and
Kai CHEN
Executive Director, Digital and Business Innovation,
Head of International Innovation Parks and Innovation Centers, AstraZeneca China

Zhenrong CHEN
Consulting Director, Frost & Sullivan

Yongbin GE
Equity Partner, Zhong Lun Law Firm Shanghai Office

Nina LIU
Senior Director, Business Operation, Galapagos

Xiong ZHANG
General Manager, International Centre of E Healthcare Executive

Xuebo ZHANG
Partner, G&G Capital

12:15-13:15

Session 4 Regulatory Roundtable Luncheon: Engaging Leaders in Dialogue for Future Drug Innovation (Invite-only)

No.2 Meeting Room, 2nd Floor, Block A
Roundtable 1: **Meeting with Hugues MALONNE** (Belgium)
Moderator
Zili LI
Special Advisor to CEO, Federal Agency for Medicines and Health Products, Belgium;
Board Member of DIA and US FDA Alumni Association

Fenghuang Hall, 2nd Floor, Block A
Roundtable 2: **Meeting with Antonio BARRA TORRES** (Brazil)
Moderator
Lu HAN
Senior Director, Central Government Affairs, BeiGene

Speaker Bio

张伟 | Wei ZHANG
中国药品监督管理研究会会长
President of China Society for Drug Regulation
Former Director-General of Drug Registration at the NMPA
Former Secretary-General of Chinese Pharmacopoeia Commission

张伟，中国药品监督管理研究会会长，主任药师。1982年毕业于北京医学院药学系（现北京大学医学部药学院）药物化学专业，获得理学学士学位。2006年获得中欧国际工商学院高级管理人员工商管理硕士（EMBA）学位。

历任北京市药品检验所检验员、化学室副主任、所长助理、副所长、北京市卫生局药政处副处长、北京市药品检验所所长、北京市药品监督管理局副局长、国家食品药品监督管理局药品注册司司长、国家药典委员会秘书长。现任《中国药品标准》主编、《中国新药杂志》副主编。

ZHANG Wei, President of China Society for Drug Regulation, Chief Pharmacist. Mr. ZHANG graduated from the Department of Pharmacy, Beijing Medical College (now the School of Pharmacy, Peking University School of Medicine) in 1982 with a Bachelor of Science degree in Medicinal Chemistry. He obtained an Executive Master of Business Administration (EMBA) degree from the China Europe International Business School (CEIBS) in 2006. He served as a Deputy Director of the Chemistry Department, Deputy Director of the Beijing Institute for Drug Control, Deputy Director of the Drug Administration Department of the Beijing Health Bureau, director of the Beijing Institute for Drug Control, Deputy Director of the Beijing Drug Administration, Director of the Drug Registration Department of the State Food and Drug Administration, and Secretary-General of the Chinese Pharmacopoeia Commission. The Editor-in-Chief of China Drug Standards and Deputy Editor-in-Chief of China Journal of New Drugs.

李自力 医学博士，公共卫生硕士 | Zili LI
比利时药品和健康产品监管管理局局长特别顾问，DIA 和美国FDA同仁会全球董事，DIA全球会士
Special Advisor to CEO, Federal Agency for Medicines and Health Products, Belgium
Board Member of DIA and US FDA Alumni Association, DIA Global Fellow

1979年，考入北京协和医学院，八年制临床医学医学专业学习。1987年毕业后赴美，在美国加州州立大学圣地亚哥公共卫生学院取得流行病学公共卫生硕士。之后，在约翰·霍普金斯大学完成住 院医师的培训，取得美国加州医师执照及美国预防医学专科特考文凭。期间，又获得约翰·霍普金斯大学的公共卫生政策及管理的公共卫生硕士学位。

2000 年 9 月，作为临床审评员正式加入美国FDA。在随后的5 年里，分别在药品安全部及新药审评部任职，参与了新药临床研究方案的审定，新药上市审批，上市药品安全性的再评价及撤市的论证 及决策。在美国 FDA 工作期间八次获奖，特别是因安全评价方面的贡献，获得了 2003 年度美国 FDA 最高科学成就奖。同年，被提升为新药临床审评组负责人。

2005 年 5 月，加入美国默克制药公司（中国国内称“默沙东”），派驻北京及上海，从事药品监管科学政策研究和提供审评能力的培训，并出任默沙东中国医学总监，管理和指导100人的医学及注册团队。2010 年 6 月返美，出任全球新兴市场药品注册战略策划部执行总监，负责除美国、欧 盟、日本外所有新兴市场药品注册战略策划部。

2013 年 5 月，出任美国比尔及梅琳达·盖茨基金会中国办公室副主任。再次回到北京，负责推动中国企业疫苗和仿制药产品 WHO 预认证的战略规划和支持中国药监部门加入 PIC/s 的战略探索。同时，积极推动了中国药监部门和盖茨基金会战略合作框架的建立，为以后的战略人才的引进奠定了基础。

2016 年 1月，重返美国 FDA，出任 FDA 仿制药部副主任，负责仿制药的国际合作。期间，直接推动 了仿制药标准在 ICH 框架下的国际协调机制。2017年5月，做为美国 FDA 代表团的核心成员，直接参与了就中国药监部门加入 ICH 在北京进行的中美磋商。对中国加入ICH起到了重要作用。

2019 年 6 月，出任美国强生集团杨森制药全球药物研发副总裁，常驻北京，负责亚太地区药物研发整体战略的制定和实施及 1200 人的研发团队的管理。2023 年 8 月退休。

为了支持新兴市场药品监督机构科学审评能力的提高和体系的现代化，同FDA 的一些前同事合作，于 2008年成立了美国FDA同仁会国际部，并在2008–13年期间担任联席主席，做了大量的宣传、推动和培训工作。为此，于2013和2014年，分别获得中国国家食品药品管理总局药品审评中心颁发的监管科学特别贡献奖和美国FDA颁发的FDA同仁会特别贡献奖。

Zili LI MD, MPH, is currently the special advisor Special Advisor to CEO, Federal Agency for Medicines and Health Products, Belgium; Board Member of DIA and US FDA Alumni Association and DIA Global Fellow.

Zili has more than 20 years of combined US FDA and industry experience in drug development and regulation. He was a Clinical Reviewer/Clinical Team Leader at the FDA's Office of New Drugs (2000-05) and Associate Director for Global Affairs at the FDA's Office of Generic Drugs (2016-19). Zili also served a variety of global, regional and county-based roles at Merck & Co., including Medical Director/Head of China R&D, Head of Asia Pacific Regulatory Policy, and Executive Director/Head of Emerging Markets Regulatory Strategy (2005-13) and worked as Head of China R&D at Bill & Melinda Gates Foundation (2013-16). He was the global VP and head of AP R&D at Johnson &Johnson innovative medicine from 2019-2023.

Zili was a frequent speaker at China National Medical Product Agency (NMPA) leadership retreats and conducted many educational activities that would advance regulatory science and sound regulatory decision-making at China NMPA. He is the only person to receive special recognition awards from both the Director of the Center of Drug Evaluation, China NMPA and the Commissioner of US FDA in 2013 and 2014, respectively. He was also recognized by the Sr. Leadership of both China NMPA and US FDA for his unique contribution to China NMPA's membership at ICH in 2017.

Zili, a graduate of Peking Union Medical College, completed his medical residency training at the Johns Hopkins. Zili also holds a master's degree in public health from the Johns Hopkins University School of Public Health.

Speaker Bio

Marwan FATHALLAH
DIA全球首席执行官
CEO, DIA Global

Marwan FATHALLAH先生是具有变革精神和战略发展的领导者。他曾担任过Ortho Clinical Diagnostics公司的运营官和执行副总裁。他在生命科学、制药、医疗器械、诊断行业的运营、供应链、制造、研发、质量和监管、临床、医疗事务和商业执行等领域拥有30年丰富的国际经验。他拥有威斯康星大学麦迪逊分校机械工程硕士学位和西北大学凯洛格管理学院工商管理硕士学位。他曾担任威斯康星大学麦迪逊分校生物医学工程系的董事会成员，拥有超过25项药物输送和医疗产品的专利。

Prior to joining DIA in 2023, FATHALLAH was the Operating Officer and EVP at Ortho Clinical Diagnostics, accountable for Operations, Post Market Product Science and Engineering, Regulatory, Quality, Medical, Clinical, Scientific Affairs, and Process Excellence. Before joining Ortho, he held Executive and Senior Leadership roles in Research and Development, Operations, and Regulatory Medical and Clinical Affairs at Avantor, Danaher, Pfizer, Hospira, and Abbott Laboratories. Fathallah holds a Master's and Bachelor of Science degrees in Mechanical Engineering from the Univ. of Wisconsin-Madison and an MBA from the Kellogg School of Management at Northwestern University.

