Join distinguished speakers from innovators, generics and regulators, including:

Dr Qian Jia, Vice President, NCPC R&D Center, China
Dr Chun-Ming Rao, Principal Scientist, NICPBP, SFDA, China
Dr Takao Hayakawa, Senior Advisor, PMDA, Japan
Dr Shyam S. Bishen, Vice President, Corporate Development, Ranbaxy, USA
Dr Yining Zhao, Senior Director, Strategic Planning, Biotherapeutics Division, Pfizer Inc, USA
Dr Steve Chang, President, CCSB, Taiwan
Dr Chris Chen, Chief Operating Officer, Shanghai Celgen Biopharmaceuticals, China
Dr Dhananjay Patankar, Chief Technology Officer, Intas Biopharmaceuticals, India
Dr Timothy Hove, VP and Assoc General Counsel, Sanofi Pasteur, USA
Dr James Lu, President, Regenex, China
Dr Scott Liu, President and CEO, Henlius Biopharmaceuticals Inc and Shanghai Henlius Biotech Co. Ltd, China
Dr Wassim Nashabeh, Senior Director, Pharma Technical Regulatory, Genentech, A Member of the Roche Group, USA
Dr Branimir Brankov, Senior Director, Strategic Business Intelligence, Merck & Co Inc, USA
Dr Hardy W. Chan, Executive Vice President and CSO, ScinoPharm Taiwan Ltd., Taiwan
Dr Qin Yuan, Vice President, R&D & Business Development, Shenzhen Main Luck Pharmaceutical, China
Dr Zheru Zhang, Director, Analytical Development - R&D Centre, Celltrion, Korea

Gather the latest global regulatory updates, discuss development strategies and explore partnership opportunities!

- Understand the latest global developments in biosimilars and uncover upcoming opportunities
- Access key regulatory and scientific concerns impacting biosimilars and FOB approvals in global markets
- Gain critical strategies and insights into biosimilar investments
- Learn about the dynamics of Asian markets and the progress of registered biosimilars
- Examine commercialisation strategies in regulated, semi-regulated and unregulated markets
- Identify and develop strategic alliances to expand your biosimilars business
- Assess the legal and operational hurdles in developing and marketing biosimilars globally

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31 May – 1 June 2010
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IBC has a global track record of consistently attracting senior decisions makers from the biopharmaceutical industry for deal-making and networking. Product & service exhibitions are also key activities in our program. The Biosimilars Asia Summit delivers a targeted audience consisting of existing and potential investors and manufacturers of biologics for maximum networking and branding opportunities. Leverage on our marketing campaign and secure your onsite presence with a number of lead-generating, networking, and branding packages including:

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**Biosimilars Asia 2010 Summit**

"Of the US$70 billion global biopharmaceutical segment, US$40 billion will genericise over the next five years... Abbreviated pathways will require an R&D investment of at least US$50 million per biogeneric."  

Kiran Mazumdar Shaw, CEO, Biocon

Of the US$70 billion global biopharmaceutical segment, US$40 billion will genericise over the next five years... Abbreviated pathways will require an R&D investment of at least US$50 million per biogeneric.  

"I believe this bill will lead to healthy competition and long-term savings for patients and payers, and will preserve innovation in the biotech marketplace... this bill guarantees that FDA has the scientific discretion to hold these drugs to the same high standard to which the original products are held. The only way we can succeed in establishing robust competition for biotech drugs is with biosimilar drugs that doctors and patients know they can count on."  

Rep Henry A. Waxman, Chairman of the House Energy and Commerce Committee

Today, total sales of off-patent biologics amount to approximately US$20 billion, of which Asia is the primary market, accounting for 34% of sales. This number is expected to increase considerably, opening up investment opportunities for both pharmaceutical and generic companies.

However, the dynamics of biosimilars presents a greater challenge than classic generics, requiring significant investments and risks, forcing producers to make careful selections on protein classes, building up new competencies and developing new models for cooperation. In general, the main differentiators for leaders in the biosimilars market will be safety, efficacy and convenience of their products and to a lesser extent the price of their drugs.

IBC’s Biosimilars Asia 2010 Summit is the ONLY premium industry conference offering you unprecedented insights from leading companies on how they plan to build the capabilities required to succeed in the biosimilar arena. From marketing first generation Follow On Biologics to developing antibody biosimilars, learn how they -- and you -- can plan your growth strategy to bring new products to market more quickly.

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**Biopharmaceutical Patent Expirations**

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Source: Technology Catalysts International. ©2010 (used with permission)

**Markets with Highest Potential for Biosimilar Penetration**

![Graph showing markets with highest potential for biosimilar penetration]

Source: Business Insights Survey

**Development of Chinese Biopharmaceutical Market, 2001-2006**

![Graph showing development of Chinese biopharmaceutical market]

Source: National Statistics Bureau of China; BioPlan Associates
1100 Assessing and Adapting Strategies for Different Markets Globally

Innovative Molecules, Fast Followers, Biosimilars and BioBetters – Which Strategy is Best For Which Markets?

