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

Co-sponsor: International Drug Information Association (DIA), Beijing Advanced Medical Equipment Industry Innovation Alliance
Organizer: DIA (Beijing) Medical Information Consulting Co., Ltd.
Beijing Economic and Technological Development Area research Institute of pharmaceutical information

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
Director and Head of China Society for Drug Regulation

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

Upon the invitation of the Beijing Government and the Organizing Committee of the 2024 International Biomedical Industry Innovation Conference Beijing Forum, DIA China will organize a two-day special sub-forum on October 24th and 25th, 2024, in Beijing, China. This forum centers on drug innovation and global collaboration, providing a platform for exchanging views and opinions on how to harness China's innovation for the benefit of the world.

Highlight

Session I: Global Regulatory Policy Session
Enhancing international cooperation to promote drug innovation

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 Session
Experts from various fields, including but not limited to drug discovery, clinical development, regulatory affairs, market access, will share their insights on how China's innovations can be harnessed to benefit global health.

DIA Night
A networking event aimed at fostering closer engagement between professionals interested in collaboration in drug innovation.

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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Scan the code to register now

The Steering Committee

Hugues MALONNE
Chief Executive Officer of the Federal Agency for Medicines and Healthc Products (FAMHP)

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

Ning LI, MD, Professor, Chief Physician
Associate President, Cancer Hospital, Chinese Academy of Medical Science
Executive Deputy Director, National Center for Quality Evaluation and Promotion of Clinical Anticancer Research
Vice Chair, DIA Advisory Council of China

The Program Committee

The Chair of the Program Committee

Janet LYU
Senior Consultant, Roche Pharmaceutical Development China Center

Member of the Program Committee

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Executive Director, Digital and Business Innovation,
Head of International Innovation Parks and Innovation Centers, AstraZeneca China

Member of the Program Committee

Irene DENG
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Head of Regulatory Affairs in China

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Lu HAN
Senior Director, Central Government Affairs, BeiGene

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Haiyan LI, Professor, Chief Physician
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, MD
Chief Strategy Officer
Clinical Service Center Co., Ltd.

Member of the Program Committee

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

Member of the Program Committee

Tongyan WANG, PhD
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 Strengthen International Cooperation to Promote Drug Innovation and Regulatory Modernization

Session Co-chair
Wei ZHANG
Director and Head of China Society for Drug Regulation

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

9:00-9:05 **Co-chair Speech**

Drug Authorities Global Leadership Forum

9:05-9:25 Report I Promoting and Protecting Public Health Through Pharmaceutical Innovation and International Cooperation-Belgium Perspective

Hugues MALONNE
Chief Executive Officer of the Federal Agency for Medicines and Health Products (FAMHP)

9:25-9:45 Report 2 Promoting and Protecting Public Health Through Pharmaceutical Innovation and International Cooperation-Brazil Perspective

Antonio BARRA TORRES
President-Director of Brazil's National Health Inspection Agency (Anvisa)

9:45-10:05 Report 3 Promoting and Protecting Public Health Through Pharmaceutical Innovation and International Cooperation-Saudi Arabia Perspective

Adel ALHARF, PhD
Vice President for Drug Sector of the Food and Drug Administration of Saudi Arabia

10:05-10:30 Report 4 Promoting and Protecting Public Health Through Pharmaceutical Innovation and International Cooperation- China Perspective

NMPA Commissioner-level speaker has been invited

10:30-11:00 Tea Break & Exhibition Foyer, Juyuan Hall

Cell and Gene Therapy Session

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

11:00-11:20 Report 5 Prospects of cell and gene therapy - Perspective from FDA

Peter MARKS, PhD | Online
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, PhD
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 R&D and Regulation of Cell Therapy

Keynote speaker from CDE NMPA has been invited

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

Wei ZHANG
Director and Head of China Society for Drug Regulation

14:00-16:00
Juyuan Hall
5th Floor
Block A

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, PhD
Director, Shanghai Center for Drug Evaluation of NMPA

Aurelie POLL
Inspector, Directorate General Inspection, Industry Division, Medicines GM(D)P Entity
Federal Agency for Medicines and Health Products (FAMHP)

15:00-16:00
No.6
Meeting Room
2nd Floor
Block A

Global Drug Regulatory Authorities Seminar (Close-door Meeting)
Global Cooperation to Address Drug Shortages - China's Impact and Role
(Target participants invite only)

Session Co-chair
Jonathan MALCORPS
Coordinator International Strategy for Shortages and Security of Supply

Co-chair from China Center for Food and Drug International Exchange has been invited

17:30-18:30
Juhui Hall
5th Floor, Block B

DIA Night - Networking Reception
(Invite-Only)

Agenda | October 25th

9:00-16:10
Juyuan Hall
5th Floor
Block A

Session 3 Drug Innovation and Globalization Session

Defining the concept of "going overseas" from the perspective of global health and global strategy, and discussing the significance and practice of drug innovation in China

