

Global Bio Pharma Conference - 2004

UB University at Buffalo
The State University of New York

Emerging Issues, Challenges and Opportunities In the New Millennium for Biologicals, Pharmaceuticals, Clinical Trials and Diagnostics

Hotel Taj Land's End, Mumbai, India

September 14 – 17, 2004

The State University of New York (SUNY) and Global Bio Pharma Conference Group (GBPCG) are bringing together world class biopharmaceutical industry leaders & subject matter experts for the first time to the Indian subcontinent.

The conference consists of three days of unique biopharmaceutical, regulatory, clinical trials, and diagnostics topics with presentations by senior executives, academicians, scientists, entrepreneurs and US-FDA. This conference offers plenary and parallel sessions, panel discussions and executive business forums. It provides an excellent interface and networking opportunity with leading multinational biopharmaceutical companies, Asia-Pacific/Indian Pharmaceutical companies and US regulatory agencies as well as Indian counterparts.

Please check the website www.gbpcg.com for program, registration, sponsorship and exhibit opportunities. Do not miss the chance to attend this global event! Register immediately!

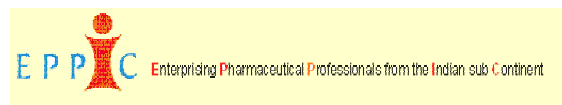
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Program

DAY 1, TUESDAY, SEPTEMBER 14, 2004

- Registration
- **Inauguration and Keynote Address by Dr. M. Venkateswarlu, Deputy Drug Controller General of India**
- Reception

DAY 2, WEDNESDAY, SEPTEMBER 15, 2004

Session 1: Plenary Session

Moderator: Dilip Shanghvi, Chairman, Sun Pharma, India

This session will address the issues of R & D productivity decline and spiraling cost for innovation and development, India and Asia-Pacific offers an alternative option. Despite the emerging new positive trends in India, availability of large talent pool as well as patient population for clinical trials, do Indian pharmaceutical companies allow to conduct quality research and development with potential for greater speed and efficiency while maintaining obvious cost-effectiveness advantages? This session will also offer how Indian and Asia-Pacific bio- and pharmaceutical companies can leverage R&D innovation from the US academic, government and industry.

Speakers:

Bruce Holm, Ph.D. Senior Vice Provost, SUNY, Buffalo, USA—"Government, Academic and Industry – at the Interface of the Pharmaceutical Future"

Rashmi Barbhuiya, Ph.D. President, Dynametics, India Ex- President, R&D; Ranbaxy, New Delhi, India - "Opportunities for Pharmaceutical R & D in India: Why

now and what to look for in developing R & D alliances"

Session 2: Opportunities & Challenges in Global Outsourcing of Biologics & Pharmaceuticals

Moderators: Ravi Pottathil, Ph.D, CEO, Accudx, USA & Hersh Mehta, Ph.D. Director, MedImmune, USA

Cost of drug development is growing at a compound annual rate of 7.3% and the average clinical phase time for new biopharmaceuticals rose from 31 months (1980s) to 74 months (2000). Therefore, outsourcing, initially a tactical tool dealing with capacity issues, is now considered a strategic business tool to maximize productivity and minimize cost and time. As a result pharmaceutical outsourcing in the US is projected to grow to \$48 billion by 2008. Drug Master Filings by Indian Pharma accounted for 19% of the world filings in 2003 as compared to only 2.4% in 1991. Global product development and increase demand for outsourcing are expected to benefit India. What business model would be mutually attractive and beneficial – Fee-for-Service or partnership? What are the key factors for successful outsourcing and in vendor/partner selection? Speakers will share their experience and vision on the topic.

Speakers:

Eric Patzer, Ph.D. President, Aridis Pharmaceuticals, USA – "Setting a Strategy for In-licensing Products and Out-sourcing R&D for a Start-up Company"

Bipin Nair, Ph D. Research Manager, MDS Pharma Services, USA – "Achieving Successful, Sustainable Relationships between CRO's & Pharmaceutical/Biotechnology Companies"

Philip Cherian, M.B.A, President, Sartorius, USA – "Macroeconomics of Outsourcing"

Woodrow Maggard, Ph.D. Technology Transfer VP, SUNY, Buffalo, USA – "University Technology Transfer and Industry Relationships"

Session 3: Advances in the R & D of Small Molecule Pharmaceuticals

Moderators: A. Sankaranarayanan, Ph.D., F.C.P. Senior Advisor (Discovery), Torrent Research Centre, India

This Session covers advances in therapeutic opportunities in small molecules.