马玉戈 药学博士 | Hugues MALONNE
比利时联邦药品和保健产品管理局局长
Chief Executive Officer of the Federal Agency for Medicines and Health Products (FAMHP),Belgium

马玉戈先生在比利时布鲁塞尔大学（ULB）获得药剂师学位、药学博士学位和医院及卫生机构管理行政硕士学位。这也是他以教授身份开始其学术生涯的地方. 在作为全球跨国制药公司高管，在意大利、中国、卢森堡、瑞士，取得了成功的国际职业 生涯之后，他回到了比利时。马玉戈先生凭借其在市场准入、公私机构伙伴关系、公共政 策和政府事务方面的专业知识，于 2017 年加入联邦药品和保健产品管理局（FAMHP），并先后担任上市后管理司和上市前管理司的司长。在他的整个职业生涯中，他一直与学术界保持着密切的联系，并继续在布鲁塞尔大学和比利时那慕尔大学任教。

自 2023 年 9 月 1 日起，他被任命为联邦药品和保健产品管理局首席执行官（局长）。他满怀信心和热情地担任这一职务，坚信他将继续带领所有员工，为公众提供优质服务，并保持联邦药品和保健产品管理局作为公共卫生守护者的角色。

马玉戈对解决全球范围内的药物短缺问题和探索创新疗法（如先进治疗药品（ATMP）和 疫苗）有着浓厚的兴趣。他致力于寻找解决方案，以确保基本药物的可用性，并促进尖端 疗法的开发和可及性，以改善公共卫生。

Hugues MALONNE holds a degree in Pharmacist, a Doctor of Pharmacy and an Executive master's degree in healthcare Facility Management from the University of Brussels (ULB). This is also where he began his academic career as a professor before entering the profession.

After a successful international career as an executive in pharmaceutical companies (Italy, China, Luxembourg, Switzerland), he returned to Belgium. With her expertise in market access, public-private partnerships, public policy and government affairs, Hugues MALONNE joined the Federal Agency for Medicines and Health Products (FAMHP) as Director General in 2017 and led the POST and PRE-Authorization Divisions. Throughout his career, he has maintained close ties with academia and continues to teach at ULB and UNamur.

As of September 1, 2023, he serves as the new CEO of FAMHP. He takes on this role with confidence and enthusiasm and is confident that he will continue to work with all staff to ensure quality service for all and maintain FAMHP's role as a guardian of public health.

Hugues MALONNE has a keen interest in addressing drug shortages around the world and exploring innovative therapies such as advanced therapeutics (ATMPs) and vaccines. He is committed to finding solutions to ensure the availability of essential medicines and to promote the development and accessibility of cutting-edge therapies to improve public health.

Speaker Bio

Antonio BARRA TORRES 医学博士
巴西国家卫生监督局(ANVISA)局长
President-Director of Brazil's National Health Regulatory Agency (ANVISA)

安东尼奥·巴拉·托雷斯（Antonio Barra Torres）是巴西国家卫生监督局（ANVISA）总裁兼主任（局长）。

Antonio 1986年毕业于医学专业，在里约热内卢的Marc í lio Dias海军医院（HNMD）完成血管和内血管外科的住院医师培训。2012年，在里约热内卢联邦大学获得卫生服务管理MBA学位。

Antonio 1987年加入巴西海军，担任医疗官员。2015年，晋升为海军中将，这是医务兵团中的第二高级别。2019年2月，从海军退役。2019年7月，被巴西参议院批准担任ANVISA主任。2020年10月，被确认为ANVISA总裁兼主任。2023年3月，被任命为国际药品监管机构联盟（ICMRA）的第二副主席。

在他的领导下，ANVISA监管的产品约占巴西国内生产总值的23%。ANVISA积极参与国际监管合作，参与ICH和PIC/S等论坛，为ANVISA成为全球卫生监管参考机构方面发挥了关键作用。参与各种医疗保健倡议和交流。

Antonio的职业生涯体现了他在医疗、管理和国际合作方面的深厚背景，以及他在推动巴西及全球卫生监管发展方面的领导作用。

Antonio BARRA TORRES is the President-Director of the Brazilian Health Regulatory Agency (ANVISA). He graduated in Medicine from Foundation Souza Marques in 1986 and completed his residency in Vascular and Endovascular surgery at Marcílio Dias Naval Hospital (HNMD) in Rio de Janeiro. He also holds an MBA in Health Services Administration from the Federal University of Rio de Janeiro, which he obtained in 2012.

In 1987, Barra Torres joined the Brazilian Navy as a medical officer and was promoted to the rank of Rear Admiral in 2015, the second highest rank in the Medical Corps. He retired from the Navy in February 2019 and was approved by the Brazilian Senate to the position of ANVISA's Director in July of the same year. He was later confirmed as President-Director in October 2020. In March 2023, he was appointed as ICMRA's second vice-chair.

During his tenure, Barra Torres has been involved in the regulation of products that constitute approximately 23% of Brazil's GDP. He has emphasized the need to expand ANVISA 's staff through public tenders to meet the growing demand for services and to serve the medical and scientific community, particularly in the release of research supplies and clinic and drug approvals.

Barra Torres has also been active in international regulatory cooperation, participating in forums like ICH and PIC/S, which has helped ANVISA become familiar with best practices and increase its trust in other regulatory organizations. He has played a key role in positioning ANVISA as a global reference agency in health regulation.

In addition to his role at ANVISA, Barra Torres has been involved in various healthcare initiatives and exchanges, including a visit to the Hamlyn Centre at Imperial College London, where he discussed healthcare innovations and potential partnerships for the exchange of ideas.

Speaker Bio

Adel AL-HARF 医学博士
沙特阿拉伯食品和药品管理局副局长
Vice President for Drug Sector of the Food and Drug Administration of Saudi Arabia

Adel AL–HARF博士自2018年2月起担任沙特食品药品监督管理局（Saudi Food and Drug Authority，简称SFDA）药品部门的副总裁。他负责药品部门的战略和战术监督工作，包括药品许可、产品评估、药物警戒、药品供应以及化妆品安全等。Al–Harf博士于2004年加入SFDA，并参与了该部门大多数部门和法规的建立。

AL–HARF博士还担任沙特知识产权局执行委员会的董事会成员和主席，国家补充和替代医学中心指导委员会成员，以及沙特患者安全中心战略委员会成员。他相信，在2030愿景下政府的大力支持将使沙特成为全球制药行业的主要中心之一。

在此之前，AL–HARF博士曾于2014年11月至2018年2月担任SFDA药物警戒和效益/风险评估总监，以及2013年4月至2014年11月担任国家药物警戒和药品安全中心主任。2019年，Al–Harf博士被提名为国际人用药品注册技术要求协调会（ICH）的药品监管机构代表。

AL–HARF博士还是多个咨询委员会的成员，包括沙特卫生委员会、药学学院（国王沙特大学）、药学学院（阿卜杜勒阿齐兹国王大学）、药学学院（焦夫大学）、科学学院（沙特王子萨塔姆大学）和药学学院（塔巴克大学）。

AL–HARF博士在伦敦国王学院获得了药理学硕士学位，在格拉斯哥大学获得了医学和治疗学博士学位，并在沙特国王大学获得了药学科学学士学位。此外，他还在哈佛商学院、宾夕法尼亚大学、牛津大学和加州大学伯克利分校完成了多个高管教育课程，并从特许管理学院获得了领导力和管理证书。

AL–HARF博士在沙特食品药品监督管理局的工作中，还参与了多项研究和出版物，包括临床试验的GCP检查、COVID–19大流行期间的临床试验结果措施、生物等效性研究、沙特阿拉伯国家药物政策的发展、药物使用情况的描述性研究以及家庭药物安全存储的评估。

此外，AL–HARF博士还参与了沙特药物警戒计划的挑战和经验教训的回顾，该计划对于公共卫生至关重要，通过采用健全的药物不良反应自发报告系统来对抗大多数由于使用药品而产生的危害。

Dr. Adel AL-HARF is a prominent figure in the pharmaceutical sector of Saudi Arabia, serving as the Vice President for the drug sector at the Saudi Food and Drug Authority (SFDA) since February 2018. In this capacity, he oversees strategic and tactical aspects of the drug sector, including licensing of medicines, product evaluations, pharmacovigilance, drug availability, and cosmetic safety.

AL-HARF has been with the SFDA since 2004 and was instrumental in establishing many of the department's regulations and divisions. He is also a board member and head of the executive committee of the Saudi Authority for Intellectual Property, a member of the steering committee of the National Center for Complementary and Alternative Medicines, and a member of the strategic committee of the Saudi Patient Safety Center. His vision aligns with Saudi Arabia's Vision 2030, which aims to position the country as a leading global hub for the pharmaceutical industry.

Before his current role, AL-HARF was the Executive Director of the Vigilance and Benefit/Risk Assessment Directorate at SFDA from November 2014 to February 2018. He also served as the director of the National Pharmacovigilance and Drug Safety Center from April 2013 to November 2014. In 2019, he was nominated as the drug authority's representative at the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.

In terms of education, Dr. AL-HARF holds a master's degree in pharmacology from King's College London and a PhD in medicine and therapeutics from the University of Glasgow. He also has a bachelor's degree in pharmaceutical sciences from King Saud University. Additionally, he has completed several executive education programs at prestigious institutions such as Harvard Business School, the University of Pennsylvania, Oxford University, and the University of California, Berkeley. He holds a certificate in leadership and management from the Chartered Management Institute.

Dr. AL-HARF's contributions extend to research and publications, with a focus on areas such as clinical trials, pharmacovigilance, bioequivalence studies, national medicine policies, and medication usage patterns. His work aims to enhance drug safety and efficacy while promoting the rational use of medicines.

