5th Annual Biosimilars Conference

Innovations, developments, and controversy- what the future holds?

19th - 21st October 2009, BSG Conference Centre, London, UK

BOOK NOW!

Key Speakers

Ray Cresswell, VP R&D Legal Operations, **GlaxoSmithKline**

Dr. Michael Muenzberg, Global Head of Medical Affairs, **Sandoz International GmbH**

Vinay Ranade, CEO, **Reliance GeneMedix**

Rasmus Rojkjaer, Vice President, Head of Global Biologics R&D, **Mylan GmbH**

Dr. C Jane Robinson, Principal Scientist, Biotherapeutics, **National Institute for Biological Standards & Control (NIBSC)**

Dr. David Goldsmith, Consultant Nephrologist, **Guy's Hospital and St Thomas' NHS Foundation Hospital**

Tommy Erdei, CFA, Executive Director, Healthcare Banking, **UBS Investment Bank**

Dr Frank Moffatt, Product Manager Biopharmaceutical and DNA Analysis, **Solvias**

Jo Pisani, Partner, **Pricewaterhousecoopers**

Ashish Menocha, Head of International Markets, **Abdi Ibrahim**

Cecil Nick, Vice President (Biotechnology), **Parexel Consulting**

Dr. Daryl Fernandes, Chief Executive, **Ludger**

Gerben Moolhuizen, Chief Business Officer, **OctoPlus N.V.**

Mateja Urlep, Director, **TikhePharma**

Keith Powell, CEO, **Polytherics**

Duncan Curley, Director, **Innovate Legal**

Pre conference Workshop, Monday 19th October 2009

Understanding the developing biosimilars framework in the United States and European Union

led by: Daniel A. Kracov, Partner and Chair, FDA and Healthcare Practice, David R. Marsh, Partner and Co-Chair, Intellectual Property Practice and Lincoln Tsang, Partner from Arnold & Porter LLP

Media Partners

pharmiweb.com BIOTECHNOLOGY - EUROPE FUTURE PHARMACEUTICALS InPharm.com

To Book Call us at: +91 22 2757 8668 / 2757 9438 | www.bharatbook.com

Conference Introduction

5th Annual Biosimilars Conference
19th – 21st October 2009, London, UK

'By 2024, total revenues for biosimilars will reach $45.46bn'

Dear Colleague,

The biological drug market is one of the fastest growing sectors of the pharmaceutical industry which corresponds to over 15% of the total pharmaceutical market. However, due to the patent expiry of many drugs, and increasing pressure from government, insurers and patient advocacy groups to reduce expenditure a number of opportunities for biosimilars have been created.

The biosimilars market is currently highly fragmented with many favorable circumstances for new or potential market entrants. With conducive regulatory developments, the biosimilars sector should pick up significantly; forming an important developing pharma market. With the new bills being passed, this is the time for progress.

Following the success of our previous Biosimilars conferences with high attendance and positive feedback, we are happy to announce the 5th Annual Biosimilars Conference. This event aims to provide a detailed analysis of the recent developments in the current market and regulatory environment for biosimilars. Join us to learn, network, benchmark against the strategies and participate in our open discussions and provide your valuable inputs.

Why Attend?

- Examine the key issues for development of biosimilars regulations
- Gain a clearer insight on how US environment differs from Europe
- Discover the acceptance criteria for immunogenicity of biosimilars
- Discuss the legal and regulatory considerations for clinical trials
- Analyse the emerging partnerships between big pharma and smaller biosimilars companies
- Investigate the factors affecting biosimilars market access
- Network and discuss ideas with the leaders in the field

I look forward to meeting you at the conference
Best regards

Pranita Nangia
Conference Producer

Media Partners:

PharmiWeb.com is the leading industry-sponsored portal for the pharmaceutical sector. Supported by most of the leading pharmaceutical corporations, PharmiWeb.com provides dynamic real-time news, features, events listings and international jobs to industry professionals across Europe and the US.