Dr Branimir Brankov, Senior Director, Strategic Business Intelligence, Pfizer Inc, USA

1140 Developing Biosimilars In Regulated/Semi-Regulated And Unregulated Markets

There will never be a harmonized global market for biosimilars due to the differences in regulations, economic development, market demand, access and reimbursement. Companies have to allocate their resources and operate based on local conditions. What are the requirements, key considerations and possible pitfalls to avoid in achieving commercial success with biosimilars across different markets?

Dr Branimir Brankov, Senior Director, Strategic Business Intelligence, Merck & Co Inc, USA

1220 Bringing Biosimilars To Global Markets

Aside from regulatory challenges, what are the major obstacles facing biosimilars in entering markets globally? Pricing and reimbursement strategies, especially in emerging markets. Strategies for bidding on government or hospital tenders. Gaining acceptance from physicians and patients can be challenging. The role of partners and distributors when expanding to new markets.

Moderator: Alexander Meyer auf der Heyde, Partner - Pharmaceuticals & Medical Products, Accenture Ltd., China

Panelists:
- Dr Branimir Brankov, Senior Director, Strategic Business Intelligence, Merck & Co Inc, USA
- Dr Yining Zhao, Senior Director, Strategic Planning, Biotherapeutics Division, Pfizer Inc, USA
- Dr Shiyam S. Bishen, Vice President, Corporate Development, Ranbaxy, USA
- Dr Chris Chen, Chief Operating Officer, Shanghai Celgen Biopharmaceuticals, China

Monday 31 May 2010
CONFERENCE DAY 1
1300 Networking Luncheon

1400 Regulatory Landscape & Biosimilars Approvals

1435 Development Of Approved Biosimilars In China: A Comparison With The EU & US

Dr Chun-Ming Rao, Principal Scientist, Division of Biopharmaceuticals, National Institute for the Control of Pharmaceutical and Biological Products (NICPBP), SFDA, China

1510 Japan’s PMDA Biosimilars Guideline: Entering Asia’s Largest Pharmaceutical Market

Dr Takao Hayakawa, Senior Advisor, PMDA, Japan

1545 Afternoon Refreshments

1615 How Did We File the First Biosimilars in Japan?

In November of 2008, JCR Pharmaceutical and Kissei filed for the approval of Japan’s first biosimilar therapeutic, a recombinant human erythropoietin for the treatment of renal anaemia in dialysis patients. This session will share with you the experience and lessons learned from the approval process in the largest Pharmaceutical market in Asia.

Dr Timothy Howe, VP and Assoc General Counsel, Sanofi Pasteur, USA

1650 Status of the US Regulatory and Legislative Landscape for Biosimilars

Dr Dhananjay Patankar, Chief Technology Officer, Intas Biopharmaceuticals, India

1725 When And Will The Floodgates Open On The US Biosimilars Market?

Biosimilar approval pathway in US: When will it eventually happen? Action plans – What should you do today to best outline your future in the US market?

Moderator: Kevin McCable, Director, Stern, Kessler, Goldstein & Fox PLLC, USA

Panellists:
- Dr Timothy Howe, VP and Assoc General Counsel, Sanofi Pasteur, USA
- Dr David X. Gu, Pharmaceutical Practice Group, McKinsey & Co., USA
- Dr Scott Liu, President and CEO, Henlius Biopharmaceuticals Inc and Shanghai Henlius Biotech Co. Ltd
- Dr Chun-Ming Rao, Principal Scientist, Division of Biopharmaceuticals, National Institute for the Control of Pharmaceutical and Biological Products (NICPBP), SFDA, China
- Dr Timothy Howe, VP and Assoc General Counsel, Sanofi Pasteur, USA
- Dr Dhananjay Patankar, Chief Technology Officer, Intas Biopharmaceuticals, India

1800 Closing Remarks by Conference Chairman & End of Conference Day 1
1200  Forging New Alliances: Generic – Innovator Partnerships
- Collaborations between pharma, biotech and generics – is this the preferred way forward?
- Assessing the pros and cons of each party and defining the responsibilities in the partnership
- What will be the new models for cooperation between generics and innovators?
  Dr Qian Jia, Vice President, NCPC R&D Center, China

1300  Networking Luncheon

1400  Development Of Biobetters For Regulated Markets
BioBetters can be created by glycosylation, PEGylation, carboxylation (to protect from enzyme degradation), protein engineering for better safety and efficacy, cell line engineering to improve yield, enhanced purity for higher safety, formulation and delivery, better disease models, comparative immunogenicity and validation of biomarkers as surrogate endpoints. This presentation will match each strategy to a launched biological to define a pathway to a competitive BioBetter.
  Dr Dhananjay Patankar, Chief Technology Officer, Intas Biopharmaceuticals, India

1435  Data Protection And Timing The Launch Of Biosimilars Relative To Patent Expirations
Data protection is a more complex issue for biologics than for small molecules as biosimilar applications establish similarity to, rather than identity with, the innovator’s brand product.
  - How long should biosimilar manufacturers wait to enter the market by relying on the innovator’s data with an abbreviated application?
  - Unlike small molecule drugs where patent protection focuses on drug composition, biologics may have more patents relating to process, which may be extensive, more complex, and difficult to defend. How can manufacturers ensure that a biosimilar is similar enough to win FDA approval through an abbreviated pathway, yet different enough to evade patent infringement?
  - Is it possible and how can a biosimilar win approval and be launched prior to expiration of innovator patents?
  Kevin McCabe, Director, Stern, Kessler, Goldstein & Fox PLLC, USA