Peter MARKS 医学博士
美国食品药品监督管理局(FDA)生物制品审评与研究中心(CBER)主任
Director, Center for Biologics Review and Research (CBER), U.S. Food and Drug Administration (FDA)

Peter MARKS博士是美国FDA生物制品评价与研究中心（CBER）主任。该中心负责确保生物产品的安全性和有效性，包括疫苗、过敏产品、血液和血液产品以及细胞、组织和基因治疗。

MARKS博士和中心工作人员致力于促进生物产品的开发，并在整个产品生命周期内给予监督，包括：在产品开发过程中检查并提供建议，根据安全性和有效性数据评估申请并做出批准决定，监测生物制品的安全性，进行支持产品开发和特性描述的研究。

Peter MARKS博士在纽约大学获得细胞和分子生物学研究生学位和医学学位。在此之后，他成为波士顿布里格姆妇女医院(Brigham and Women's Hospital) 的内科住院医师并在此完成了血液学/医学肿瘤学研究。随后他成为主治医师，并最终担任血液学临床主任。

随后，他在制药行业工作了数年，从事血液学和肿瘤学产品的临床开发。在此之后他回到耶鲁大学医学部，担任Smilow癌症医院的首席临床官领导，领导成人白血病的服务项目，MARKS博士于2012年加入FDA，担任CBER中心副主任，并于2016年成为中心主任。MARKS博士是认证的内科、血液学专家，同时也是美国医师学会的会员。

Peter MARKS received his graduate degree in cell and molecular biology and his medical degree at New York University and completed Internal Medicine residency and Hematology/Medical Oncology training at Brigham and Women's Hospital in Boston. He has worked in academic settings teaching and caring for patients and in industry on drug development. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in January 2016. He is a Fellow of the American College of Physicians and in 2022 he was elected to the National Academy of Medicine.

Speaker Bio

丸山良亮 医学博士 | Yoshiaki MARUYAMA
日本独立行政法人医药品医疗器械综合机构(PMDA)细胞和组织产品办公室主任
Director of the Office of Cellular and Tissue-based Products at the Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Yoshiaki MARUYAMA目前是日本独立行政法人医药品医疗器械综合机构（PMDA）细胞和组织产品办公室主任。2008年，他加入PMDA，担任合规与标准办公室以及日本药典秘书处的官员，直到2012年。他以厚生劳动省（MHLW）和PMDA课题负责人的身份参与了制定ICH指导原则和附录（Q4B）。在加入PMDA之前，Yoshiaki于2001年至2005年在加拿大卡尔加里大学担任研究员，并于2005年至2008年在日本东京国家神经病学和精神病学中心（NCNP）担任研究员。

Yoshiaki MARUYAMA is currently the Review Director at the Office of Cellular and Tissue-based Products at the Pharmaceuticals and Medical Devices Agency (PMDA), Japan. In 2008, he joined PMDA as an officer in the Office of Compliance and Standards where he was also a secretariat for the Japanese Pharmacopoeia till 2012. He participated as Ministry of Health, Labour and Welfare (MHLW) and the PMDA topic leader for the development of ICH guidelines and Annexes on Evaluation and Recommendation of Pharmacopoeia Texts for use in the ICH Regions (Q4B). Prior to joining PMDA, Yoshiaki was a research fellow at the University of Calgary, Canada from 2001 till 2005 and National Center of Neurology and Psychiatry (NCNP) Tokyo, Japan from 2005 till 2008.

陈桂良 博士 | Guiliang CHEN
主任药师、博士生导师、二级教授
上海药品审评核查中心主任
Director, Shanghai Center for Drug Evaluation and Inspection, Shanghai Municipal Medical Products Administration

陈桂良博士长期从事药品监管科学研究，拥有丰富的药物分析和吸入制剂研发经验。他曾获得上海市科学技术进步奖。陈桂良主任在推动药品监管科学发展和提升药品标准质量方面发挥了重要作用。

Dr. CHEN has been engaged in scientific research on drug regulation for a long time, and has rich experience in drug analysis and inhalation preparation research and development. He has won the Shanghai Science and Technology Progress Award. Dr. Chen has played an important role in promoting the scientific development of drug regulation and improving the quality of drug standards.

王涛 医学博士 | Tao WANG
中国国家药品监督管理局药品审评中心副主任
Deputy Director, Center for Drug Evaluation of the National Medical Products Administration (NMPA)

王涛，医学博士，科研博士后，现任国家药监局药品审评中心副主任，享受国务院政府特殊津贴，曾获中共中央、国务院、中央军委“全国抗击新冠肺炎疫情优秀个人”、“军队科技成果二等奖”等多项荣誉。

他主要负责化学药品和生物制品等的审评工作，在药品审评制度改革和药品监管科学学科体系建设中发挥了关键作用。他领导指南的起草、定稿和质量保证，在重大疾病领域、罕见病用药政策、儿科用药等监管科学研究项目中发挥领导作用。他以第一作者或通讯作者的身份发表了60多篇文章，并翻译了《临床试验设计和实施管理指南》。

Tao Wang, a Doctor of Medicine and research follow, now serving as Deputy Director of Center for Drug Evaluation, NMPA, enjoys a special government allowance from the State Council, and has been granted multiple awards, such as Outstanding Individual in the National Fight Against COVID-19 by the CPC Central Committee, the State Council and the Central Military Commission, the Second Prize for Military Scientific and Technological Achievements, etc.

He primarily oversees the review of chemical drugs and biological products, etc., playing a key role in the reform of the drug evaluation system and the development of a scientific discipline system for drug regulation. He leads the drafting, finalization, and quality assurance of guidelines, embodying a leadership role in regulatory science research projects focused on major disease areas, medication policies for rare diseases, pediatric medication, etc. He has published over sixty articles as either the first or corresponding author and has translated the work A Manager's Guide to the Design and Conduct of Clinical Trials.

Speaker Bio

Aurélie POLL
比利时联邦药品和保健产品管理局资深GMP检查员
Senior GMP Inspector, Federal Agency for Medicines and Health Products (FAMHP), Belgium

Aurélie POLL 博士是比利时联邦药品与健康产品管理局（FAMHP）的一位资深高级GMP检查员，该机构是比利时的药品和健康产品监管机构。自2007年加入FAMHP以来，Aurélie在确保GMP合规性方面发挥了关键作用。

Aurélie 拥有超过20年的职业经验，曾在全球范围内开展了众多GMP检查，特别专注于生物活性物质、疫苗和先进治疗药物（ATMP）的检查。她在生物制品和ATMP领域的专业知识使她成为监管领域的知名人物，尤其是在高复杂性产品的质量标准评估和执法方面。

Aurélie 负责协调FAMHP内部新版EU GMP附录1的实施工作，与同事密切合作，确保该法规框架成功整合到机构的监管体系中。这项工作体现了她在无菌生产和污染控制方面保持最高标准的承诺。

Aurélie 拥有比利时布鲁塞尔天主教鲁汶大学（UCL）的药学学位和生物医学科学博士学位。她的学术和职业背景结合了深厚的科学知识与丰富的监管经验，使她在制药领域拥有独特的视角。

Aurélie Poll is a highly experienced Senior GMP Inspector at the Federal Agency for Medicines and Health Products (FAMHP), Belgium's regulatory authority for pharmaceuticals and healthcare products. Since joining FAMHP in 2007, Aurélie has played a pivotal role in ensuring compliance with Good Manufacturing Practices (GMP) across a wide range of pharmaceutical sectors.

With a career spanning over 20 years, Aurélie has conducted numerous GMP inspections globally, specializing in biologic active substances, medicinal products, vaccines, and advanced therapy medicinal products (ATMPs). Her expertise in biologics and ATMPs has made her a respected figure in the regulatory community, particularly in the evaluation and enforcement of quality standards for high-complexity products.

In her leadership role, Aurélie coordinates the implementation of the revised EU GMP Annex 1 at FAMHP, collaborating closely with colleagues to ensure its successful integration into the agency's regulatory framework. This work reflects her commitment to maintaining the highest standards in sterile manufacturing and contamination control.

Aurélie holds a degree in Pharmacy and a PhD in Biomedical Sciences from the Catholic University of Louvain (UCL) in Brussels, Belgium. Her academic and professional background provides her with a unique perspective, combining in-depth scientific knowledge with extensive regulatory experience in the pharmaceutical field.

Jonathan MALCORPS
比利时联邦药品和保健产品管理局药品短缺协调员
Coordinator for International Strategy on Shortages and Security of Supply at the Federal Agency for Medicines and Health Products (FAMHP), Belgium

Jonathan MALCORPS是比利时联邦药品和保健产品管理局（FAMHP）负责药品短缺与供应安全国际战略的协调员。在该职位上，他在建立国际合作伙伴关系以应对关键药品短缺问题方面发挥了关键作用，尤其关注供应链安全。

Jonathan在欧洲卫生政策方面有着丰富的经验，他曾在比利时担任欧盟理事会轮值主席期间，积极参与欧盟药品立法的高层谈判。此外，他还在组织重要活动方面发挥了重要作用，如药品管理机构负责人会议和以健康相关需求为推动力的卫生政策与创新高层会议。

在目前的职位之前，Jonathan曾在Acumen PA担任公共事务顾问，专注于欧盟卫生政策和宣传活动，特别是在罕见病、基因疗法和先进治疗药物（ATMP）领域。他的学术背景包括医学学士学位和欧洲卫生经济与管理硕士学位，这进一步增强了他在国际关系和卫生政策方面的专业知识。

Jonathan MALCORPS is the Coordinator for International Strategy on Shortages and Security of Supply at the Federal Agency for Medicines and Health Products (FAMHP) in Belgium. In this role, he plays a pivotal part in developing international partnerships to address critical medicine shortages, with a particular focus on supply chain security.