For further information please email: corporate@pharmiweb.com

BIOTECHNOLOGY EUROPE is owned by BIOTECHNOLOGY WORLD. It is based and located in Warsaw, Poland. Biotechnology World was founded in 2007 to provide the world's biotech and pharma information and market to make it universally accessible and useful for scientific and business processes. Its first step to fulfilling that mission was building the BIOTECHNOLOGY EUROPE platform that will allow a quick spread of information in different channels. BIOTECHNOLOGY EUROPE offers companies completed internet public relations, publication and marketing solutions. One of the mains goals of BIOTECHNOLOGY EUROPE is to integrate the Biotech and Pharma Sector in Europe to global biotechnology, pharmaceutical and life science activities.

For further information please visit www.biotechnology-europe.com

Future Pharmaceuticals has forged powerful relationships with key industry leaders to provide a platform for successful brand recognition, and for senior decision-makers to have the means to procure and plan implementation strategies based on the topics covered. Positioned to be an authoritative resource within top pharma companies as well as small, specialty, and biotech, Future Pharmaceuticals magazine is geared to create a deep penetration into a highly targeted and responsive audience, bridging the gap between the industries' top issues and the solutions top-tier vendors can provide.

For further information please visit: www.futurepharmaus.com

InPharm is the online platform for exclusive pharmaceutical news, comment, contracts, services, jobs and events and is home to InPharmjobs.com, Pharmafile and Pharmafocus.

For further information please visit: www.In-Pharm.com

Biosimilars and Follow-On Biologics Report:
The Global Outlook 2009-2024

Who should attend?

Branded Biotechnology, Pharmaceuticals & Generic Pharmaceutical Companies, Drug Regulators, Healthcare Agencies, Government Departments, Contract Research/Bio manufacturing, Organisations, Regulatory Affairs, Pharmacovigilance

VPs, Directors, Heads, Managers of:

- Follow on Biologics/Follow on Proteins/Biosimilars
- Biologics/Biotechnology/ Biogenerics
- Legal Affairs
- Intellectual Property
- Health Economics
- Pricing and Reimbursement
- Biopharmaceuticals/ Biotherapeutics
- Clinical Immunology
- Principal Scientist
- Chief Scientific Officer
- 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
- Business Operations
- Scientific Affairs
- Commercial Affairs
- Marketing

Sponsorship and exhibition opportunities:

This event offers a unique opportunity to meet and do business with some of the key players in the pharmaceutical and biotech industries. If you have a service or product to promote, you can do so at this event by:

- Hosting a networking drinks reception
- Taking an exhibition space at the conference
- Advertising in the delegate documentation pack
- Providing branded bags, pens, gifts, etc.

If you would like more information on the range of sponsorship or exhibition possibilities for 5th Annual Biosimilars Conference, please contact us:

Bharat Book Bureau
207, Hermes Atrium, Sector , PO Box.54, CBD Belapur, Navi Mumbai - 400 64, India.
Phone :+9 22 2757 66 / 2757 943
Fax :+9 22 2757 93
E-mail :info@bharatbook.com
Website :www.bharatbook.com

Pre-Conference Interactive Workshop

5th Annual Biosimilars Conference
Monday 19th October 2009, London, UK

Understanding the developing biosimilars framework in the United States and European Union

Led by:

Daniel A. Kracov, Partner and, Chair, FDA and Healthcare Practice, **Arnold & Porter LLP, Washington D.C.**

David R. Marsh, Ph.D., Partner and Co-Chair, Intellectual Property Practice, **Arnold & Porter LLP, Washington, D.C.**

Lincoln Tsang, Ph.D., Partner, **Arnold & Porter LLP, London**

Timings: 09:30 - 10:00 Coffee & Registration
10:00 - 15:00 Workshop

Timing includes lunch and refreshment breaks

Agenda:

Session 1 by Daniel A. Kracov : Overview of U.S. biosimilars legislation: FDA standards, processes and exclusivity

This session will look at the standards and mechanisms for biosimilar licensure under pending legislation (or statute if enacted).

- Biosimilars application review processes
- Requirements for FDA guidance
- Standards for biosimilar and interchangeability determinations
- Data requirements and FDA waiver authorities
- Exclusivity for innovator biologics
- Exclusivity for interchangeable biosimilars
- Nomenclature for biosimilars
- Potential innovator and biosimilar strategies

Session 2 by David R. Marsh: Biosimilar patent issues

This session will examine the mechanisms for handling patent disputes in pending legislation (or statute if enacted), and the impact on biotech patent litigation.

