

6th International

China Pharmaceutical R&D Summit

April 11-13, 2011 • Grand Hyatt Hotel • Shanghai, China

Co-Organizers:



BayHelix
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**Clinical &
Regulatory
Summit**

**Discovery
to PreClinical
Development &
Partnerships**

**Biologics &
Biosimilars
Development**

Transformation & Innovation in China – The Next Stage in China's Life Sciences Industry

Hear first-hand from the government and pharma leadership in China on:

**Dialogue Between the Stakeholders of Innovation
in China – Where Does Innovation Originate From –
Locally or Globally?**

Transformation & Innovation: Moving Up the Value Chain

Showcase: IBC-BayHelix Class of 2010

Featuring:

The 2nd Annual
IBC-Bayhelix

**China Pharma
R&D Awards**

Bronze Sponsor:  **HEC** 东阳光药业集团
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Your Registration Includes Access to All 3 Conferences

Monday, April 11, 2011

Exhibit Hall Hours: 10:10am – 6:30pm

	Clinical & Regulatory Summit	Discovery to PreClinical Development & Partnerships	Biologics & Biosimilars Development
8:40am-9:10am	Regulatory Environment	Featured Presentation: Joseph Cho, President & CEO, Astellas Pharma China Inc.; Vice Chairman, R&D Pharmaceutical Association in China (RDPAC)	Featured Presentation: William Strohl, Ph.D., Vice President, Biologics Research, Biotechnology Center of Excellence, Centocor
9:10am - 10:10am	Regulatory Environment (<i>continued</i>)	MNC Strategies for New Drug R&D in China	Development of Biologics/Biosimilars
10:10am - 10:45am	<i>Networking Refreshment Break and Opening of Exhibit & Poster Hall</i>		
10:45am - 12:45pm	Design & Strategy of Programs	NCE Discovery & Development from Domestic Companies	Development of Biologics/Biosimilars
12:45pm - 1:55pm	<i>Networking Luncheon with Exhibit & Poster Viewing</i>		
1:55pm - 3:30pm	Design & Strategy of Programs	NCE Discovery & Development from Domestic Companies	Development of Biologics/Biosimilars
3:30pm - 4:00pm	<i>Networking Refreshment Break with Exhibit & Poster Viewing</i>		
4:00pm - 5:35pm	Keynote Presentations: David Nicholson, Ph.D., Senior Vice President, Worldwide Licensing and Knowledge Management, Merck Research Laboratories Clive Wood, Ph.D., Senior Vice President, Head of Global Biologics, Bayer Healthcare Sam Waskal, Ph.D., Chairman & CEO, Kadmon Pharmaceuticals		
5:35pm-6:30pm	<i>Welcome Cocktail Reception in Exhibit & Poster Hall</i>		

Tuesday, April 12, 2011

Exhibit Hall Hours: 10:20am – 5:30pm

	Clinical & Regulatory Summit	Discovery to PreClinical Development & Partnerships	Biologics & Biosimilars Development
8:45am-10:20am	Plenary Session: Transformation & Innovation in China		
10:20am - 10:50am	<i>Networking Refreshment Break with Exhibit & Poster Viewing</i>		
10:50am - 12:30pm	Plenary Session: Transformation & Innovation in China		
12:30pm - 1:55pm	<i>Networking Luncheon and Presentation of IBC-BayHelix 2nd Annual China Pharma R&D Awards</i>		
1:55pm - 3:30pm	Real-World Evidence Studies	Creating Value through Partnerships	Strategies & Success Stories of Large Molecule Development
3:30pm - 4:00pm	<i>Networking Refreshment Break & Last Chance for Exhibit & Poster Viewing</i>		
4:00pm - 5:30pm	Clinical Pharmacology, Safety & Pharmacovigilance	Creating Value through Partnerships	Strategies & Success Stories of Large Molecule Development

Wednesday, April 13, 2011

Exhibit Hall Closed

	Clinical & Regulatory Summit	Discovery to PreClinical Development & Partnerships
8:50am - 10:30am	Global Simultaneous Development	Toxicology and DMPK Challenges
10:30am - 11:00am	<i>Networking Refreshment Break</i>	
11:00am - 1:00pm	Clinical Site Management & Operations	Creating Value Through Partnerships II

Supporting Organizations



Media Partners



A never-before line-up of over 80 Speakers from international pharma, MNCs in China, and domestic Chinese pharma/biotechs will be sharing their expert opinions and experiences on transformation & innovation in China, clinical challenges, regulatory updates, NCE discovery efforts, preclinical partnerships, biosimilars development and more!

The 2011 event will feature 3 concurrent conferences – Clinical & Regulatory Summit; Discovery to PreClinical Development & Partnerships; and Biologics & Biosimilars Development, with shared Keynotes and a Plenary Session focusing on Transformation & Innovation in China – the Next Stage in China's Life Sciences Industry. Participants will be able to choose the conference of their choice or mix-and-match sessions from all 3 conferences, while taking advantage of the shared sessions and networking breaks to meet with other executives and scientists at the event.

With proven attendance from top-level executives from China's major pharma and biotech companies, this is **THE MEETING PLACE** to network and share experiences, meet potential partners and foster business relationships.

Clinical & Regulatory Summit:

■ Understand the Regulatory Environment in China

- Hear from a tuned-in clinical CRO on the changing Chinese regulatory system; a US company's insight on conducting global trials in Asia's dynamic regulatory environment; and a leading consultant's strategy to bring Chinese-originated drugs and biologics to US market.