Jonathan has extensive experience in European health policy, having been actively involved in high-level negotiations on the EU's pharmaceutical legislation during Belgium's Presidency of the Council of the EU. He has also been instrumental in organizing key events such as the Heads of Medicines Agencies meetings and the High-Level Conference on Health-related Needs as Drivers for Healthcare Policy and Innovation.

Before his current role, Jonathan worked as a Public Affairs Consultant at Acumen PA, where he specialized in EU health policy and advocacy campaigns, particularly in the fields of rare diseases, gene therapies, and Advanced Therapy Medicinal Products (ATMPs). His academic background includes a Bachelor's degree in Medicine and a European Master's in Health Economics and Management, further complementing his expertise in international relations and healthcare policy.

Speaker Bio

何静 医学博士 | Jing HE
阿斯利康全球高级副总裁兼全球研发中国负责人, DIA中国顾问委员会主席
Senior Vice President of AstraZeneca, Head of AstraZeneca Global R&D China Center
Chair, Advisory Council of China, DIA

何静博士于2020年4月加入阿斯利康，担任阿斯利康全球肿瘤研发高级副总裁（SVP）、全球研发中国中心总裁，全面负责肿瘤、呼吸及免疫、心血管、肾脏及代谢、罕见病等领域产品管线在中国的研发工作。

何静博士是一名专业的医学肿瘤学家，拥有西安医科大学临床医学学士学位、肿瘤学硕士学位、中国医学科学院肿瘤医院临床肿瘤学博士学位，在肿瘤领域拥有8年临床实践经验。加入阿斯利康之前，何静博士曾在罗氏工作了14年，并在中国和美国基因泰克带领肿瘤开发团队担任过多个职位。

Jing He is a trained Medical Oncologist. She has had her M.D. in Xi'an Jiaotong University and then Ph.D. in Cancer Hospital of Chinese Academy of Medical Science.

Jing Joined Roche China in 2006 after 8 years of clinical practice. Jing has increased responsibilities in Roche in both Medical Affairs and Development. She has led Roche oncology development in China, leading to important approvals including Avastin, Herceptin, Perjeta in China. She moved to South San Francisco to take Global Development Lead role in Genentech in early 2015, where she led a cross functional team, responsible for the creation and implementation of global development plan for a few oncology products. Jing has been appointed as Site Head for Roche Product Development and moved back to China in 2018.

Jing joined AZ in April 2020 and now serves as the SVP for AZ R&D China. Under her leadership, the AZ R&D China pipeline has increased significantly with more than 80% projects being in simultaneous global development.

陆舜 教授 | Shun LU
上海市肺部肿瘤临床医学中心主任
Director, Center for Clinical Medicine of Lung Cancer, Shanghai Chest Hospital, Shanghai Jiaotong University, China

主任医师，博士生导师，二级教授，国家卫生健康突出贡献中青年专家，上海市领军人才，上海市优秀学术带头人，国家重点专项首席专家，享受国务院特殊津贴

上海交通大学医学院学术委员会委员

中国抗癌协会理事，肺癌专业委员会前任主任委员

中国临床肿瘤学会（CSCO）常务理事，希斯科基金会副理事长

前DIA中国顾问委员会主席

上海市医学会肿瘤学会前任主任委员

中华医学会肿瘤学会常委，肺癌专家委员会主任委员

上海市医师协会肿瘤科分会副会长，专科规培组长

国际肺癌研究会（IASLC）出版委员会委员

美国临床肿瘤协会（ASCO)中国区代表

国际肺癌研究会官方杂志Journal of Thoracic Oncology，Lung Cancer副主编，The Oncologist杂志编委

上海市抗癌协会常务理事

中国医药生物技术协会精准医疗分会副主任委员

作为负责人主持科技部国家慢病重点专项，国际合作课题；国家新药创新重大专项，863重大课题子课题2项；国家自然基金重点项目和面上项目

中国抗癌协会科技奖一等奖；上海市医学科技奖一等奖；华夏医学科技奖二等奖；上海市科技进步一等奖；上海交通大学校长奖; 2018年获得仁心医者・上海市杰出专科医师提名奖，2021获“药明康德生命化学研究奖”

Dr. LU is a Member of the Academic Committee of Shanghai Jiaotong University School of Medicine.

Dr. LU serves as the Council Member of Chinese Anti-Cancer Association; Council Executive Member of Chinese Society of Clinical Oncology (CSCO).

Dr. LU serves on the International Affairs Committee of the American Society of Clinical Oncology (ASCO), and Multidisciplinary Cancer Management Courses Working Group. He is also a member of the State Food and Drug Administration Expert Panel, Commissioner of the Oncology Society Chinese Medical Association, Selected Director of the Chinese Lung Cancer Study Association, and Standing Director & Deputy Secretary of the Chinese Society of Clinical Oncology.

Dr. LU is a member of the International Association for the Study of Lung Cancer, Associate Editor of the Journal of Thoracic Oncology, and serves on the editorial board of The Oncologist.

Speaker Bio

王翔宇 博士 | Xiangyu WANG
中国国家药品监督管理局中国食品药品国际交流中心副主任
Deputy Director General, Center for Food and Drug International Exchange, National Medical Products Administration (NMPA)

王翔宇博士拥有23年中国食品药品监管体系工作经验，对食品药品监管事务有着广泛的了解，曾于2001年、2004年、2006年、2008年、2010年、2014年和2022年在中国参与NRA评估，并与世卫组织、联合国工发组织、盖茨基金会等合作，有20年的项目管理经验。代表中国药品监督管理局积极参与国际人用药品统一理事会（ICH）、世界卫生组织（WHO）药品认证计划（COPP）、药品检验合作计划（PIC/S）等工作。

毕业于中国北京外国语大学，获英国文学和国际法学士学位。2010.09–2011.09在德国慕尼黑知识产权法中心学习，获知识产权法法学硕士学位。2022年，他获得了中国北京大学法学博士学位。

Dr. Xiangyu WANG has 23 Years' working experience in the Food and Drug Regulatory System in China, wide range of knowledge on the regulatory affairs on food and drug, taking part in the NRA assessment in 2001, 2004, 2006, 2008, 2010, 2014 and 2022 in China and 20 years' experience on program management by cooperating with WHO, UNIDO, Gates Foundation, etc. On behalf of Chinese Drug Regulatory Agency, Dr. Wang takes an active participation in International Council on Harmonization of Human used Medicines (ICH), the Certificate of Pharmaceutical Products Program of WHO (COPP), Pharmaceutical Inspection Cooperation Scheme (PIC/S), etc.

Xiangyu owns bachelor's degree on English Literature and International Law from Beijing Foreign Studies University, China. During 2010.09-2011.09, he studied in Munich Intellectual Property Law Center, Germany and obtained LLM on Intellectual Property Law. He also obtained the PhD degree on Law in Peking University, China in 2022.

杨志敏 | Zhimin YANG
中国国家药品监督管理局药品审评中心副主任

Deputy Director, Center for Drug Evaluation of the National Medical Products Administration (NMPA)

杨志敏现任国家药品监督管理局药品审评中心副主任。毕业于北京大学医学中心临床医学专业。她曾在北京大学人民医院工作，是一名著名的儿科医生。

2001年进入药物审评中心担任临床审评员，有20年临床审评经验。她在澳大利亚和美国接受过药物开发和评估方面的培训。她领导了新药开发技术指南的开发，是ICH E11a和E6R3专家组的成员。

Ms. YANG is currently the Deputy Director-General, Center for Drug Evaluation of the National Medical Products Administration. She graduated from Peking University Medical Center, majoring in clinical medicine. She is used to be a known pediatrician working at Peking University People's Hospital.

In 2001, her entered Center for Drug Evaluation as a clinical reviewer and has 20 years of clinical evaluation experience. She is trained in drug development and evaluation in Australia and the United States. Ms. YANG led the development of technical guidelines for new drug development and was a member of the ICH E11a and E6R3 expert group.

Ana CAROLINA MARINO
巴西国家卫生监督局国际事务负责人
Head of International Affairs Office, Brazil's National Health Regulatory Agency (ANVISA)

Ana CAROLINA MARINO是巴西国家卫生监督局 (ANVISA) 国际事务办公室负责人。自2007年3月起在ANVISA任职，是巴西健康法规专家，具有技术和管理方面的经验：第四理事会/ANVISA顾问；核查及执法部门主管；医疗仪器核查及执法部经理；药品审批变更办公室经理。2002年获得Brasília大学学位，2009年获得Fiocruz卫生法规和监测研究生资格，2012年获得弗鲁米嫩塞联邦大学制药技术研究生资格。在ICH，PICs，IMDRF和MDSAP中代表ANVISA。

Ana CAROLINA MARINO is Head of the International Affairs Office at ANVISA. Holds a permanent position at ANVISA as government employee, Health Regulatory Expert, since March 2007. Has experience in both technical and management roles: Advisor at the Fourth Directorate/ANVISA; Head for Inspectorate and Law enforcement department; Manager for the Medical Device Inspectorate and Law Enforcement Department; Manager for the Drugs Post Approval Changes Office. Pharmacist with a degree from the University of Brasília (2002), and postgraduate qualifications in Health Regulation and Surveillance (2009) from Fiocruz and Pharmaceutical Technology (2012) from the Federal University Fluminense. Represented ANVISA in ICH, PICs, IMDRF and MDSAP.