Speakers:

A. Sankaranarayanan, Ph.D., F.C.P. Senior Advisor (Discovery), Torrent Research Centre, India

Mohan Sopori, Ph.D. Director, LRRI, NM, USA – "Therapeutic Potential of Nicotine against Inflammatory Disease"

T. Rajamannar, Ph.D. Sr. VP R&D, Sun Pharma, India – "Anti Diabetic Drugs: Dipeptidyl Peptidase IV Inhibitors- Pharmacophore Analysis"

Rama Mukerjee, Ph.D. VP, R&D, Dabur Research Foundation, India - "Nanoparticle based Delivery of Drugs"

Jamson Lwebuga-Mukasa, MD, Ph.D, Buffalo General Hospital, Dept. of Medicine, SUNY, Buffalo, USA – "Molecular Mechanisms of Asthma and COPD and Current and Future Therapeutic Opportunities"

DAY 3, THURSDAY, SEPTEMBER 16, 2004

Session 4: Advances in Bioprocess Development and Manufacturing

Moderators: Hari Pujar, Ph.D. Merck, USA & Niranjan Kumar Ph.D. EMTM, Aventis-Pasteur, USA

This session will deal with recent advances in bioprocess development and manufacturing of biologics, vaccines and therapeutic monoclonal antibodies as well as on specific issues relating to the Indian environment. Talks will cover the evolution of the Indian bioprocess capabilities from industrial enzymes to modern biologics, advances in cell culture and downstream purification operations, and process development strategy keeping future manufacturing in mind.

Speakers:

Shrikumar Suryanarayan, Ph.D. President R&D, Biocon, India, - "Fermentation based Bio-product Manufacturing in India: Enzymes, Small molecules and Biologicals. The Biocon India Experience."

Vijay Singh, Ph.D. President, WaveBiotech, NJ, USA - "Disposable Cell Culture Bioreactors for Low Cost Manufacturing".

Jay Madan, Ph.D, Millipore, USA – "Advances in Monoclonal Antibody Purification"

Hari Pujar, Ph.D. Sr. Research Fellow, Merck & Co, USA – "Process Development of Modern Vaccines"

Dhananjay Patankar, Ph.D, Intaspharma, India – "Manufacturing Perspective to Process Development".

Session 5: Emerging Issues: Patents, Compliance and Marketing in the New Era

Moderators: Mr. Prashant Tewari, Managing Director, USV Limited, India, & Preeti Loyalka-Pinto, M.S. Sr. Director Regulatory Affairs, Astra Zeneca, USA

This session will cover both the industry and US-FDA perspective on current regulatory issues in pre/post licensing, manufacturing & marketing of pharmaceuticals.

What are the current regulatory challenges for a successful development, manufacturing and launch of new small molecules and monoclonal antibodies in the US? What strategies can be implemented in the development phase for a successful launch post approval?

There is an increasing focus on integrity of records and the use of a risk-based approach to appropriately determine the "right" amount of effort to apply to computer system validation. Where is the value in computer validation and how much is enough? Two talks, one from European and the other from US experience present pre/post licensing and manufacturing compliances including quality systems and their validation status in this session.

Speakers:

Preeti Loyalka-Pinto, M.S., Sr. Director Regulatory Affairs, Astra Zeneca, USA and Kurt Brorson, CDER, FDA, USA – "Advertisement and Marketing in US: Industry and Regulatory Perspective"

Gopakumar Nair, Ph.D., Ex-President IDMA, GN Associates, India – "Off Patent Biogenerics: Global Markets & WTO Countdown 2005"

Keith L. Carson, B.S, M.B.A, Chairman, The Williamsburg BioProcessing Foundation, USA - "Progress & Issues in Biological Product Development with Implications for Programs in Developing Countries"

Joseph Schenk, President, QAEdge, DE, USA – "Emerging Issues for Computer System Compliance and Part 11"

Rudi Segers, Ph.D. Manager, Bio Analytical division, SGS Bio Pharma, Belgium- "Compliance to 21CFR Part 11: Validation of Laboratory Computer Systems with Respect to Bio Analysis"

Session 6: Chemistry, Manufacturing and Controls (CMC) and Comparability Issues

Moderators: James Ackland, Ph.D., VP, Biologics Consulting Group, USA, & Robert Boykins, CBER, FDA, USA

This session will address the issues involved in the manufacture and control of vaccines and biological products such as therapeutic proteins/monoclonal antibodies and peptide drugs). The development of novel bio-pharmaceutical products generally includes significant process scale-up or transfer during the clinical development and prior to commercial manufacture. This presents challenges to companies and regulatory agencies in assessing the implications of these changes especially when biological processes are involved. Topics to be discussed during this session include process scale up, transfer and validation, analytical development and validation and the regulatory requirements for the manufacture and control of protein and peptide drugs.