■ Benefit from these Tried & Proven Clinical Strategies and Case Studies:

- FIH Study in China: from IND Application to Study Completion
- Getting Ready for Global Trials in China
- Conducting Health Economics & Outcomes Research in China
- Developing Risk Management Plan in Clinical Trials
- Bridging China Data with Global Data – Global Simultaneous Development
- Trials & Tribulations of Starting Clinical Trials in a New Geographic Region



Discovery to Preclinical Development & Partnerships:

■ Hear the Latest in NCE Development from these Domestic Chinese Companies:

- HEC Pharm Co., Ltd., Ascentage Pharma, IMPACT Therapeutics, Sunwei Therapeutics, Argusina Shanghai, Nanjing Changao Pharmaceutical, Luye Pharma Group and TOT Shanghai

■ Get Exciting Partnering Strategies and Updates from:

- Roche, Simcere Pharmaceuticals, Pfizer, AstraZeneca, Fosun Pharmaceutical, Synta Pharmaceuticals, DCB Taiwan, GSK and Eli Lilly

Biologics & Biosimilars Development

■ Hear Rarely-Told Stories of China's Biologics Development:

- History of Licartin – a I-131 Labeled Anti-CD147 Launched in China for Liver Cancer
- EGFR mAb – a 10-Year Development Effort
- Etanercept and Beyond: Developing High Quality Bioproducts for the Emerging Markets
- TPO – an Innovative Biopharmaceutical Product in China
- Interleukin-7 Receptor: A New Therapeutic Target for Biological Approach
- Developing Oral Insulin in China – Experiences and Lessons

■ Learn from Success Stories of Large Molecule Development from Around the World:

- Alternatives to Antibodies – High Affinity Mirror-Image Oligonucleotides
- Story of Abgenix: from XenoMouse to Panitumumab and Beyond
- Development of Cell Therapy in China
- Peptide Therapeutics in China



Clinical & Regulatory Summit

- 8:30 **Chairperson's Opening Remarks**
Maria Xuemei Song, Ph.D, M.D, R. Pharmacist,
M.A., President, VPS-CRO Group

Understanding the Regulatory Environment in China for Drug Development & Clinical Trials

- 8:40 **Navigating the Changing Chinese Regulatory System**
 2010 is the first year of the implementation of the emerging strategic industries development. The Chinese government is planning to launch a series of helpful measures to support more and faster development of large-sized enterprises and innovative enterprises, as well as to leapfrog development timelines. Faced with the current changing regulatory landscape, many are confused. This presentation will help alleviate some of the concerns of managing your business in this rapidly changing environment.
Maria Xuemei Song, Ph.D, M.D, R. Pharmacist,
M.A., President, VPS-CRO Group

- 9:10 **IND and Commercialization Strategies for Chinese Drugs and Biologics into US Market**
 A strategy to optimize drug/biologic development and marketing exclusivity in the US provides important commercial value to your product sourced/initially developed in China. Development of this strategy should start as early in product development as possible.
Paul Nemeth, Ph.D., CEO and Executive Vice President,
CSR Pharma Services

- 9:40 **Sponsored Presentation TBD**
 10:10 *Networking Refreshment Break and Opening of Exhibit & Poster Hall*

Design & Strategy of Programs

- 10:45 **Ipsen Settlement in China: An Experience from a French Company with More than 80 Years History**
 After the sustainable and successful experience of a manufacturing unit in China for around 20 years, Ipsen, a French pharmaceutical company, decided to expand its scope of activity in China with a long-term perspective and a holistic approach. This talk will present a series of initiatives, from research to medical affairs, that are being put in place by teams comprising of French and Chinese employees.
Anne Verny, M.D., MBA, Vice President, Clinical Development, Ipsen
Ying Liu, M.D., Medical Director,
Medical Development, Beaufour-Ipsen (Tianjin) Pharmaceutical
- 11:15 **A Hutchison MediPharma's Drug Development Footprint: From China Discovery Projects to Global Phase 3 Clinical Trials**
 Abstract not available at time of print. Please visit www.IBCLifeSciences.com/China for updates.
Xun Zhang, Ph.D., Senior Vice President,

Discovery to PreClinical Development & Partnerships

- 8:30 **Chairperson's Opening Remarks**
Seymour Mong, Ph.D., Independent Consultant

Featured Presentation

- 8:40 **Challenges and Opportunities for Drug Innovation in China**
 The challenges lie in insufficient IPR protection, reviewing and approving process for clinical research for new drugs, drug administration and licensing system, clinical research resources, compliance of GCP and market access which is not encouraging drug innovation. Recently, importance of drug innovation has been recognized and reflected in the 12th 5 year plan and some measures have been initiated by the government and industrial groups, but lots of effort are still needed to create a more R&D friendly environment for drug innovation in China.
Joseph (YungChing) Cho, President & CEO,
Astellas Pharma China Inc.; Vice Chairman, R&D Pharmaceutical Association in China (RDPAC)

MNCs' Strategies for New Drug R&D in China

- 9:10 **Bridging Research and Development – Fast to POC**
 This presentation will elaborate ways to improve probability of success for compounds and to decrease compound development time. With innovative technology advancement in target delivery and formulation development, many of the previously non-developable compounds could be developed for market uses. In many ways, this could revolutionize the drug development landscape in future. With the right regulation in place from SFDA, China could play a significant role in this exciting development period.
Nick (Yafei) Zhang, Ph.D., Head of CPP China,
China Novartis Institutes for BioMedical Research
- 9:40 **Creating Value through Partnerships**
 At this time of unprecedented opportunities, creative solutions and continued research collaborations are required. The new sanofi-aventis R&D values networks and focuses on partnership and collaboration. Aiming to incorporate innovation into the main fabric of R&D, we set up a unique structure revolving around networks of creativity spread across regions, technologies and scientific areas of excellence.
Binhui (Ben) Ni, Ph.D., Head of Scouting and Partnership, China, sanofi-aventis

- 10:10 *Networking Refreshment Break and Opening of Exhibit & Poster Hall*

NCE Discovery & Development from Domestic Companies

- 10:45 **Best-in-Class in China: Generic New Drugs**
 Generic new drugs are being pushed to develop multiple Best-in-Class drugs to cover all patient population of all income levels in China and around the globe. The general approach as well as Dongyangguang's effort toward generic new drugs will be discussed.
PengCho Tang, Ph.D., Chief Scientific Officer,
HEC Pharm Co., Ltd.
- 11:15 **Innovative Drug R&D in China – A Possible Path**
 - Trend in Global and China Pharmaceutical Industry
 - Possible Approaches for NCE Drug R&D in China**Ming Guo, Ph.D., Co-Founder & COO,**
Ascentage Pharma

Biologics & Biosimilars Development

- 8:30 **Chairperson's Opening Remarks**
Chris Chen, Ph.D., Chief Executive Officer,
Shanghai Kanda Biotechnology Co. Ltd.