- Processes for handling biosimilar patent disputes
- Impact on strategies for innovator biologic product patenting, patent disputes and resolution
- Potential biosimilar patent strategies
- Potential changes in the biologic product patent litigation dynamic

Session 3 by Lincoln Tsang: Comparing the developing US framework to biosimilars in the EU

This session will provide an overview of the EU framework for biosimilars, including:

- Key differences in the developing US and EU biosimilar framework and pathways
- Biosimilars exclusivity and patent issues in the EU
- Applications and data requirements for EU biosimilars
- Experience to date under the EU biosimilars framework
- Developing global innovator and biosimilar strategies

About: Arnold & Porter LLP

ARNOLD & PORTER LLP

Arnold & Porter LLP is an international law firm with nearly 700 attorneys practicing worldwide in more than 25 practice areas spanning a broad spectrum of the law, with a primary focus on litigation, transactional matters, and regulatory issues. Our attorneys, many of whom have previous government agency experience, routinely counsel pharmaceutical, biotechnology, medical device, and diagnostic companies, as well as other healthcare entities, in responding to complex legal challenges in the US and Europe. Arnold & Porter professionals work together to provide our clients with seamless, comprehensive, and sophisticated analyses, and strong and zealous advocacy.

For further information, please visit: www.arnoldporter.com

About your workshop leaders:

Daniel A. Kracov

Dan Kracov heads the FDA and healthcare practice. He assists clients, including start-up companies, trade associations, and large manufacturing companies, in negotiating the challenges relating to the development, approval and marketing of drugs, biologics, and medical devices. His experience in US Food and Drug Administration (FDA) strategic advice and crisis management won him a spot on the Fall 2005 Legal Times list of "Leading Lawyers in Food & Drug Law."

Mr. Kracov regularly handles product and compliance-related investigations, the development of regulatory corporate compliance programs, and due diligence in financings, mergers and acquisitions. He has a widely-recognized experience in biomedical product-related public policy matters, including Congressional investigations and FDA-related legislative strategies.

David R. Marsh

Dr. David Marsh is co-chair of Arnold & Porter's intellectual property practice. He focuses extensively on intellectual property counseling, interferences and patent procurement, predominantly in the chemical, pharmaceutical, and biotechnology areas. He has argued multiple matters before the United States Patent and Trademark Office's Board of Patent Appeals and Interferences. He also manages multiple European Opposition proceedings, and represents clients in patent and other intellectual property litigation or dispute resolution proceedings. Dr. Marsh is also an American Arbitration Association and World Intellectual Property Organization neutral arbitrator. As an adjunct professor at Georgetown Law School, Dr. Marsh teaches "Biotechnology and Patent Law." He has also written numerous articles on patent law, is a frequent speaker at conferences in the US and Europe, and is an editor of BioScience Law Review. The Legal Timesrecognized Mr. Marsh as a "Leading Life Sciences Lawyer in Washington, DC" for 2006. He was ranked by Practical Law Companies Cross-border Life Sciences Handbook 2006/2007 as "Highly Recommended in Patent Counselling" and "Recommend in Intellectual Property" in both Washington, DC and in the USA. He is also a Fellow of the Royal Society for the encouragement of Arts, Manufactures and Commerce.

Dr. Marsh carried out his graduate work in molecular biology at Cambridge, England and his post-doctoral work at Yale University. His research experience includes molecular biology, immunology, biochemistry, and mammalian and plant genetics.

Lincoln Tsang

Dr Lincoln Tsang is a partner in the firm's London office. He is both a lawyer and a registered pharmacist with post-graduate qualifications in toxicology and biochemistry. His practice relates to life sciences industry including pharmaceuticals, biotechnology, medical devices, in vitro diagnostic devices, cosmetics and food with particular emphasis on the intersection of the law and public policy relating to life sciences. He assists clients in developing strategies for research and development including product life cycle management, product acquisition, risk and crisis management.