Speaker Bio

刘国恩 教授，博士生导师 | Gordon LIU
北京大学全球健康发展研究院院长
Dean, Institute for Global Health and Development, Peking University

刘国恩，经济学博士，教育部经济学长江学者特聘教授、北京大学国家发展研究院博雅特聘教授、北京大学全球健康发展研究院院长；北京大学中国卫生经济研究中心主任，北京大学教育经济研究所学术委员会主任，中国医学科学院学部委员。《中美健康二轨对话》中方召集人；国务院医改专家咨询委员会委员；中国药物经济学专业委员会荣誉主任委员。国际健康经济学SCI一流期刊《Health Economics》副主编（2014 – ），《Value in Health》副主编（2001–2012），《中国药物经济学》期刊主编。刘国恩教授曾执教美国南加州大学、北卡大学教堂山分校、北大光华管理学院。他曾担任中国留美经济学会（CES）2004–2005届主席、国际药物经济学会（ISPOR）亚太联合会2004–2006届主席。

目前主要在研课题：1）基于四川大凉山的健康脱贫实验经济学（国家自科基金重点项目）；2）医学机器人卫生经济技术评估（全球健康发展基金课题）；3）同一健康地图册（One Health Atlas）开发项目。

Gordon G. Liu is Peking University BOYA Distinguished Professor of Economics at PKU National School of Development, Dean of PKU Institute for Global Health and Development, Director of PKU China Center for Health Economic Research, Academic Committee Chair for PKU Institute of Educational Economics, and an elected fellow of the Chinese Academy of Medicine. For social responsibilities, Prof. Liu is the co-organizer for the "US-China Track II Dialogue on Health", and served on the China National Expert Panel on COVID19, and the State Council Health Reform Advisory Commission. He has served as associate editor for academic journals including China Economic Quarterly, Health Economics, and the Editor-in-Chief for China Journal of Pharmaceutical Economics. Prior to joining Peking University, he was on fulltime faculty at University of Southern California, and University of North Carolina at Chapel Hill. He was the 2004-2005 President of Chinese Economists Society (CES), and the 2004-2006 President of ISPOR Asian Pacific Consortion.

兰宝石 | Baoshi LAN
北京大学光华管理学院95级MBA。二十年风险投资行业经历，主要投资干细胞、细胞治疗、诊断试剂等生命科技领域。现任农工党中央健康中国建设工作委员会秘书长,，中国初级卫生保健基金会副理事长，中关村国际生物试剂物流中心董事长
Secretary-General of the Chinese Peasants And Workers Democratic Party
Vice Chair, Primary Health Care Foundation of China
Chairman, Beijing Bio-Platform International Logistics Service Platform

LAN Baoshi, MBA 95, Guanghua School of Management, Peking University. 20 years of experience in venture capital industry, mainly investing in stem cells, cell therapy, diagnostic reagents and other life technology fields. He is currently the Secretary-General of the Healthy China Construction Working Committee of the Central Committee of the Peasants and Labor Party, the Vice Chairman of China Primary Health Care Foundation, and the Chairman of Zhongguancun International Biological Reagent Logistics Center.

王思振 | Sizhen WANG
泛生子联合创始人、董事长兼首席执行官
Co-founder, Chairman and CEO of Genetron Health

2013年创立泛生子品牌，目前已成为中国肿瘤精准医疗领域先行者，于2020年6月在美国纳斯达克挂牌上市（GTH），达成全球癌症精准医学领域史上最大IPO（按绿鞋前计）。凭借"癌症早筛+癌症诊断与监测+药物研发服务"的业务组合，泛生子已广泛服务于中国的医疗机构、科研机构和国内外药企，参与多项政府民生项目和社会公益项目。2021年，作为项目主要参与者，王思振带领泛生子团队，与四川大学华西医院深度合作"肺癌早期精准诊断关键技术的建立与临床应用"项目，并获得2020年度国家科技进步二等奖。

王思振先生是巴黎高等商学院MBA，中国农工民主党中央第17届健康中国建设工作委员会医药与生物技术分会委员、优秀科技工作者、脱贫攻坚工作先进个人。曾在金融行业顶级企业——美国第一资本投资国际集团、GD Capital任职近10年。

Sizhen co-founded Genetron Health in 2013, which at present has become a leading precision oncology platform company in China. It was listed on Nasdaq (GTH) in June 2020 and became the largest precision oncology IPO in the world at that time. With the service portfolio of "cancer early screening + cancer diagnosis and monitoring + biopharma services", Genetron Health has served the top hospitals and physical examination institutions, dozens of pharmaceutical enterprises and scientific research institutions in China and participated in a number of government livelihood projects and social welfare projects. In 2021, under Sizhen's leadership, Genetron Health's early precision lung cancer diagnosis and treatment project, a joint initiative with the West China Hospital of Sichuan University, won the second prize of China's National Science and Technology Progress Award.

Sizhen graduated from the HEC Paris School of Management with an MBA degree. Sizhen also has ten years of experience working in the finance industry, including at Capital One and GD Capital.

李宁 医学博士，教授，主任医师 | Ning LI
中国医学科学院肿瘤医院副院长，DIA 中国顾问委员会副主席
Vice President of Cancer Hospital Chinese Academy of Medical Sciences
Vice Chair, Advisory Council of China, DIA

1997年就读于中国协和医科大学八年制临床医学专业，2005年获博士学位，2011至2012年赴美国哈佛大学医学院学习。致力于肺癌微创治疗、靶向生物治疗，肿瘤临床科研设计、开展，抗肿瘤新药、新技术临床试验管理和推动。第一、通讯作者在Lancet Oncology、Jama Oncology、Cancer Cell等学术刊物上发表文章数十篇，累计影响因子400余分；作为课题负责人承担国家自然科学基金，973分课题等多项研究，中国医学科学院临床试验能力提升平台（GCP）首席专家。

Prof. Ning LI is committed to minimally invasive treatment and research of lung cancer, targeted biological therapy, as well as the management and promotion of anti-cancer new drugs and new technology. As corresponding author, he has published dozens of articles in high-impact journal such as Lancet Oncology, Jama Oncology, Cancer Cell, etc., with a cumulative impact factor of more than 400. He is the chief expert of the Clinical Trial Capacity Improvement Platform of the Chinese Academy of Medical Sciences, as well as many other well-known studies such as the National Natural Science Foundation of China and 973 projects.

Speaker Bio

吕玉真 | Janet LYU
罗氏药品开发中国中心资深顾问
Senior Advisor, Roche Pharma Product Development China

吕玉真，执业药剂师，北京大学国际药物工程管理硕士，上海医科大学药学学士。

现任罗氏全球药品开发中国中心资深顾问。

吕玉真女士于2010年3月加入罗氏并担任亚太区注册部负责人，主要负责亚太地区新产品开发策略和中国区的注册事务。2014年10月被任命为罗氏药品临床研发亚太中心副总负责人。在过去的30年中，吕玉真女士曾就职于普强、法玛西亚普强、法玛西亚、辉瑞和默沙东公司，主要负责中国区的注册事务。

作为一个资深的监管政策进步倡导者，吕女士历任RDPAC法规事务工作组主席/联席主席/顾问，DIA中国顾问委员会药政事务小组负责人和亦弘商学院研究员。

加入制药公司之前，吕玉真女士曾是上海医科大学（现为复旦大学）药学院药剂学教研室的一名助教。

Janet Lu (Yuzhen LYU) currently served Senior Advisor to Roche Pharma Product Development China. Janet joined Roche in March 2010 as Head of Regulatory Affairs, Asia Pacific and was appointed as Deputy Site Head of PDY (Product development in Asia Pacific) since October 2014. In her role, Janet focused more on Asia Pacific New Product Development Strategy and was also accountable for China regulatory deliverables. Effectively from January 1, 2019, she is dedicatedly responsible for Regulatory Affairs in China. In the past 30 years, she worked with Upjohn, Pharmacia & Upjohn, Pharmacia, Pfizer and MSD and was mainly responsible for Regulatory Affairs in China.

Janet is also a seasoned regulatory policy advocator, and serves the leader's role of Regulatory Affairs Working Group for RDPAC and DIA China ACC, while a researcher of Yeehong Business School.

Before joining industry, Janet was a teacher assistant in Pharmacy Department of Shanghai Medical University (current FU DAN University). Janet obtained her bachelor's degree and master's degree from Shanghai Medical University and Peking University, majored in Pharmacy and International Pharmaceutical Engineering Management respectively.