Featured Presentation

- 8:40 **The Future of Monoclonal Antibodies – How Should We Approach It?**
 Abstract not available at time of print. Please visit www.IBCLifeSciences.com/China for updates.
William Strohl, Ph.D., Vice President, Biologics Research, Biotechnology Center of Excellence,
Centocor

Development of Biologics/Biosimilars in China

- 9:10 **Development History of Licartin, a I-131 Labeled Anti-CD147 Launched in China for Liver Cancer**
 Abstract not available at time of print. Please visit www.IBCLifeSciences.com/China for updates.
Xiaochun Chen, President, Pacific Meinouke
- 9:40 **EGFR mAb Development : 10 Year Development Efforts**
 Abstract not available at time of print. Please visit www.IBCLifeSciences.com/China for updates.
XianHong Bai, Ph.D., Chief Executive Officer,
Beijing Baitai Biotech Co.
- 10:10 *Networking Refreshment Break and Opening of Exhibit & Poster Hall*
- 10:45 **Etanercept and Beyond: Developing High Quality Bioproducts for the Emerging Markets**
 Abstract not available at time of print. Please visit www.IBCLifeSciences.com/China for updates.
Zeling Cai, Ph.D., Senior Vice President,
Shanghai Celgen Biopharmaceuticals Co. Ltd.



Group Bonus

Register groups of 3 or more and save up to US\$475 or RMB 2,625 off the standard rates.

Clinical & Regulatory Summit

Hutchison Medipharma, Ltd.

11:45 Opportunity and Challenge of Global Clinical Trials in a Dynamic Regulatory Environment

Most large phase III registration trials require global participation. Currently, the regional and country specific regulatory requirements are very challenging. This talk will examine the opportunities for Asia countries, opportunities for Chinese study centers as well as for Chinese local CROs.

Oliver Kong, M.D., MPH, Senior Director, Clinical R/D Oncology, Celgene Corporation

12:15 FIH Study in China: from IND Application to Study Completion

First-in-human study is a critical step to translate scientific findings during discovery stage into potential clinical application. With more and more firms establishing an R&D center in China, it is worthwhile to exam the status of FIH study in China, including SFDA regulations, GCP center performance and its development in near future, safety handling issue and IRB consideration.

Dan Zhang, M.D., MPH, Co-Founder & CEO, Fountain Medical Development

12:45 Networking Luncheon with Exhibit & Poster Viewing

1:55 Chairperson's Remarks

Dan Zhang, M.D., MPH, Co-Founder & CEO, Fountain Medical Development

2:00 Phase IIB Clinical Study of Sifuvirtide in China

For combination therapy with other antiretroviral agents in IIB clinical trial, Sifuvirtide could substantially improve the efficacy over traditional treatment after 24 week. The rate of undetectable viral loads for Sifuvirtide group is 59% better. Injection site reaction is 7% for Sifuvirtide comparing 98% for T20.

Jingzong Qi, Ph.D., Vice President, Business Development, FusoGen Pharmaceutical, Inc.

2:30 Creating Readiness for Global Trials in China

Abstract not available at time of print. Please visit www.IBCLifeSciences.com/China for updates.

Juan Qiao, Ph.D., Director of Clinical Sciences, Primary Care Business Unit, Pfizer (China) R&D Center

3:00 Long-Term Strategy to Ensure Persistent Clinical Research Development in China

In China, we have already about 20 year's operation experience on conducting global clinical studies. Recently, as always, changes come to the clinical research arena very frequently, working environments both internally and externally have been changed; sponsor operation strategy changed a lot as well. How to maintain a persistent development and overcome the current challenges is key to our future business success.

Jennifer Huang, Research Director, Global Clinical Trial Operation, MSD China

3:30 Networking Refreshment Break with Exhibit & Poster Viewing

Discovery to PreClinical Development & Partnerships

11:45 Drug Discovery in China, an IMPACT Perspective

The flagging productivity in the pharmaceutical R&D is largely due to disconnection between in vitro and in vivo evaluation of both drug-likeness and pharmacological properties; as well as disconnection between preclinical and clinical significance. The presentation will be focused on a new business model with successful cases.

Haijun Dong, Ph.D., President & CEO, IMPACT Therapeutics, Inc.

12:15 Strategies for Drug Discovery and Development in China

To reduce risk and maximize return on investment, we have implemented a novel strategy that enables us to significantly abbreviate the timeline for drug discovery and development processes. Examples will be given to illustrate our model for drug development in China.

Xinqiang Li, Ph.D., President, Sunwei Therapeutics (Suzhou), Inc.

12:45 Networking Luncheon with Exhibit & Poster Viewing

1:55 Chairperson's Remarks

Canwen Jiang, M.D., Ph.D., Vice President & Head of R&D Asia, Genzyme

2:00 Drug Discovery, Is China Ready?

Argusina is developing NCEs for type 2 diabetes and obesity. Harnessing drug discovery expertise from the US and the talent pool in China, we have developed a unique model to bring innovation to the global drug discovery arena.

Kanyin E. Zhang, Ph.D., Vice President and General Manager, Argusina (Shanghai) Ltd.

2:25 Discussion on the New Drug R&D Circumstance and Pattern in China

This talk will present the effect of R&D circumstance and policy on drug innovation, how to create new drug development pattern in China in the coming "golden decade" of the 12th five-year plan, and the introduction of some successful cases.

Zhan Li, Ph.D., MBA, General Manager, Nanjing Changao Pharmaceutical Science & Technology Co., Ltd.; Executive Director, C&O Pharmaceutical Technology (Holdings) Limited; Chairman of the Board, Shanghai Sun-Sail Pharmaceutical Science & Technology Co., Limited

2:50 Long Term Sustained Release Formulation of a Novel Dopamine Receptor Agonist – A Potential Continuous Dopaminergic Simulation for the Treatment of Parkinson's Disease

In the de novo patient it is believed that providing a more continuous dopaminergic stimulation (CDS) from the start of antiparkinson therapy may prevent priming for motor fluctuations and dyskinesia. But there is no available formulation of CDS in the clinic application, except infusion, up to date. Long term sustained release system of the microspheres has the potential to offer CDS treatment of Parkinson's patients.

Youxin Li, Ph.D., Vice President, R&D, Luye Pharma Group Ltd.

3:15 Innovative Drug Discovery Efforts in TOT RD Center

TOT RD Center focuses on developing cancer gene therapy/immune therapy technology and products, especially developing new oncolytic virus products. In this talk, the efforts and rationale of current oncolytic virus projects in TOT RD Center will be discussed.

Min Liang, Ph.D., General Manager, TOT Shanghai RD Center Co., Ltd.