In addition to advising industry, Dr Tsang also advises foreign governments, various trade associations and not-for-profit and/or charity organizations. He maintains an active pro bono practice. He presents and writes widely on regulatory law and public policy.

Day 1

5th Annual Biosimilars Conference
Tuesday 20th October 2009, London, UK

09:30 Registration and refreshments

10:00 Opening address from the chair

10:10 Opportunities and challenges for biosimilars in the global market

- Commercial drivers for the biosimilar market
- Competition faced by potential biosimilars from second-generation products
- Impact of pricing strategies of originator products

Jo Pisani
Partner
Pricewaterhousecoopers

10:50 Attractiveness of next generation biosimilars or similar

- Latest advantages in biological research
- Examining the key dynamics of future biosimilars

Rasmus Rojkjaer
Vice-president, Head of Global Biologic
Mylan

11:30 Morning refreshments

11:50 Biosimilars meeting the challenges & lessons learned

- Economic factors market potential
- Status of regulations EUR & USA
- Risks - biologics versus small molecule drugs
- Comparability - CMC Quality - Case studies
- Lessons learned

Dr Frank Moffatt
Product Manager Biopharmaceutical and DNA Analysis
Solvias

12:30 EU legal framework for biosimilars

- Examining the legal basis for generics and biosimilars in the EU
- Specific guidelines for EU product
- Comparison of EU and US law on biosimilars

Ray Cresswell
VP R&D Legal Operations
Glaxosmithkline

13:10 Networking lunch

14:30 Development of biosimilar medicines - intellectual property issues

- Originator patent landscapes for biologicals
- The importance of process patents
  - method of use patents
  - supplementary protection certificates
  - upcoming patent and SPC expiries

Duncan Curley
Director
Innovate Legal

15:10 Emerging partnerships between Big Pharma and smaller biosimilars companies

Ashish Menocha
Head of International Markets
Abdi Ibrahim

15:50 Afternoon refreshments

16:10 Differentiating between biosimilars and innovators' biopharmaceutical products by their glycosylation patterns

- How innovators and designers of biosimilars can enhance their drugs by engineering glycosylation
- How designers of biosimilars can avoid infringing innovators' patents that involve glycosylation
- How to demonstrate comparability of glycosylation between different drugs
- What potential buyers should consider regarding biopharmaceutical glycosylation when choosing between an innovator's drug and biosimilars or follow-on biologics

Dr. Daryl Fernandes
Chief Executive
Ludger

16:50 Biosimilar Erythropoietins - Challenge vs opportunity

- Assessing the opportunities in biosimilar erythropoietins
- Discussing the recent applications for biosimilar erythropoietins

Dr David Goldsmith
Consultant Nephrologist
Guy's Hospital and St Thomas' NHS Foundation Hospital

17:30 Closing remarks from the chair

17:35 17:35 Networking Drinks

Take your discussions further and build new relationships in a relaxed and informal setting.

Day 2
5th Annual Biosimilars Conference
Wednesday 21st October 2009, London, UK

09:30 Registration and refreshments

10:00 Opening address from the chair

10:10 Analysing the global biosimilars market

- Identification of the most important biologic drugs with potential for commercial biosimilar development
- Examination of strengths, weakness, opportunities and threats facing major stakeholders in the industry

Mateja Urlep
Director, **Tikhe Pharma**
Former Global Head of Marketing and Medical, **Sandoz**

10:50 Use of bioassays for testing biosimilars

- Regulatory requirements for bioassays
- Logistical and scientific issues
- Why bioassays are particularly problematic
- Examples of bioassays used for approved biosimilars

Dr. C Jane Robinson
Principal Scientist, Biotherapeutics
National Institute for Biological Standards & Control

11:30 Morning refreshments

11:50 Presentation to be announced

Tommy Erdei
CFA, Executive Director, Healthcare Banking
UBS Investment Bank

12:30 Biosimilars: Applying EU lessons to new targets, new challenges in a global market

- Key lessons from the EU experience
- Is the prevailing view of biosimilarity too narrow?
- The challenges of monclonal biosimilars
- Formulating a global biosimilar program
- Ingredients for success