梅林 教授 ， 博士生导师 | Lin MEI
首都医学科学创新中心主任、特聘研究员，首都医科大学讲席教授
Distinguished Investigator & Director, Chinese Institutes for Medical Research, Beijing
Chair Professor, Capital Medical University

2023至今是首都医学科学创新中心特聘研究员、主任，也是首都医科大学 讲席教授。

2017–2023年担任美国凯斯西储大学医学院神经生物学系教授、系主任、Allen C. Holmes讲席教授；克利夫兰脑健康计划首任主任。2004–2017年担任美国奥古斯特大学乔治亚医学院分子医学与遗传学研究所教授、所长（2009–2014）；奥古斯特大学神经科学和再生医学系教授、首任系主任（2014–2017）。1999–2004年担任美国阿拉巴马大学伯明翰分校助理教授、副教授；1994–1999年在美国弗吉尼亚大学医学院任助理教授；1989–1994年，美国约翰霍普金斯大学医学院博士后。梅林教授于江西医学院（现南昌大学）获得临床医学学士，于美国亚利桑那大学获得药理毒理学博士。

梅林实验室关注突触形成、传递和可塑性的机制，进一步理解中枢神经疾病（包括精神分裂症、自闭症、抑郁症）和外周神经疾病（脊髓侧索硬化、重症肌无力）的病理机制并提供潜在的治疗策略。

2023-present, Distinguished Investigator & Director, Chinese Institutes for Medical Research, Beijing, China

2023-present, Chair Professor, Capital Medical University, China

2017-2023, Professor and Chair, Department of Neurosciences, Allen C. Holmes Professor, and Inaugural Director, Cleveland Brain Health Initiative (CBHI), Case Western Reserve University School of Medicine, USA

2004-2017, Professor and Georgia Eminent Scholar, Institute of Molecular Medicine and Genetics (as Director, 2009-2014), Medical College of Georgia, Augusta University, and Inaugural Chair of Department of Neuroscience and Regenerative Medicine (2014-2017), USA

1999-2004, Assistant Professor and Associate professor, University of Alabama at Birmingham, USA

1994-1999, Assistant Professor, University of Virginia, USA

1989-1994, Postdoctoral Fellow, Johns Hopkins University School of Medicine, USA

Research Direction

Research in Mei lab has focused on mechanisms of synapse formation, neurotransmission, and synaptic plasticity. Our goal is to contribute to a better understanding of these processes and development of potential therapeutic strategies for psychiatric disorders such as schizophrenia, autism, and depression and neurological disorders such as neuromuscular disorders and ALS.

B.S. in Clinical Medicine Science, Jiangxi Medical College, China

Ph. D. in Pharmacology and Toxicology, University of Arizona, USA

Speaker Bio

何为无 博士 | Weiwu HE
CASI Pharmaceuticals Inc. 创始人、董事长兼首席执行官
Founder, Chairman and CEO, CASI Pharmaceuticals Inc.

何为无博士自2012年2月起担任CASI公司董事会主席，2018年2月起担任董事会执行主席，从2019年起兼任首席执行官。

何为无博士是ETP基金创始人、合伙人，ETP是一家专注于生命科学领域的风险投资公司，成立于2000年。在职业生涯中，何博士投资和创办了包括凯信远达、傲锐东源、泛生子、博雅辑因等100余家生物技术公司。

在职业生涯的早期，何博士是人类基因编组的首批科学家。在此之前他曾在美国麻省总院和梅奥诊所做博士后研究。何博士发表了超过30篇研究文献，并且是32项专利的发明人。他拥有贝勒医学院分子生物学博士，并获得沃顿商学院的MBA学位。

Dr. Wei-Wu HE has served as Chairman of the Board of Directors of CASI since February 2012 and Executive Chairman of the Board since February 2018. Since 2019, he has concurrently served as the Chief Executive Officer.

Dr. HE is also the founder and general partner of Emerging Technology Partners, LLC, a life sciences-focused venture fund established in 2000. Dr. HE has founded or funded over 100 biotech companies throughout his career, including CASI, OriGene, GENETRON, and EdiGene.

In the earlier part of his career, Dr. HE was one of the pioneering scientists in the Human Genome Project. Before that, he was a Massachusetts General Hospital and Mayo Clinic research fellow. Dr. HE is the author of more than 30 research publications and the inventor of 32 issued patents. He holds a PhD in Molecular Biology from Baylor College of Medicine and an MBA from The Wharton School of the University of Pennsylvania.

Thad HUSTON
比利时Galapagos公司CFO兼COO
CFO and COO of Galapagos, Belgium

何赛德(Thad HUSTON) 是一位资深的医疗健康高管，拥有丰富的全球金融、商业、业务发展和运营经验。何赛德于2023年6月加入Galapagos公司，担任首席财务官、首席运营官，并成为执行委员会成员。

此前，他曾担任吉利德公司旗下Kite Pharma的高级副总裁，负责财务和企业运营事务，全面负责全球领先的细胞治疗业务的所有财务方面工作。他也是Kite领导团队、吉利德首席财务官领导团队的成员，并担任复星凯特合资公司的董事会成员。

在2021年加入Kite之前，萨德曾在LivaNova PLC担任首席财务官，这是一家专注于心血管和神经调节产品的医疗器械公司。在那里，他在外部研发创新和并购方面发挥了关键作用，并领导了跨职能的全球团队。

在加入LivaNova之前，萨德在强生公司 (Johnson & Johnson, J&J) 任职超过25年，担任多个领导职务，包括强生制药研发部门的首席财务官兼首席运营官，强生全球外科和医疗器械集团的首席财务官，管理年度收入高达210亿美元。此外，他还曾担任西安杨森的总裁，领导强生在中国的制药部门。在此之前，他在强生位于美国、比利时、俄罗斯和匈牙利的多个地点担任高级财务职务。

萨德热衷于通过转型业务来加速内部和外部创新，从而为全球患者带来真正的改变并取得成果.

Thad HUSTON is a senior healthcare executive with extensive global financial, commercial, business development, and operational experience. Thad joined Galapagos in June 2023 as Chief Financial Officer, Chief Operating Officer, and member of the Executive Committee.

He previously served a Senior Vice President, Finance and Corporate Operations of Kite Pharma, a Gilead Company, where he was responsible for all financial aspects of the market leading cell therapy business worldwide. He was also a member of the Kite Leadership Team, the Gilead CFO Leadership Teams and the board of Directors of Fosun-Kite Joint Venture.

Before joining Kite in 2021, Thad served as Chief Financial Officer at LivaNova PLC, a medical device company specializing in cardiovascular and neuromodulation products, where he played a key role in external R&D innovation and M&A and led the global, cross-functional teams across the group.

Prior to LivaNova, he spent over 25 years in leadership positions at Johnson & Johnson (J&J), which included roles as Chief Financial Officer and Chief Operating Officer of J&J Pharmaceutical Research and Development, Chief Financial Officer of J&J's Global Surgery and Medical Devices groups managing up to $21 billion in annual revenue, and President of Xian-Janssen, leading J&J's pharmaceutical division in China. Before that, he held senior financial roles at various J&J locations in the U.S., Belgium, Russia, and Hungary.

Thad is passionate about delivering results by transforming businesses to accelerate internal and external innovation to make a real difference for patients around the world.

Speaker Bio

蔡景愚 | Jingyu CAI
普华永道思略特大中华区制药和生命科学行业咨询合伙人
Partner, China/HK Pharma & Life Sciences Industry Sector, PwC

蔡景愚先生现任普华永道管理咨询团队医药和生命科学行业管理咨询合伙人，拥有超过19年的企业管理和咨询经验。在他的职业生涯中，蔡先生在行业监管政策解读、企业战略规划与落地、商业模式转型、运营优化领域积累了大量经验。同时，蔡先生还领导了大量医药医疗企业并购前商务尽职调查以及并购后业务整合的项目。

他服务过的主要客户包括：辉瑞、晖致、罗氏、礼来、诺和诺德、武田、安进、勃林格殷格翰、杰特贝林、利奥制药、赫力昂、国药集团、上海医药、云南沃森、青岛百洋、碧迪医疗器械、丹纳赫医疗器械、生物梅里埃、费森尤斯卡比、卡尔蔡司等，以及专注于大健康领域的投资机构和健康险公司。

蔡景愚先生被复旦大学、亦弘商学院聘为客座讲师，并担任国家药物信息协会（DIA）中国“人才发展及国际交流专业委员会”委员。

Mr. Cai Jingyu is PwC China Consulting Partner focusing on pharmaceutical and life science sector. He has more than 19 years combined industry and consulting experience. Mr. Cai has accumulated profound experience in regulatory environment interpretation, strategy development and execution, business model transformation, and operation optimization. Moreover, he has led many global and domestic pharma M&A cases.

His main clients include Pfizer, Roche, Lilly, Novo Nordisk, Takeda, Amgen, BI, CSL, LEO pharma, Sinopharm, Shanghai Pharma, Walvax, Baheal, Becton Dickinson, Medtronic, Danaher, Fresenius Group, bioMerieux, Carl Zeiss, etc., as well as investment funds and healthcare commercial insurance companies.

Mr. Cai is appointed as lecturer in Fudan University and YeeHong Business School. He is a member of Drug Information Association (DIA).

孙敏敏 博士 | Minmin SUN
上海易慕峰生物科技有限公司创始人，董事长兼首席执行官
Founder, Chairman and Chief Executive Officer, Shanghai EmuFon Biotechnology Co.

孙敏敏拥有10余年药品法规注册和研发项目管理经历，多年创业型生物医药企业和多个生物制品IND和NDA申报工作经验。

在创办易慕峰之前，孙敏敏作为创始团队成员加入复星凯特，担任总裁助理兼药政注册及公共事务总监，推动中国第一个CAR–T的NDA申报和细胞治疗药品监管法规建立，在此期间还担任上海医药质量协会细胞免疫治疗质量控制专委会秘书长。

此前，孙敏敏在复宏汉霖从事药政注册工作，曾推动中国首个生物类似药汉利康®的NDA批准上市，以及中国生物类似药法规的建立。在复宏汉霖期间，她还负责申报了10个IND项目和2个中欧双报项目。

孙敏敏博士毕业于复旦大学，硕士毕业于清华大学，专业为药理学，研究方向为肿瘤免疫。

Ms. SUN has a solid foundation serving executive positions at multiple entrepreneurial biopharmaceutical companies. She has a reputation in drug registration, regulatory affairs and senior project management, and had been secretary general of Shanghai Medicine Quality Association Cell Therapy Committee. She has completed more than ten IND and NDA applications for bio/immunotherapy drugs. Mrs. Sun had served Fosun Kite biotechnology Co., Ltd. and Henlius, and was in charge of the NDA approvals for the first CAR-T product FKC876's in China, and the first biosimilar drug汉利康® (HLX-01, rituximab injection) in China.