9:00-9:10 Opening Remarks

9:00-9:05 **Marwan FATHALLAH**
CEO, DIA Global

9:05-9:10 China Center for Food and Drug International Exchange has been invided

China's Drug Innovation for Global Health: Is China Ready? - Chapter China

9:10-10:30 Sub-session 1

Cultivating the Soil of Drug Innovation Cooperation in the Whole Industry Chain

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

9:10-9:25 Report I Regulatory Science: Promote the Synchronous Development and Marketing of Global Drugs Through the Innovation of Regulatory Policies

Head of CDE, NMPA (To be confirmed)

9:25-9:40 Report 2 Clinical Trials: The Core of Creating A Clinical Trial Ecological Environment in China - Principal Investigator

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

9:40-9:55 Report 3 Market Access: Valuation and Market Access of Drugs

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

9:55-10:30 Panel Discussion: Discuss the Key Factors and Strategies for Further Promoting China's Innovative Drug Ecosystem

Session Chair has been invited

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

Bing CHEN
Vice President, International Business Development, Venture Fund
Managing Director, Co-founder, AZ-CICC Healthcare Investment Fund

Yuwen LIU
Co-Founder of the BOHE Angel Fund

Representative of Beijing Municipal Science & Technology Commission (invited)

Representative of China Customs (invited)

10:30-10:40 Tea Break & Exhibition Foyer, Juyuan Hall

10:40-12:15
Juyuan Hall
5th Floor
Block A

Sub-session 2

Incubate Innovative Products that Better Meet Global Health Needs

Session Chair
Ning LI, MD, Professor, Chief Physician
Vice President of China Medical Cancer Hospital, Vice Chairman of DIA China Advisory Committee

10:45-11:10 Report 1 To Promote Zero-to-One Innovation of Biomedicine Through the Unique University System and Mechanism to Serve Global Health

Hongtao YU, PhD
Chair Professor of Cell Biology
Dean of the School of Life Science at Westlake University

11:10-11:35 Report 2 Analyse the Competitive Advantage of China's ATMP Industry from the Perspective of R&D Quality and Cost

Jingyu CAI
Partner, Pharmaceuticals and Life Sciences, PricewaterhouseCoopers Eliot

11:35-12:15 Panel Discussion What is the Definition of an Innovative Product? What Will China's Innovation Contribute to Global Health?

Session Chair
Minmin SUN, PhD
Founder, Chairman and Chief Executive Officer, Shanghai EmuFon Biotechnology Co

Panelist
All Session Speakers and
Bing CHEN
Vice President, International Business Development, Venture Fund
Managing Director, Co-founder, AZ-CICC Healthcare Investment Fund

Zonghai LI, MD, PhD
Co-founder, Chairman of the Board, CEO, CSO of CARsgen®

Dongyao NI, PhD
Senior Vice President, Global BD Head & General Affairs, AbelZeta Inc.

12:30-13:30
No.6
Meeting Room
2nd Floor
Block A

China-Saudi Close-door Meeting (under development Invited Only)

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

12:30-13:30
No.5
Meeting Room
2nd Floor
Block A

Brazil-China Close-door Meeting (under development Invited Only)

Host
Lu HAN
Senior Director, Central Government Affairs, BeiGene

14:00-16:10
Juyuan Hall
5th Floor
Block A

Drug Innovation: Focusing on Global Health and Addressing Unmet Clinical Needs – Chapter World

Session Chair
Janet LYU
Senior Consultant, Roche Pharmaceutical Development China Center

14:05-14:25 Report 1 Discuss Geopolitics and Drug Innovation from a Global Health Perspective

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

14:25-14:45 Report 2 Interpretation of the New European GMP Annex 1, Ensuring the Quality of Pharmaceutical Products in the EU Market - a Regulatory Perspective

Aurelie POLL
Inspector, Directorate General Inspection, Industry Division, Medicines GM(D)P Entity
Federal Agency for Medicines and Health Products (FAMHP)

14:45-15:05 Report 3 Drug Innovation in China to Meet Global Health Needs - an International Start-up Perspective

Thad HUSTON
CFO and COO of Galapagos, Belgium

15:05-15:25 Report 4 Drug Innovation in China to Meet Global Health Needs - the Perspective of Overseas Industry Associations

Speaker (Invited)

15:25-16:10 Panel Discussion New Impetus of Drug Innovation - Focusing on Unmet Clinical Needs in Global Health and Emerging Markets

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

Panelist
All Session Speakers and
Zhenrong CHEN
Director of Frost & Sullivan

Yongbin GE
Equity Partner Zhong Lun Law Firm Shanghai Office

Xiang ZHANG
General Manager of International Centre of E Healthcare Executive

Xuebo ZHANG, PhD
Partner of G&G Capital