3:40 Networking Refreshment Break with Exhibit & Poster Viewing

Biologics & Biosimilars Development

11:15 Research & Development of TPO – An Innovative Biopharmaceutical Product – in China

This talk will present the 3S Bio's strategy on how they choose their drug target and candidate in a rational way, and how they have executed the R&D of the candidate with strong technical and financial support to become a truly innovative biopharmaceutical product in China.

Yingfei Wei, Ph.D., Chief Scientific Officer, Shenyang Sunshine Pharmaceuticals

11:45 Interleukin 7 Receptor: A New Therapeutic Target Using a Biological Approach for the Treatment of Inflammatory Disease

Abstract not available at time of print. Please visit www.IBCLifeSciences.com/China for updates.

Hongtao Lu, Ph.D., Head & Senior Director, Neuroimmunology Drug Discovery Performance Unit (DPU), GlaxoSmithKline

12:15 Oral Insulin: Beyond Convenience

Oral insulin is considered the crown jewel of biopharmaceutical delivery and is the business focus of NOD Pharmaceuticals. The presentation summarizes current status of oral insulin development on a global stage and illustrated the different challenges facing the oral insulin project compared with insulin injections. The experiences and lessons of developing oral insulin in China are updated and shared.

William Lee, Ph.D., Chief Executive Officer, NOD Pharmaceuticals, Inc.

12:45 Networking Luncheon with Exhibit & Poster Viewing

Clinical Development Strategies for Biologics in China

2:00 Challenges in Registration of Biological Products in China

Abstract not available at time of print. Please visit www.IBCLifeSciences.com/China for updates.

Rong Chen, M.D., Ph.D., Head of Regulatory Center of Excellence, GlaxoSmithKline China/HK

2:30 Strategy for Anti-Drug Antibody (ADA) Detection in Non-Clinical and Clinical Safety Evaluation of New Biologics

In nonclinical/clinical studies, most biologics elicit some level of anti-drug antibody (ADA) response, which might affect PK and PD profiles, and lead to potentially serious side effects or loss of efficacy. Therefore, the immunogenicity is one of the major concerns during R&D of biologics. Herein, strategy and approaches for ADA testing are discussed.

Haifeng Song, Ph.D., Professor, Department of Pharmacology & Toxicology, Institute of Radiation Medicine, Academy of Military Medical Sciences

3:00 Development of Cell Therapy in China

To ensure patients' safety and evaluate the effectiveness of cell therapies, the Ministry of Health has led the government's efforts to establish a regulatory framework. Compared to the cell therapy regulations established in the US, EU and Japan, however, the regulations and their reinforcement are still evolving. For example, autologous cell therapy, regulated as a new medical technology in China, represents challenges for both development and commercialization. We will briefly discuss the current regulations in the US and share our experience in China.

Canwen Jiang, M.D., Ph.D., Vice President & Head of R&D Asia, Genzyme

3:30 Networking Refreshment Break with Exhibit & Poster Viewing

Keynote Presentations (Shared Session for all 3 Conferences)

4:00 **Chairperson's Remarks and Introduction of Keynotes**

Tony Zhang, Ph.D., Vice President, Global External R&D, Asia, Eli Lilly & Co.

4:05 **Emerging Markets and R&D Partnering**

David Nicholson, Ph.D., Senior Vice President, Worldwide Licensing and Knowledge Management, Merck Research Laboratories

4:35 **Innovation in Protein Therapeutics Research and Development**

Clive R. Wood, Ph.D., Senior Vice President, Head of Global Biologics, Bayer Healthcare

5:05 **How to Introduce the Concept of "Change" in Biopharmaceuticals**

Sam Waskal, Ph.D., Chairman & CEO, Kadmon Pharmaceuticals

5:35 **Cocktail Reception in Exhibit & Poster Hall**

Tuesday, April 12, 2011

Plenary Session: Transformation & Innovation in China

8:45 **Chairperson's Opening Remarks and Introduction of Keynote Speaker**

Xian-Ping Lu, Ph.D., CEO & Chief Scientific Officer, Shenzhen Chipscreen Biosciences, Ltd.

8:50 **Keynote to be announced**

9:20 **Panel Discussion:**

Dialogue Between the Stakeholders of Innovation in China – Where Does Innovation Originate From? Locally or Globally?

- Chinese government's innovation initiatives
- Chinese government's investment in biotechnology firms in 12th – 5 year planning phase
- Role of MNCs in business growth/innovation in China
- How can MNCs and domestic companies bridge the gap and leverage on each other's expertise, funding and resources?
- How can MNCs assist in innovation initiatives by domestic companies?

Moderator:

Kewen Jin, M.D., General Manager, Preclinical Services, Charles River Laboratories Greater China

Panelists:

Xian-Ping Lu, Ph.D., CEO & Chief Scientific Officer, Shenzhen Chipscreen Biosciences, Ltd.

Frank Jiang, M.D., Ph.D., Vice President & Head, Asia Pacific R&D, Sanofi-Aventis

Charles Hsu, Venture Partner, Bay City Capital LLC

10:20 **Networking Refreshment Break with Exhibit & Poster Viewing**

10:50 **Panel Discussion:**

Transformation & Innovation: Moving Up the Value Chain

- What's the next stage for China's life sciences industry?
- What are the pros and cons of the different approaches of global pharma?
- How can China transform itself and expand from manufacturing and service to product and technology innovation?
- Lessons learned from other industries
- Global pharma R&D Productivity challenge and how China can help?

Moderator:

Steve Yang, Ph.D., Vice President, Head of R&D, Asia, Pfizer Global Research & Development

Panelists:

Robert Armstrong, Ph.D., Vice President, Global External Research, Eli Lilly

Bin Li, Ph.D., Executive Director, Senior Equity Research Analyst, China Healthcare, Morgan Stanley

George Baeder, Senior Partner, Monitor Group

Li Chen, Ph.D., Chief Executive Officer, Hua Medicine

12:00 **Showcase: IBC-BayHelix Class of 2010**

ASLAN Pharmaceuticals - An Asia-Enabled Pharmaceutical Company that Develops Novel Medicines for Global Markets

Carl Firth, Ph.D., MBA, Chief Executive Officer, ASLAN Pharmaceuticals

Hua Medicine – An Innovator's Approach to Accelerated Development

John Choi, M.D., Ph.D., Co-Founder and Chief Strategy & Business Officer, Hua Medicine

Moderator: **Li Chen, Ph.D.**, Chief Executive Officer, Hua Medicine

Trans-Pacific Biotech Company Delivering Best-In-Class Therapeutics

Sofie Qiao, Ph.D., President, CEO & Co-Founder, LinQ Pharmaceuticals, Inc.