Cecil Nick
Vice President (Biotechnology)
Parexel Consulting

13:10 Networking lunch

14:30 Biosimilars and pharmacovigilance

- The EMEA Biosimilar Pathway allows a submission with less clinical data compared to the originator - e.g. no Phase II data required
- The Pharmacovigilance Programme of a Biosimilar does not differ in complexity from an originator
- The Post Approval Commitments are a massive burden for the manufacturers of Biosimilars

Dr. Michael Muenzberg
Global Head of Medical Affairs
Sandoz International GmbH

15:10 All potential biosimilars are under threat from improved products

- Interferon alpha – longer dosing interval /improved activity/reduced side effects
- EPO – Cost of goods reduction
- Interferon beta – Cost of goods and as for alpha
- GCSF – A ready made biobetter

Keith Powell
CEO
Polytherics

15:50 Afternoon refreshments

16:10 Biosimilar, biobetter, biosuperior: how to differentiate follow-on biologicals with controlled release technology

- The added value of drug delivery technologies for follow-on biologicals
- What are the success factors for effective long-acting drug delivery?
- Phase II clinical proof of concept case study

Gerben Moolhuizen
Chief Business Officer
OctoPlus

16:30 Emerging biosimilars opportunities in Asia

- Whats are the challenges?
- What are the advantages of outsourcing the development of biosimilars?

Vinay Ranade
CEO
Reliance GeneMedix

17:30 Chair's closing remarks

17:40 End of Conference

* Invited

Registration Form

5th Annual Biosimilars Conference
19th – 21st October 2009, London, UK

Conference title

.....

For multiple bookings

Photocopy this form

Conf. code **BHARAT**

Standard Prices

Conference and workshop	**Fee: £1699**	**VAT: £254.85**	**Total: £1953.85** ☐
Conference only	**Fee: £1299**	**VAT: £194.85**	**Total: £1493.85** ☐
Workshop only	**Fee: £599**	**VAT: £89.85**	**Total: £688.85** ☐

Promotional Literature Distribution

Distribution of your company's promotional literature to all conference attendees

Fee: £999 VAT: £149.85 Total: £1148.85 ☐

Details

Forename: ..... Surname: .....

Job Title: ..... Company: .....

Main Switchboard Number: .....

Address: .....

.....

Country: ..... Postcode: .....

Phone: ..... Fax: .....

Email: .....

Signature: .....

I confirm that I have read and agree to the terms and conditions of booking ☐

Methods of payment

Payment must be made in sterling

By Mail: Complete and return your signed registration form together with your cheque payable to Bharat Book Bureau and send to: S.Raju, Marketing Manager, Bharat Book Bureau, 207, Hermes Atrium, Sector - 11, C B D Belapur, Navi Mumbai - 400 614, INDIA

By Fax: Complete and fax your signed registration form with your credit card details to (0091 22) 27579131

By Phone: Call us on (00 91 22) 27578668 / 27579438 with your credit card details

By Credit Card: Fill in your card details below and fax back to (0091 22) 27579131

By Bank Transfer:
ABN AMRO BANK N.V
335, MADISON AVENUE
NEW YORK.N.Y 10017
ACCOUNT NO: 661-001007341
SWIFT CODE NO: ABNAUS33
ABA No: 958
Routing No: 026009580

UNDER ADVICE TO;
ABNAMRO BANK N.V
14, VEER NARIMAN ROAD
MUMBAI-400023
SWIFT CODE NO: ABNAINBB
OUR CURRENT ACCOUNT NO: 1189883

BENEFICIARY
Name: M/s. Bharat Book Bureau International
Account No : 1189883

If you are making payment by wire transfer, please add GBP £10.00 towards bank charges.

Please debit my credit card:

☐ Access ☐ MasterCard ☐ Visa ☐ American Express

Card number: | | | | | | | | | | | | | | | | |

Expiry Date: | | | |

Security number (last 3 digits on back of credit card): .....

Signature: .....