Dr. SUN completed her Ph.D. at Fudan University and obtained her Master's degree from Tsinghua University, with a major in pharmacology and a research focus on tumor immunology.

陈冰 | Bing CHEN
阿斯利康国际业务拓展合作与战略投资副总裁
阿斯利康中金医疗产业基金创始管理合伙人
Vice President, AstraZeneca International Business Development and Venture Fund
Managing Director and Co-founder of AZ-CICC Healthcare Investment Fund

陈冰先生现任阿斯利康国际业务拓展合作与战略投资副总裁、阿斯利康中金医疗产业基金创始管理合伙人。

陈冰先生用其丰富的行业经验及敏锐的商业判断力成功领导了多项与国内外医药企业的战略合作，覆盖肿瘤、心血管代谢、呼吸等多个疾病领域，持续助力业务增长，并助力中国创新走向全球。

陈冰先生联合创立了阿斯利康中金医疗产业基金，携手战略伙伴中金资本，致力于发现、孵化本土医药源头创新，并为其发展进行高质量赋能，释放巨大的价值潜力。

陈冰先生在加入阿斯利康之前，就职于麦肯锡公司，任大中华区全球副董事。

Mr. Bing CHEN is currently Vice President of AstraZeneca International Business Development and Venture Fund, Managing Director and Co-founder of AZ-CICC Healthcare Investment Fund.

He has successfully led a number of collaborations with both international and China local pharmaceutical companies, leveraging his extensive industry experiences and sharp business acumen. These collaborations cover multiple disease areas including Oncology, CVRM and Respiratory TAs, continuously driving business growth and supporting China's innovation to go global.

He also co-founded the AstraZeneca-CICC Healthcare Investment Fund, working together with strategic partner CICC Capital, dedicated to discovering and incubating local innovation, and providing high-quality empowerment for their development, unlocking tremendous value potential.

Prior to joining AstraZeneca, Mr. Bing CHEN served at McKinsey & Company for nearly seven years as Associate Principal, Greater China Office.

Speaker Bio

刘妮娜 | Nina LIU
比利时Galapagos公司运营高级总监
Senior Director, Business Operations Lead at Galapagos

刘妮娜，医学学士，信息系统管理硕士，工商管理硕士，现任Galapagos公司运营高级总监，拥有超过20年的药物早期发现、业务发展和联盟管理经验，专注于肿瘤学、细胞疗法和罕见疾病领域。她在建立Galapagos中国分公司及设立生产和临床试验方面发挥了关键作用.

她的职业生涯始于哈佛医学院和麻省总医院，之后在默克、诺华和Kite/吉利德科学等公司供职, 参与了关键项目研发并代表美方股东管理复星敞特合资企业，以及成功争取商业权益，为药物顺利上市铺平了道路。

此外，刘妮娜还在NECINA担任总经理职务，创建了项目管理办公室，并担任默克亚太协会主席，领导波士顿团队7年。她还为SkillCloud提供咨询，这家公司后来被SCC集团收购。她在波士顿组织了许多有影响力的科学会议。

Nina LIU, MD, MSIS, MBA, is the Senior Director, Business Operations Lead at Galapagos, with over 20 years of experience in pre-clinical drug discovery, business development, and alliance management, focusing on Oncology, Cell Therapy, and rare diseases. She was instrumental in establishing Galapagos's China entity and setting up manufacturing and clinical trials.

Her career began at Harvard Medical School and Mass General Hospital, followed by roles at Merck, Novartis, and Kite/Gilead, contributed to key programs and managed FSK joint venture, secured commercial rights for successful launching.

Outside her professional work, Nina is the General Manager at NECINA, where she built Project Management Office, and as President of Merck APA, led the Boston team for 7 years. She advised SkillCloud which was acquired by SCC Group, and has organized impactful scientific conferences.

倪东耀 | Dongyao NI
西比曼生物商业开发与合作高级副总裁
Senior Vice President, Global BD Head & General Affairs, AbelZeta Inc.

倪东耀先生是西比曼生物科技负责商业开发和业务整合的高级副总裁，在基因治疗领域有着近十年的丰富经验。曾经作为共同创始人参与创建了深圳市亦诺微医药科技有限公司，并担任首席研发官（董事会成员），负责了两个溶瘤病毒产品的CMC、非临床研究、注册和早期临床研究工作，首次在国际上实现了溶瘤病毒产品在中国、美国和澳大利亚的同步临床试验研究。其后又在圆因生物担任首席运营官，参与了公司首个环状RNA疫苗的早期研发和临床研究工作。2023年7月倪东耀加入西比曼生物科技，目前主要负责公司国内、国际的商业开发和业务整合工作。倪东耀毕业于上海交通大学临床医学系。2015年回国创业前，倪东耀先后在美国普林斯顿大学和芝加哥大学从事免疫学特别是自身免疫病的研究。

Mr. Dongyao NI is the Senior Vice President of Business Development and General Affair at AbelZeta, with nearly ten years of extensive experience in the field of cell and gene therapy. He was a co-founder of ImmVira Ltd, where he served as the Chief Research and Development Officer (Board Member), responsible for CMC, non-clinical research, registration, and early clinical research of oncolytic virus products. Subsequently, he served as the Chief Operating Officer at Circle RNA, where he participated in the early research and clinical studies of the company's first circular RNA vaccine. In July 2023, Dongyao joined AbelZeta, where he is currently responsible for domestic and international business development and company general affairs. Dongyao Ni graduated from the Clinical Medicine Department of Shanghai Jiao Tong University School of Medicine. Before returning to China to start his business in 2015, he conducted research on immunology, particularly autoimmune diseases, at Princeton University and the University of Chicago in the United States.

张金华 | Jinhua ZHANG
驯鹿生物创始人、董事长兼首席执行官
Founder, Chairwoman, and CEO, IASO Bio

张金华女士毕业于东北财经大学，法学硕士，资深证券律师，曾就职于投资银行和行业领先的证券律师事务所。作为项目主导人，兼任财务顾问和律师双重身份，曾主办几十家中国企业的上市和并购重组项目，包括国内A股改制上市、香港上市、美国纳斯达克上市、加拿大多伦多交易所上市项目。张金华女士自2003年后主办过近20个上市公司的并购重组业务，累计协助几十家企业完成境内外上市。2015年作为天使投资人投资了早期从事CAR–T研发的公司，并出任董事。2017年，张金华女士创办驯鹿生物，以“专注创新生物疗法，为患者带来治愈的希望”为使命，致力于解决中国乃至全球患者尚未满足的临床需求。公司成立至今，张金华女士带领并管理一支由生物技术、医学、抗体开发、医药销售等领域的专业人才组成的核心团队，共同致力于细胞治疗技术的研发、临床、生产以及商业化。张金华女士为江苏省企业联合会、江苏省企业家协会常务理事。

Ms. Jin-Hua Zhang is the Founder, Chairwoman, and CEO of IASO Bio. She graduated from Dongbei University of Finance and Economics with a Master's degree in Law and is a seasoned securities lawyer. Her career includes significant roles in investment banking and leading securities law firms. As a project leader, she has successfully dual-hatted as both financial advisor and lawyer, overseeing numerous IPOs and M&A projects for Chinese companies. Her expertise spans domestic A-share restructurings, and listings on the Hong Kong Stock Exchange, NASDAQ in the U.S., and the Toronto Stock Exchange in Canada. Since 2003, Ms. Zhang has led nearly 20 M&A projects for publicly listed companies and has facilitated the listings of dozens of companies both domestically and internationally. In 2015, she made an angel investment in an early-stage company focused on CAR-T research and served as a board member. In 2017, Ms. Zhang founded IASO Bio with the mission of “focusing on innovative biological therapies to bring hope of a cure to patients,” dedicated to addressing the unmet clinical needs of patients in China and worldwide. Since its inception, she has led and managed a core team of experts from biotechnology, medicine, antibody development, and pharmaceutical sales fields, all working together on the research, clinical development, production, and commercialization of cell therapy technologies. Ms. Zhang is also an Executive Director of the Jiangsu Federation of Enterprises and the Jiangsu Entrepreneur Association.

Speaker Bio

孙华龙 医学博士 | Hualong SUN
苏州科林利康医药科技有限公司首席战略官
Chief Strategy Officer (CSO), Co-Founder, Clinical Service Center Co. Ltd

苏州科林利康医药科技有限公司首席战略官 日本东京大学医学博士 25年临床开发经验，曾先后就职于默克雪兰诺、 PAREXEL等跨国药企和CRO； 先后担当生物统计、数据管理、医学事务、项目主管、数据管理部门、及临床运营负责人； 主要有肿瘤、泌尿生殖、心血管、免疫等治疗领域的相关临床试验经验 ； 全球药物信息协会（DIA）中国地区顾问委员会理事会成员；SCDM中国指导委员会委员；中国临床试验数据管理学组核心成员； 中国医疗器械行业协会数据分析专业委员会成员；中国药科大学硕士研究生校外导师； 《中国临床数据管理学》编委。

Dr. SUN has 24+ years' experience in clinical development, served to Merck Serno and PAREXEL etc global pharmaceutical and CRO companies as a Biostatistician, Data Managaer, head of DM Department, clinical operations, and chief operating officer etc. His is well experienced in clinical trials across phase I-IV in fields of oncology, Fertility, Urinary, Immunology, Psychiatry, Gastroenterology, Infectious Disease, and Medical Devices. He currently is the member of Advisory Council of China (ACC), China.