Additional presenters to be announced. To present in the Showcase, please contact Mimi Langley at mlangley@ibcusa.com

12:30 **Networking Luncheon in Exhibit & Poster Hall with Presentation of 2nd Annual IBC-BayHelix China Pharma R&D Awards**

- China Scientific Discovery of the Year Award
- China Drug Discovery of the Year Award
- China R&D Award

Moderator: **Tony Zhang, Ph.D.**, Vice President, Global External R&D, Asia, Eli Lilly & Co.

Clinical & Regulatory Summit

1:55 **Chairperson's Opening Remarks**

Zhengqing Li, Ph.D., Vice President, China Clinical Research, Bristol-Myers Squibb

Real World Evidence Studies

2:00 **Patient Chart Review for CML in China**

This talk highlights the process of conducting an epidemiological study for CML among 15 hospitals in China in 2006-2007. Data from real world practice can help to enhance clinical guidelines while conducting such a study can help to foster good engagement with local thought leaders in the respective disease areas in China. Epidemiological studies in China can generate real world data not only for outcomes research, but also as background information for regulatory filing.

Hong Li, Ph.D., Group Director, Global Health Economics & Outcomes Research, Bristol-Myers Squibb Company

Discovery to PreClinical Development & Partnerships

1:55 **Chairperson's Opening Remarks**

Stella Xu, Ph.D., Executive Director, Roche Partnering, Shanghai Roche (R&D) Center

Creating Value through Partnerships

2:00 **Drug Discovery R&D in China: Opportunities and Challenges**

To fully capitalize on the initial investment and turn China into a RED (research and early development) hub for global MNCs, several hurdles need to be overcome, especially in the early clinical development area. This lecture will highlight these challenges and opportunities.

Mingqiang Zhang, Ph.D., FRSC, Chief Technology Officer and Vice President of External Innovation, Roche Research and Early Development, China

Biologics & Biosimilars Development

1:55 **Chairperson's Opening Remarks**

Guoliang Yu, Ph.D., President & CEO, Epitomics, Inc.

Strategies & Success Stories of Biologics Development Internationally

2:00 **Endosialin/TEM1 Targeting via MORAb-004 Antibody: a Novel Anti-Tumor Stroma Approach**

Studies have found endosialin to play a key role in tumor growth and neovessel formation in numerous cancer types. We are currently evaluating the therapeutic efficacy of MORAb-004, a human monoclonal IgG targeting TEM-1, in a Phase I clinical trial. In the presentation, target validation, preclinical models and potential MOA of the antibody will be discussed.

Yuhong Zhou, Ph. D., Senior Director of Antibody Development, Morphotek, Inc.

Clinical & Regulatory Summit

- 2:30 **Conducting HE&OR Studies in China: Novartis Experience**
Abstract not available at time of print. Please visit www.IBCLifeSciences.com/China for updates.
Jennifer Sung, Executive Director, Global Health Economics & Outcomes Research, Novartis Pharmaceuticals
- 3:00 **Real World Evidence Study in China**
RWE data plays a big role in exploring the standard treatment, identifying the unmet medical needs and giving advice to the payer etc. It is a key component of the product life cycle management plan. Considering that the current China healthcare database system is not well developed, pharmaceutical companies are facing a daunting challenge when designing and conducting high quality RWE studies.
Helen Lin, MBA, Medical Science & Medical Affairs Director, R&D, AstraZeneca China
- 3:30 **Networking Refreshment Break and Last Chance for Exhibit & Poster Viewing**

Clinical Pharmacology, Safety & Pharmacovigilance

- 4:00 **Clinical Pharmacology in New Drug Innovation: Science-Driven Programs and Study Designs**
 - Key clinical pharmacology questions addressed for development of an NCE in the West
 - China Regulation pertaining to clinical pharmacology and real-life experiences
 - Future opportunities**Hequn Yin, Ph.D.**, Director, Oncology Clinical Pharmacology, Novartis Pharmaceuticals
- 4:30 **Safety Monitoring of Clinical Trials in General and in China**
Developmental risk management plan should be prepared with the first-in-man study and continue throughout the clinical development program. As drug safety is an evolving science in China, a concerted effort by the academia, SFDA and industry is required to ensure patient protection and quality safety data collection from clinical trials conducted in the country.
Rebecca Wang, M.D., FRCP, FACC, Head, Product Safety Operation, Asia Pacific, Shanghai Roche Pharmaceuticals, Ltd.
- 5:00 **How to Develop Risk Management Plan in Clinical Trials in China**
China SFDA issued Special Review Procedure in 2009 to encourage the innovation and control the risk effectively during the drug development in China. According to this procedure, Risk Control Plan (Risk Management Plan) is required when the sponsor submits the clinical trial application in China. This presentation will cover the SFDA's requirement on risk management plan, the sharing of practices and challenges, etc.
Xiaojun Guo, M.D., Senior Patient Safety Manager, R&D China, AstraZeneca
- 5:30 *Close of Day Two*