Card Holder Name:

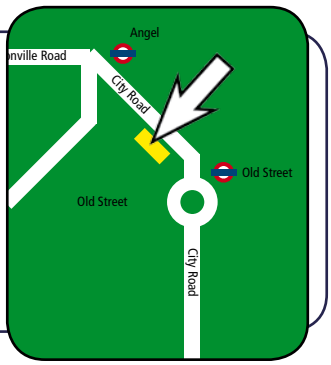
Please tick if you do not want to receive email news updates in the future ☐

5th Annual Biosimilars Conference

19th - 21st October 2009

Location: BSG Conference Centre

Address:
226-236 City Road
London
EC1V 2TT
UK



How to book

Email: raju@bharatbook.com
Web: www.bharatbook.com

Office:
Tel: (00 91 22) 27578668 / 27579438
Fax: (0091 22) 27579131

Bharat Book Bureau
207, Hermes Atrium
Sector - 11, C B D Belapur
Navi Mumbai - 400 614, INDIA

General information

Venue: Directions: BSG Conference Centre 226 – 236 City Road, London, EC1V 2TT. United Kingdom. Closest tube station is Old Street (Northern Line). Accommodation: Travelodge London City Road Hotel, 7-12 City Road, London, EC1Y 1AE, Tel: 0871 984 6333, Fax: 0207 628 2503, http://www.travelodge.co.uk/search_and_book/hotel_overview.php?hotel_id=340

Payment terms: Bharat Book Bureau require the full amount to be paid before the conference. We refuse entry to delegates who have not paid their invoice in full. A credit card guarantee may be requested if payment has not been received in full before the event. We reserves the right to charge interest on unpaid invoices.

Substitutions/name changes or cancellations: There is a 50% liability on all bookings once made, whether by post, fax, email or web. There is a no refund policy for cancellations received on or after one month before the start of the event. Should you decide to cancel after this date, the full invoice must be paid. Conference notes will then be sent to you. Unfortunately, we are unable to transfer places between conferences and executive briefings. However, if you cannot attend the conference, you may make a substitution/name change at any time, as long as we are informed in writing by email, fax or post. Name changes and substitutions must be from the same company or organisation and are not transferable between countries.

Invoice alterations: There will be an administration charge of £50 for any changes to an invoice, excluding substitutions/name changes, requested by the customer. This will be charged to the customer by credit card prior to the changes being made.

Indemnity: We reserves the right to make alterations to the conference/executive briefing content, timing, speakers or venue without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of BharatBook if such a situation arises, we will try to reschedule the event. However, BharatBook canot be held responsible for any cost, damage or expenses, which may be incurred by the customer as a consequence of the event being postponed or cancelled. We therefore strongly advise all our conference clients to take out insurance to cover the cost of the registration, travel and expenses.

Data Protection: Bharat Book gathers and manages data in accordance with the Data Protection Act 1988. Your personal information contained in this form may be used to update you on Bharat Book products and services via post, telephone, fax or email, unless you state otherwise. We may also share your data with external companies offering complementary products or services. If you wish for your details to be amended, suppressed or not passed on to any external third party, please send your request to the Database Manager, Bharat Book Bureau, 207, Hermes Atrium, Sector 11, PO Box.54, CBD Belapur, Navi Mumbai - 400 614, India.
Please allow approximately 30 days for your removal or update request to be applied to our database. Following your removal or update request, you may receive additional pieces of communication from Bharatbook during the transitional period, whilst the changes are coming into effect.

Fee: The conference fee includes lunch, refreshments and conference papers provided on the day. This fee does not include travel, hotel accommodation, transfers or insurance, (which we strongly recommend you obtain).

VAT: VAT will be charged at the local rate on each conference. Delegates may be able to recover VAT incurred by contacting Eurocash Corporation plc +44 (0) 1273 325000, eurocash@eurocashvat.com. Eurocash specialise in recovering cross-border VAT.

How we will contact you: Bharat Book's preferred method of communication is by email and phone. Please ensure that you complete the registration form in full so that we can contact you.

Unable to attend

Obviously nothing compares to being there but you need not miss out. Simply tick the box and send with your payment. You will receive your copy of the event CD Rom two weeks after the event.

Yes, please send me a copy of the CD for Price£550 VAT:£82.50 Total:£632.50 ☐

Office use only

A B C D E F G H I J K L M