2ND ANNUAL
BIOSIMILARS
APAC SUMMIT

2 – 3 November 2016 » Mandarin Orchard Singapore

KEY CONFERENCE THEMES:

Commercialisation & Investment Schemes of Biosimilars
Legal Hurdles & Intellectual Property Protection
Biosimilars vs. Biobetters
Advances in Biosimilar Production & Technologies
Biosimilar Comparability & Interchangeability
Upstream & Downstream Process Development

2016 NEW SPEAKERS INCLUDE:

Paul Song
Vice President and Head of Cell Engineering Team, Samsung Bioepis, South Korea

Edward Madden
Head of Legal (Global), Biosimilars, Biogen, Switzerland

Srinivasan Raman
Vice President & Head of Malaysia Operations, Biocon Sdn Bhd, Malaysia

Anita Patil
Group Leader for Biopharmaceutics Formulation Development, Wockhardt, India

Hee-Kyoung Spiritas Cho
Assistant Professor of Law, Hongik University, South Korea

Daniel Furtner
Senior Medical Manager, Therapeutic Area Lead Rheumatology & Biotherapeutics Japan-Asia-Pacific Global Medical Affairs, AbbVie, Singapore

Alok Sharma
Assistant Director, Analytical Development, Biotech Division, Lupin Limited, India

Ikhsan Rambia
Regulatory Affairs Manager, Business Development Team, Sanbe Farma, Indonesia

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Legal Hurdles & Intellectual Property Protection

14:10 Non-traditional Strategies for Protecting Intellectual Property for Biopharmaceutical Enterprises
- Border measures under TRIPS Agreement
- World Trade Organisation (WTO) dispute resolution process
- Protection under bilateral investment treaties

Hee-Kyoun Spiritas Cho, Assistant Professor of Law, Hongik University, South Korea

14:50 Overcoming the Legal Hurdles in Launching Biosimilars
For more information about this session, kindly visit www.biosimilarsapac.com

15:30 Afternoon Networking & Refreshment Break

Biosimilars vs. Biobetters

16:00 Biosimilars & Biobetters: Ongoing Legal Issues Impacting Market Access
- The patent hurdle – truth vs reality: Are patents really an obstacle to the emergence of biosimilars?
- Developing a saleable product: A lawyer’s view of the commercial landscape and the impact of onerous regulatory pathways on product viability
- Emerging legal issues and what the future holds for biosimilar and biobetter development and uptake
- Legal issues affecting approval, market access and commercialisation of products

Edward Madden, Head of Legal (Global), Biosimilars, Biogen, Switzerland

16:40 Is it More Prudent to Develop a Biobetter Rather than a Biosimilar or Vice Versa?
- Considering the time and investment in developing a biobetter as well as a different regulatory approval process
- Under what circumstances should companies consider biobetters and what circumstances should they consider biosimilars?

Panelists:
Hee-Kyoun Spiritas Cho, Assistant Professor of Law, Hongik University, South Korea
Anita Patil, Group Leader for Biopharmaceutics Formulation Development, Wockhardt, India

17:20 Chairperson’s Summary & End of Conference Day One
Upstream & Downstream Process Development

14:00 Upstream Process Development Tools for Biosimilar Production
- How to produce biomolecules as similar to the original molecules?
- Retaining high product quality as the original molecule
- Achieving consistency in biosimilar manufacturing by reducing raw material variability
  
  For more information about this session, kindly visit www.biosimilarsapac.com

14:40 Challenges in Biosimilar Monoclonal Antibody Cell Culture Process

15:20 Afternoon Networking & Refreshment Break

16:00 What’s Next for the Biopharma Industry in Asia Pacific?
Share your ideas, ask questions, listen to each suggestion and bring back to the office the key takeaways from this session
- What are your anticipated concerns and pitfalls?
- The road forward – what needs to be done?
  
  For more information about this session, kindly visit www.biosimilarsapac.com

17:00 End of Main Conference

**Advances in Biosimilar Production & Technologies**

09:10 Process Analytical Technology (PAT) for Biosimilars Development
- Concept of PAT
- Statistical methods
- Process Analytical Methods and associated software
- Discussing different applications
  
  Anita Patil, Group Leader for Biopharmaceutics Formulation Development, Wockhardt, India

- Our approach and experience with development of biosimilars
- CHEF1 expression technology
- Process optimization to achieve biosimilarity
  
  Torben P. Frandsen, Ph.D., Vice President, Process Development, CMC Biologics A/S, Denmark

**Biosimilar Comparability & Interchangeability**

11:00 Biosimilar Interchangeability & Substitution – Clinical Considerations
- Does biosimilarity imply interchangeability?
- Considerations on potential switch scenarios
- Current evidence on non-medical switching
  
  Daniel Furtner, Senior Medical Manager, Therapeutic Area Lead Rheumatology & Biotherapeutics Japan-Asia-Pacific, Global Medical Affairs, AbbVie, Singapore

11:40 Implementing Comparability Studies for Biosimilars
- Challenges in comparability studies
- Data requirements for comparability exercises
- Residual uncertainties
  
  Alok Sharma, Assistant Director, Analytical Development, Biotech Division, Lupin Limited, India

12:20 Comparative Data of Follow-on Biologics/Similar Biological Medical Product of Antibody Drug
  
  For more information about this session, kindly visit www.biosimilarsapac.com

13:00 Networking Lunch

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**Register Today!**

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Asia Pacific is developing more biosimilar products currently than anywhere else in the world and leading to a wealth of opportunities for investigators and patients interested to take part in biosimilars. In addition, the region has increasing demand due to the growing prevalence of chronic diseases. Collaboration with local players is proven as the key opportunity for Biosimilars in Asia Pacific economies. IBC’s 2nd Annual Biosimilars APAC Summit discusses the market readiness and future uptake of Biosimilars development of regulatory frameworks, best practice commercialisation strategies, and advancement of processes with focus on drug substance.

**TOP REASONS TO ATTEND**

- Gain in-depth knowledge from key regional players on their perspectives on APAC biosimilar investment and opportunities
- Evaluate Biosimilars market access in regulated and less regulated markets
- Understand the latest regulatory development and strategies to align your business goals
- Learn the innovative and cost effective approach in biosimilar development
- Find out what are the new and existing technologies and research done to speed up improvement of drug substance
- Insights on key success factors in a win-win partnerships and investment opportunity in Asia Pacific

**“Great experience; able to network well and get updated on current industry practices on Biosimilars. Was able to understand development in different geographies and learn best practices!”**

~ Regional Regulatory Affairs Manager, Sanofi

**WHO SHOULD ATTEND**

**INDUSTRIES**
- Innovator Pharma MNCs, Biologics, Biotechnology, Pharmaceuticals 35%
- Generics & Biosimilars Companies 20%
- CRAMS/ CMOs, CROs 20%
- Biopharma Technology & Solution Providers 15%
- Drug Regulators, Healthcare Agencies, Government Departments 5%
- Patent/IP Lawyers/Business Consultant 5%

**GEOGRAPHY**
- Singapore, Malaysia and Rest of South East Asia 60%
- North Asia 15%
- Australia, New Zealand 10%
- Europe, US 10%
- Rest of the World 5%

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