Discovery to PreClinical Development & Partnerships

- 2:30 **Simcere's R&D: International Collaboration as a Major Strategy**
Abstract not available at time of print. Please visit www.IBCLifeSciences.com/China for updates.
Peng Wang, Ph.D., Chief Scientific Officer, Simcere Pharmaceuticals
- 3:00 **Sponsored Presentation Available**
IBC's Sponsored Presentations offer supplier and service companies the opportunity to present product and service offers directly to the audience at the conference. For more information, contact: US/Europe: Sherry Johnson, sjohnson@ibcusa.com Asia Pacific: Kell Yang, kell.yang@ibcasia.com.sg
- 3:30 **Networking Refreshment Break and Last Chance for Exhibit & Poster Viewing**
- 4:00 **Partnering for Success: an Overview of Pfizer's External R&D Innovation Strategy and Asia Initiatives**
World leading pharmaceutical and biotech companies are attracted to China for a variety of partnership opportunities to leverage the country's strong basic research, talented scientific staff, and large patient pools. This talk will discuss biomedical R&D landscape in China, opportunities and challenges as well as Pfizer's strategy in building up R&D capability in China.
Yuan-Hua Ding, Ph.D., Senior Director & Head of External R&D Innovation - Asia, Pfizer Inc
- 4:30 **AstraZeneca's Approach to Drug Discovery & Development in China**
The wave of MNCs setting up R&D centers in China is intensifying, although no two centers are same in strategy and operation model. Our experience in Shanghai for the last four years will be shared in pursuing parallel approaches with both in house research capabilities and external collaborations for new drug R&D.
Richard Wang, Ph. D., MBA, Director, Strategic Alliance Asia & Portfolio and Operation Management, Innovation Center China, AstraZeneca Global R&D
- 5:00 **Partnering a Chinese Local Company with a Licensing and Co-Development Model: Providing FDA Standard Clinical Data in China for NDA in Both FDA and SFDA.**
To reduce the licensing fees and to take advantage of the low cost structure for R&D and the abundance of patient population in China, this presentation will introduce an efficient model that we have created, and which have made several successful deals. We will especially highlight a well-known case of in-licensing a FDA phase III potential blockbuster for stroke from Israel by partnering with a Chinese local company to provide FDA-standard clinical data in China for NDA in both FDA and SFDA.
Allan Riting Liu, M.D., Ph.D., M.B.A., Vice President, Wanbang Biopharmaceuticals; Director of Business Development, Fosun Pharmaceutical Group
- 5:30 *Close of Day Two*

Biologics & Biosimilars Development

- 2:30 **High Affinity Mirror-Image Oligonucleotides (Spiegelmers) as Alternatives to Antibodies in Drug Development: Clinical Data on MCP-1 Inhibitor NOX-E36 and SDF-1 Inhibitor NOX-A12**
Using its proprietary drug discovery platform NOXXON has identified mirror-image oligonucleotides (Spiegelmers) against MCP-1 (NOX-E36) and SDF-1 (NOX-A12). Both compounds demonstrated an exceptional safety profile in regulatory toxicity studies and in multiple ascending dose Phase I studies. An update on clinical experience with Spiegelmers will be presented.
Sven Klussmann, Ph.D., Chief Scientific Officer, NOXXON Pharma AG, Germany
- 3:00 **The Story of Abgenix: from Xenomouse to Panitumumab and Beyond**
Abgenix was a highly successful biopharmaceutical company and created enormous value by successfully making the transition from its technology focus into a fully integrated product development company. Its success sets a precedent and role model for developing and executing innovative business models and strategies in the biotech industry.
Xiaodong Yang, M.D., Ph.D., President & CEO, Apexigen Inc.
- 3:30 **Networking Refreshment Break and Last Chance for Exhibit & Poster Viewing**
- 4:00 **Strategy for Cost-Effective Development of Biosimilar Monoclonal Antibodies for Rapid Introduction to Emerging Market**
This presentation will review cell line platforms, process development and optimization, regulatory filing practice for commercially viable mAbs beyond R&D applications, in an attempt to develop a sound strategy for rapid introduction of mAbs to one of the most promising emerging market, namely China. Moreover, a unique business model designed to enter the market with cost-effective biosimilar products will be discussed.
Steven S. Lee, Ph.D., Chief Executive Officer, A-Bio Pharma Pte. Ltd., Singapore

Development of Cell Therapy

- 4:30 **Production of Therapeutic Proteins in the Milk of Transgenic Animals**
GTC has developed a platform for the efficient and cost-effective production of protein therapeutics in the milk of transgenic animals. The platform received regulatory validation when transgenically produced ATryn (recombinant human antithrombin) was approved in Europe and in US. This talk will present GTC's experience in producing a variety of therapeutic proteins from the milk. We will discuss the low cost, high capacity nature of this production method that is well suited for developing biosimilars for large markets.
Li-How Chen, Ph.D., Senior Director, R&D, GTC Biotherapeutics
- 5:00 **Peptide Therapeutics & Peptide API Manufacturing in China/Asia**
As a third party approved peptide CMP/CRO, many CPC's products are currently under Phase I/II/III clinical trials in US, Japan and Europe. CPC also participates in many NCE from China and passed PAI inspection for Leuprolide.
Shawn Lee, Ph.D., President & CEO, CPC Scientific, Inc.
- 5:30 *Close of Biologics & Biosimilars Development*

Clinical & Regulatory Summit

- 8:50 **Chairperson's Opening Remarks**
Li Ding, MSc., Head of Trial Operations-China & Asia Pacific, Clinical Science & Operations, **Sanofi-Aventis**

Global Simultaneous Development

- 9:00 **Panel Discussion:**
Global Simultaneous Development and Bridging of China Data with Global Data

Moderator:

Frank Shen, Ph.D., Asia Pacific Head of GPD Biometrics, **Roche Global Products Development Asia Pacific**

Panelists:

William Wang, Ph.D., Associate Director, Biostatistics and Research Decision Sciences, **Merck & Co., Inc.**

Simon Day, Ph.D., Statistical Expert, Statistics Methods and Research, **Roche Products Limited, United Kingdom**

Bob Powell, Ph.D., Scientific Advisor, **Roche Shanghai R&D Center**

Ruiping Dong, M.D., Ph.D., Senior Vice President, Head of Emerging Markets R&D, **Merck Research Laboratories**

Ling Su, Ph.D., Senior Vice President and Head of Development Greater China, **Novartis Pharma**

- 10:30 *Networking Refreshment Break*

Clinical Site Management & Operations

- 11:00 **Site Management and Monitoring in the New Healthcare Environment**

Investigator sites involved in clinical trial activities must be managed and monitored to ensure that the activities are performed in compliance with the protocol, all applicable operating guidelines and study plans, with GCP, the applicable regulatory requirements, and the basic principles of Operational Quality Standard. We will discuss the changes in healthcare environment and the impact on site management and monitoring practice.

Li Ding, MSc., Head of Trial Operations-China & Asia Pacific, Clinical Science & Operations, **Sanofi-Aventis**

- 11:30 **Collaborations between East-West Laboratories for Better Regulatory Compliance during Drug Discovery & Development**

Pharmaceutical industry has led global initiatives to develop consensus around acceptable benchmark practices applicable to standardizing laboratory and good management systems for regulated R&D programs. Collaboration between West and East has become increasingly important for the quality of data, implementations, and products approved for public use by regulatory agencies.