1500  Clinical Development Strategies For Biosimilars
- How to determine the budget and timeline required to develop/market biosimilars
- Besides bioequivalence, what else is required to ensure compliance with regulatory requirements?
- What are the main considerations and provisions for drug safety management and pharmacovigilance?
- Antibody biosimilars - key challenges and possible strategies employed?”
  Dr Jeffrey J. Freitag, Senior Vice President, PharmaNet Consulting, USA

1545  Afternoon Refreshments

1615  From Dream To Reality: The Real-Life Battle For Recognition Of Therapeutic Equivalence
- How will similarity be defined and tested – what standards will the FDA set?
- Achieving therapeutic equivalence with non-inferior clinical outcomes to overcome originator propaganda to physicians and patients
  Peter Simpson, Chairman, Biogenerics Australia Pty Ltd
Comparability During Monoclonal Antibody Biosimilar Development

There is much interest in developing monoclonal antibody biosimilars in Asia, which makes the analytical testing and characterization for demonstrating comparability of biosimilars to the reference product critical. In this session, a case will be shared about comparability studies of a monoclonal antibody biosimilar, which includes in-depth physicochemical and biological analyses to define the development target, continuous comparison and a final comparability exercise for confirmation of achieved similarity.

Dr. Zheru Zhang, Director, Analytical Development - R&D Centre, Celltrion, Korea

Who Should Attend Biosimilars Asia 2010

By Industry


By Job Title

VPs, Directors & Heads of:

- Follow on Biologics/ Follow on Proteins/ Biosimilars
- Biologics/ Biotechnology/ Biogenerics
- Legal Affairs/ Intellectual Property
- Health Economics
- Pricing and Reimbursement
- Biopharmaceuticals/ Biotherapeutics
- Clinical Immunology
- Process Control and Analytical Technologies
- Analytical Characterisation
- Regulatory Compliance
- Pharmacovigilance
- Drug Safety & Risk Management
- Quality Affairs/ Quality Control
- New Product Development
- Process Science
- Portfolio Management
- Research & Development
- Business Development
- Scientific Affairs
- Commercial Affairs
- Marketing

Attendee Profile

Pharmaceutical Companies/ Biotech Firm 35%
CMOs/CROs 7%
Academic Institutes /Governments 18%
Business Consultants 10%
Lawyers 3%

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Who Should Attend

The workshop has been designed for personnel in Product Development, Regulatory Affairs, Quality Assurance / Quality Control, Manufacturing and Engineering

Workshop Overview

This workshop presents a brief introduction to FDA inspections that are conducted in accordance with the FDA Pre-Approval Inspection Program. It highlights a number of activities that are normally performed well in advance of the PAI inspection. A review is made of the Biologics License Application (BLA) and Supplemental Biologics License Application (sBLA) process. Described are the strategies that may be followed to ensure that facilities and personnel are prepared to respond to the pre-approval and post approval inspection activities in accordance with the FDA Compliance Programs 7346.832 and 7346.843

The workshop will break the PAI down into three major phases; Preparation, During and Post Inspection. Strategies are proposed for the management of each phase to ensure facility and personnel readiness.

Preparing for FDA Pre-Approval Inspections on Biological Products

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Workshop Outline

The workshop will review the following areas:

- BLA and sBLA review process
- How to prepare for the inspection
- Managing the inspection
- Simple Do’s and Don’ts
- What happens next (following the inspection)

About Your Workshop Leader

Scott S. Liu
PhD, President and CEO
Henlius Biopharmaceuticals Inc and Shanghai Henlius Biotech Co. Ltd

Scott has 18 years’ experience in biologics R&D, cGMP quality operations, and CMC regulatory affairs.

After obtaining a Ph.D. degree in biological science and training in Purdue and Stanford, Scott joined UBI Company as a R&D director. He subsequently managed IND submission for immunotherapy peptide and QA/QC operation for GMP production of human biologics. In 2003, he joined BMS as Associate Director of Biologics Quality Control and then Amgen as Director of Quality Analytical Labs. He was a key member of the CMC teams involved in the late-phase development and commercialization of two recently approved (by FDA and EMEA) biologics.

Scott founded Henlius Biopharmaceuticals in Feb 2009 and later on set up a JV with Shanghai Fosun Pharma for development and commercialization of biosimilars and bio-betters.
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Fee includes luncheons, refreshments and complete set of documentation. It does not include the cost of accommodation and travel.

REGISTRATION CANCELLATIONS/SUBSTITUTION

Should you be unable to attend, a substitute delegate is welcome at no extra charge. Cancellations must be received in writing at least 10 business days before the start of the event, to receive a refund less 10% processing fee per registration. The company regrets that no refund will be made available for cancellation notifications received less than 10 business days before the event.