He is the Deputy Chairman of DIA Data Science Committee, Core Member of China Clinical Data Management Working Group, Member of Steer Committee of SCDM China.

Hualong SUN owns PhD from University of Tokyo.

陈锴 | Kai (Chandler) CHEN
阿斯利康中国数字化与商业创新部执行总监 国际创新园及创新中心负责人
Executive Director and Head of iCampus & Regional Innovation Center
Digital & Commercial Innovation
AstraZeneca China

陈锴先生负责阿斯利康全国8个创新园与创新中心 (iCampus)，分布在北京、上海、广州、杭州、无锡、成都、青岛、香港，打造开发合作生态圈创新平台，引入并孵化创新企业，创立iCampus基金投资合作伙伴，带领中国医疗创新项目出海新兴市场，并在利雅得设立了首个国际创新平台（SCSC中沙医疗创新中心）。中欧国际工商学院MBA，外交学院国际经济本科。

Chandler Chen is the Executive Director of AstraZeneca China, heading the iCampus and Regional Innovation Center, with a network of innovation hub across 8 cities in China: Beijing, Shanghai, Guangzhou, Hangzhou, Wuxi, Chengdu, Qingdao, and Hong Kong. In this role, he aims to build an innovation ecosystem and partnership platform, incubate and accelerate innovation partners, and manage iCampus fund to support strategic partners scaling from China to global markets. Very first ex-China innovation hub program will soon launch in Riyadh for Saudi China Scientific Collaboration (SCSC).

Chandler holds MBA from China Europe International Business School (CEIBS) and a Bachelor degree in International Economics from China Foreign Affairs University (CFAU).

陈镇荣 | Zhenrong (Neo) CHEN
弗若斯特沙利文咨询有限公司咨询总监
Consulting Director, Frost&Sullivan

陈镇荣先生是F&S沙利文大中华区咨询总监暨生命科学投融资业务负责人。在IPO行业咨询、新产品市场准入及定价方面拥有十分丰富的专业知识和经验。深度参与大健康企业投融资计划，通过产业链资源对接、园区落地、对外宣发等方式实现企业增长需求。服务对象包括生命科学领域生物医药、医疗器械及医疗服务板块的国内及国际领先企业，积累了丰富的产业经验。负责并主导了多家知名生物医药、医疗器械及医疗服务企业于美股、港股及A股IPO上市中的行业研究工作，在创新药研发生产领域有着深入且综合的行业理解。

Mr. Neo CHEN is the Head of Growth and Investment Business, Director of Frost & Sullivan Greater China Area Life Science Sector. Neo provides professional consulting services in IPO industry research, business and products valuation, new market entry strategy, and product pricing. He is deeply involved in investment and financing plans for healthcare companies, offering comprehensive services including industrial chain resource matching, park establishment, and brand promotion to facilitate growth. He serves domestic and international leading enterprises in the biopharmaceutical, medical device, and healthcare service sectors, and has accumulated deep industry experience. Neo successfully led industry researches for multiple renowned companies in their IPOs on the US, Hong Kong H-share, and Chinese A-share markets, and has a deep understanding of the innovative drug R&D industry.

葛永彬 | Yongbin GE
北京市中伦律师事务所高级合伙人
Equity Partner, Zhonglun Law Firm

葛永彬是中伦律师事务所资深合伙人，擅长为创新药企提供DCT合规咨询及项目合规管理、医药数据跨境合规、GCP/GLP/GMP/GSP/GVP合规咨询，参与撰写《远程智能临床试验蓝皮书》《远程智能临床试验专家共识》，在《中国食品药品监管》杂志发表了《去中心化临床试验中的供应商合规管理》《利用医疗大数据开展真实世界临床研究的合规性要求》《临床研究合规管理探讨》《真实世界数据合规探讨》《新修订<药品管理法>诠释“最严厉的处罚”——通过经典案例探讨药企合规风险防范》等多篇合规论文，受到业内高度认可。葛律师现担任中国医药创新促进会合规委员会副主任、中国食品药品监管杂志审稿专家、DIA中国法律顾问、DCT联盟专家委员会副主任，先后获得美国UC Berkeley法学硕士、南京大学法学硕士、中欧国际工商学院EMBA、中国人民大学经济学硕士和上海交通大学机械工程专业学士学位。

With profound practice in the PRC legal market for over 20 years, Mr. Ge is a senior partner of Zhonglun with rich practical experience in the legal service in Healthcare and Life Science. Mr. Ge is specialized in all-round legal services in Corporate Compliance, BD (IP Licensing & Collaboration), VC/PE Financing, M&A and IPO. With compound educational background in engineering, law, finance and business administration, as well as a wide range of work experience in international trading, management, overseas operations, and law practice, Mr. Ge is highly welcomed by numerous entrepreneurs and investors for his laudable professional legal service, known as a sophisticated negotiator and good deal maker. Mr. Ge is often praised by clients as seasoned lawyer with business thinking.

Speaker Bio

张熊 | Xiong ZHANG
E药经理人国际中心总经理
General Manager of International Centre of E Healthcare Executive

张熊，毕业于中国药科大学药事管理专业，硕士学位。现任E药经理人国际中心总经理。曾任中国医药保健品进出口商会药融圈分会秘书长。2011–2017年在中国驻尼日利亚使馆经商处、驻拉各斯总领馆经商室、驻珀斯总领馆经商室工作。在非洲工作期间，曾参与中国与尼日利亚两国政府药品监管国际合作项目。现主要致力于医药企业出海，国际交流及合作等工作。

ZHANG Xiong graduated from China Pharmaceutical University with a master's degree in Pharmaceutics. Currently He is the general manager of the International Center of E- Healthcare Executives. He was the Secretary General of Pharnex Branch of China Chamber of Commerce for Import & Export of Medicines and Health Products. He has rich overseas work experience. From 2011 to 2017, he worked in the Economic and Commercial Office of the Chinese Embassy in Nigeria, the Commercial Office of the Chinese Consulate General in Lagos and the Commercial Office of the Chinese Consulate General in Perth. During his work in Africa, he participated in the international cooperation project on drug regulation between the governments of China and Nigeria. Now he is focusing on promoting Chinese pharmaceutical enterprises going overseas and doing international collaborations.

张学博 博士 | Xuebo ZHANG
歌路资本合伙人
Partner at G&G Capital

张学博，歌路资本合伙人，DIA药物发现及转化专业委员会委员。曾在国家药监局、中检院及深圳院工作十年，参与药品、器械、化妆品、食品等的质控和监管工作。北京协和医学院生物化学药学博士，美国约翰霍普金斯大学MBA。目前专注于创新药和创新器械的投融资，关注领域包括先进治疗、消费医疗、上游装备和材料等。

Xuebo Zhang is a Partner at G&G Capital in Beijing and a member of the DIA Drug Discovery and Translational Medicine Professional Committee. Prior to his role at G&G Capital, he served at the Chinese NMPA from 2009 to 2019, where he was involved in quality control and administrative affairs related to drugs, medical devices, and cosmetics. With a deep understanding of the healthcare industry and a vast network of industry resources, he is focused on investing in advanced therapies, consumer-oriented medical products, and upstream equipments as well as novel materials. He holds a Ph.D. in Pharmaceutical Sciences from Peking Union Medical College and an MBA from Johns Hopkins University.

韩露 | Lu (Shirley) HAN
百济神州生物制药有限公司中央政府事务高级总监
Central Government Affairs Senior Director, BeiGene

韩露女士在百济神州担任中央政务高级总监负责创新药全球化出海相关政务和国际合作，在新产品国际化战略及全球健康创新合作方面有超过10年的工作经验。曾任职于阿斯利康国际部负责肿瘤管线产品在亚洲、拉丁美洲、中东&非洲、俄罗斯&中亚，以及大洋洲的市场战略，商业化创新及政府合作；在她的推动下，肿瘤国际业务成为重要的高速增长引擎，她曾搭建多项国际合作促进中外专家学术交流及合作，同时引领创新产品和解决方案出海“一带一路”国家，解决当地迫在眉睫的卫生挑战增进健康福祉，推动“健康丝绸之路”建设。在此之前，韩露还曾就职于百时美施贵宝，葛兰素史克及辉瑞等跨国药企，担任销售，市场/战略等高级管理岗位。韩露女士毕业于美国杜克大学获得MBA学位，同时拥有重庆大学药物化学硕士学位。

Shirley Han is Central Gov Affairs Senior Director from BeiGene responsible for globalization and international collabrations. Shirley have more than 10-year experience in international new products commercialization & strategy development, and international business innovation & collaboration. Prior to BeiGene, Shirley work as Director of International Oncology at AstraZeneca covering Asia, LATAM, Middle East & Africa, Russia, Australia & New Zealand. With her effort and contribution, international oncology business achieved high double-digit growth, enhance medical society exchange & collaboration between China and “Belt and Road” countries, and brought innovative products and ecosystem solutions to 30+ countries around the world to solve urgent healthcare challenge and to improve health wellbeing. Shirley also has Global & China local commercial leadership experience with BMS, GSK and Pfizer. Shirley has MBA degree from Duke University and Master of Pharmaceutical Chemistry from Chongqing University.

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