Michael Zhou, Director, Bioanalytical Chemistry/DMPK, Synta Pharmaceuticals

- 12:00 **A New Integrated CRO Model for Managing Pharmaceutical Trials in Asia**

This presentation will present a new integrated approach to working with CROs, which offers cost and structural benefits. This case study will also examine the new roles implemented in clinical operations in Asia.

Donald Russell, Ph.D., Senior Director, International Clinical Operations, **Eli Lilly & Co.**

- 12:30 *Close of Clinical & Regulatory Summit*

Discovery to PreClinical Development & Partnerships

- 8:50 **Chairperson's Opening Remarks**
Gene Hsu, Ph.D., DABT, Deputy Director, National Shanghai Center for New Drug Safety Evaluation & Research

Toxicology & DMPK Challenges

- 9:00 **Benefits and Challenges of Conducting PreClinical Safety Study in China: Perspective from a Drug Development Company**

The preclinical development in China has been established and rapidly progressed during last several years. Recently, the pharmaceutical companies and CROs continue to make solid progress in China and are moving into conducting late stage drug development studies, such as GLP toxicity study, to support the clinical trials and drug registration. This presentation will focus on illustrating the benefits and challenges of conducting preclinical toxicity study in China and discuss the strategies or solutions of overcoming some of these challenges based on the working experiences with different preclinical CROs.

James Yan, Ph.D., M.D., DABT, Executive Director, Head of Drug Safety Evaluation, **Hutchison MediPharma Ltd.**

- 9:30 **Adventuring into Preclinical Development in China**

GLP concept has been implemented in a fast pace in China. As one of the critical paths, pivotal preclinical data are expected to be generated from qualified CROs in China to support MNC's regional and global new drug submission. For small pharma, quality preclinical data are also highly valued to gain international acceptance. In today's Chinese preclinical arena, however, there are still lots of challenges to tackle such as the shortage of trained professionals, ICH guideline implementation, and acceptance with OECD MAD.

Yi Yang, M.D., Ph.D., Head of PreClinical Safety, China R&D, Director of Drug Safety Evaluation, **sanofi-aventis China**

- 10:00 **Sponsored Presentation Available**

IBC's Sponsored Presentations offer supplier and service companies the opportunity to present product and service offers directly to the audience at the conference. For more information, contact:
 US/Europe: Sherry Johnson, sjohnson@ibcusa.com
 Asia Pacific: Kell Yang, kell.yang@ibcasia.com.sg

- 10:30 *Networking Refreshment Break*

Creating Value through Partnerships II

- 11:00 **Challenges Of Selecting a Preclinical CRO for Your Multi-National IND Submissions**

- What are the challenges
- What are the choices of Chinese CROs?
- Are these Chinese CROs GLP-compliant in terms of western standards?
- Should you outsource your preclinical studies to a Chinese CRO? If so, why. If not, why not.

Gene Hsu, Ph.D., DABT, Deputy Director, National Shanghai Center for New Drug Safety Evaluation & Research

- 11:30 **Taiwan Biotech's Collaborations with China Companies**

An overview of Taiwan's biotech industry will be presented. The content of the presentation includes: current status of biotech development in Taiwan, Taiwan's biotech policy & promotion status, Diamond action plan for biotech takeoff, recent accomplishments of Taiwan's biotech industry, and Taiwan biotech's collaborations with China companies.

Chia-Lin J. Wang, Ph.D., President, Development Center for Biotechnology, **Taiwan**

- 12:00 **Innovative Strategies for Accessing External Innovation: GSK's Experience**

Abstract not available at time of print. Please visit www.IBCLifeSciences.com/China for updates.

Paul B. Bolno, M.D., MBA, Vice President, Worldwide Business Development, Head of Asia, **GlaxoSmithKline**

- 12:30 **Partnering with Eli Lilly**

Eli Lilly and Company is a global pharmaceutical company with extensive capabilities and expertise in the development of small and large molecule. This presentation will discuss Lilly's evolving strategies in identifying outstanding partners around the globe to discover, develop and commercialize innovative medicines that improve patient outcomes.

Yetunde Taiwo, Ph.D., Senior Director, Global External R&D, **Eli Lilly & Co.**

- 1:00 *Close of Discovery to PreClinical Development & Partnerships*



Call for Posters: Deadline March 11, 2011

Limited space is available for poster presentations at this event. If you have new results/data on topics relevant to this conference, we encourage you to submit a poster abstract for consideration. To present a poster, complete the conference registration form and submit poster title and one page poster abstract online at www.IBCLifeSciences.com/China. See registration form for poster fees.

About the Conference Organizers



IBC Life Sciences, a division of Informa Plc, leads the market in providing quality, expert-led conferences and courses; delivering the expert knowledge our clients need to excel in their professional roles and guaranteeing a competitive advantage for their organizations. Our diverse portfolio covers the most critical topics and areas within the life sciences including Analytical, Biologicals, Bioprocessing, Diagnostics, Discovery/R&D, Formulation/Delivery, Manufacturing, Pre-Clinical/Clinical, Process Development, QA/QC/Safety, and Regulatory/Validation.

Since IBC Life Sciences launched the China Pharmaceutical R&D Summit in 2006, it has emerged as THE leading high-level pharmaceutical business conferences in China, with attendance and participation of over 300 very senior executives every year from many top tier companies including Roche, Eli Lilly, Merck, AstraZeneca, GSK among others.

This is the one event that's endorsed by the industry leaders in China, and has proven year after year to bring together top level executives and scientists to discuss and explore global pharma's vision for China, its future growth, and its influence and impact on global pharma industry. It is also a place for scientists and executives to get together to seek opportunities for collaboration, find out where the latest academic innovation points towards, and figure out the latest regulations with regards to clinical trials, NCE discovery & development, biologics/biosimilars and other pertinent development.



BayHelix is a non-profit, invitation-only organization for business leaders of Chinese heritage in life sciences and healthcare. Founded in 2001 in San Francisco, it has more than 250 members in North America and the Greater China area. Its members are experienced and influential business professionals, entrepreneurs, venture investors, senior company executives, or academic leaders. The group holds frequent networking events, advises government bodies, and organizes conferences for the missions of creating business opportunities and nurturing the ecosystem for life science innovation across the Pacific Rim and beyond.

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Plenary Sessions and Overall Program

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Tony Zhang, Ph.D., *Vice President, Global External R&D, Asia, Eli Lilly & Co.*

Xian-Ping Lu, Ph.D., *CEO & Chief Scientific Officer, henzhen Chipscreen Biosciences, Ltd.*

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Li Chen, Ph.D., *Chief Executive Officer, Hua Medicine*

Clinical & Regulatory Summit

Ruiping Dong, M.D., Ph.D., *Senior Vice President, Head of Emerging Markets R&D, Merck Research Laboratories*

Maria Song, Ph.D., M.D., R. Pharmacist, M.A., *President, VPS-CRO Group*

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Li Ding, MSc., *China Site Head, Clinical Data Management, sanofi-aventis*

Frank Shen, Ph.D., *Asia Pacific Head of GPD Biometrics, Roche Global Products Development Asia Pacific*

Dan Zhang, M.D., MPH, *Co-Founder & CEO, Fountain Medical Development*

Discovery to PreClinical Development & Partnerships

Seymour Mong, Ph.D., *Independent Consultant*

Canwen Jiang, M.D., Ph.D., *Vice President & Head of R&D China, Genzyme*

Zhengyu Yuan, Ph.D., *President & CEO, MicuRx Pharmaceuticals, Inc.*

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Stella Xu, Ph.D., *Executive Director, Roche Partnering, Roche (Shanghai) R&D Center*

Kewei Wang, Ph.D., M.D., *Changjiang Professor, Neurobiology, Neuroscience Research Institute, Peking University School of Medicine*

Biologics & Biosimilars Development

Chris Chen, Ph.D., *Chief Executive Officer, Shanghai Kanda Biotechnology Co. Ltd.*

Guo-Liang Yu, Ph.D., *President & CEO, Epitomics. Inc.*

Steven Lee, Ph.D., *Chief Executive Officer, A-Bio Pharma Pte. Ltd.*

China Pharmaceutical R&D Summit is the Longest Standing International Conference in China

A Look at Our Past History and Highlights...

2010

We tackled the topics of restructured models and emerging market strategies due to global recession and expiring patents; explored the impact of China's recently announced Healthcare Reform; dug into the latest scientific achievements to come out from the academic labs, and discussed how China is transforming itself into a clinical trial hub of the region.

2009

China is now the #1 choice for pharmaceutical companies' globalization efforts. It is also the year where the financial crisis reverberated around the world. This year's Summit grounded the audience with examples and strategies on innovative R&D, legal and regulatory improvements; initiatives from government and industry sectors; as well as new areas for investment and innovative R&D.

2008

The turning point in China's life sciences industry. China has arrived. Companies cannot afford not to have a "China Strategy". The Summit turns its focus on the various R&D developments in China - NCE discovery & preclinical development; clinical research in China; biologics and bio-betters; TCM-based drug discovery etc.

2007

We focused on the integration of China into the global strategy and examined how companies are leveraging drug discovery partnerships in China to stay ahead of the competition; reviewed the intricacies of clinical trials in China as well as offer a first glimpse of the rise of biotechnology in China and its unique business models.

2006

The Summit looked at China's biopharma opportunities from the angles of global alliances and partnering, corporate strategies and operating models, demystifying the landscape as well as offering a showcase of Chinese companies available for strategic partnerships. Additional topics such as IP and investment are also of great interest at that time.

2nd Annual IBC-BayHelix China Pharma R&D Awards

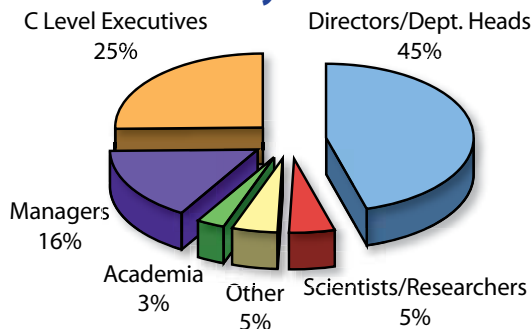
IBC Life Sciences and BayHelix Group are pleased to host the 2nd Annual IBC-BayHelix China Pharma R&D Awards in honor and recognition of individuals and companies who have contributed to the advancement of China's pharmaceutical industry.

The following 3 Awards will be presented at the China 2011 Pharmaceutical R&D Summit, on Tuesday April 12, 2011 during the Luncheon:

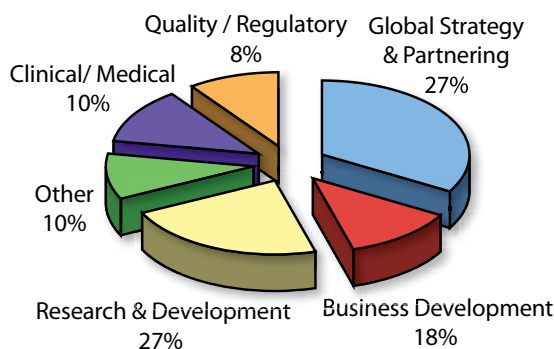
- **IBC China Scientific Discovery of the Year Award:** recognizing the most significant discovery in life science in China
- **IBC China Drug Discovery of the Year Award:** recognizing the most significant achievement in new drug R&D milestones
- **IBC China R&D Award:** recognizing outstanding individuals whose contributions changed the landscape, reputation, and ecosystem for drug R&D in China

For more information or to nominate candidates for the awards, please visit www.IBCLifeSciences.com/China

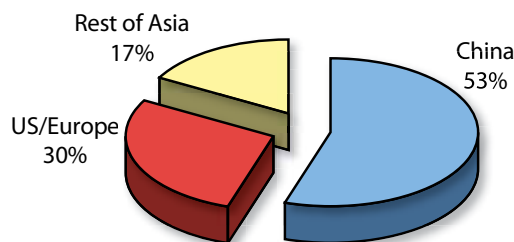
Attendees by Job Function



Attendees by Department



Attendees by Geographic Distribution



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Keynote Presentations

Emerging Markets and R&D Partnering

David Nicholson, Ph.D., *Senior Vice President, Worldwide Licensing
and Knowledge Management, Merck Research Laboratories*

Innovation in Protein Therapeutics Research & Development

Clive R. Wood, Ph.D., *Senior Vice President, Head of Global Biologics, Bayer Healthcare*

How to Introduce the Concept of "Change" in Biopharmaceuticals

Sam Waskal, Ph.D., *Chairman & CEO, Kadmon Pharmaceuticals*

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