Speakers:

Kurt Brorson, Ph.D, CDER, US-FDA, USA- "Regulation of Monoclonal Antibodies in the US".

James Ackland, Ph.D., VP, Biologics Consulting Group, USA, - "Process Scale up, Transfer and Validation for Vaccines and Biological Products"

Robert Boykins, M.S, CBER, FDA, USA - "CMC Concerns during the Development of Protein & Peptide Based Drugs"

Rajesh Gupta, Ph.D. Senior Consultant, Biologics Consulting Group, USA – “Development & Validation of Analytical Methods for Testing & Characterization of Vaccines”

Session 7: Regulatory Issues and Challenges in Nutraceutical Development and Manufacturing

Moderators: Madhavan Nair, Ph.D. Professor of Medicine, SUNY @ Buffalo, NY, USA & K. G. Rajendran, Ph.D. USV, India

Speakers:

K.G. Rajendran, Ph.D. USV Limited, India – “Herbal-based Nutraceuticals in Prevention and Management of Diabetes and Cardiovascular Diseases”.

Yesu T. Das, Ph.D. President, ISSI Laboratories, Inc., NJ, USA – “Safety Issues in the International Trade of Nutraceuticals”

DAY 4, FRIDAY SEPTEMBER 17, 2004

Session 8: Opportunities & Challenges in Global Clinical Development of Biopharmaceuticals

Moderators: Rayasam Prasad, Ph.D. Sr. VP, Technical Affairs, Titan Pharmaceuticals, CA, USA & Sanjay Gurunathan, MD, Director, Clinical Development, Aventis-Pasteur, USA
The clinical development of vaccines and pharmaceuticals is a complex process that requires the execution of a plan that is closely aligned and integrated with both manufacturing and marketing needs for the product. Conducting clinical studies in developing countries offer both unique opportunities and challenges for rapid clinical development. Our panel of speakers will highlight these opportunities and challenges by providing some specific examples

Speakers:

Sanjay Gurunathan, M.D., Director, Clinical Development, Aventis-Pasteur, USA “Overview of Clinical Development of Vaccines and Pharmaceuticals”

Raymond J. Tesi, M.D. FACS, Executive VP of Clinical Development & Medical Affairs, Cellarant Therapeutics, CA –“Clinical, Operational and Regulatory Issues in the Execution of Clinical Trails Performed in US, Europe, Eastern Europe and Asia”

Anil Dutta, M.D, Director, Aventis-Pasteur, France ‘ “Challenges and Opportunities of Developing Pediatric Combination Vaccines in Developing Countries”

Radhika Bobba, M.D., Country Manager, Pharm-Olam International (India) Pvt. Ltd Pharm-Olam International, Bangalore, India

Session 9: The Past, Present and Future of Clinical Laboratory Diagnostics

Moderators: Subhash Dhawan, Ph.D. US-FDA, USA & Hemant Vaidya, Ph.D. VP, Dade-Behring, USA

Clinical laboratory diagnostics has come a long way in the last century to be a \$20 billion industry. The technologies used in this industry have evolved from a simple chemistry in a test tube for metabolite detection to a complex gene detection that causes disease with the use of complex automated systems. An estimated 75 million units of blood are collected from normal donors every year worldwide (and a much larger number from diseased individuals). Transfusion, needle injuries, and other injection practices contribute to nearly 8-16 million hepatitis B infections, 2.3-4.7 million hepatitis C infections, 80,000-160,000 HIV infections, and various other blood-borne infections. During the session you will learn about the evolution of technologies that are used in the clinical laboratories for diagnosis of

metabolic, viral and bacterial diseases and emerging clinical challenges associated with them. In addition, we will discuss regulatory requirements by the United States Food and Drug Administration, and submission of applications for various in vitro diagnostic products. In addition, Economic impact of clinical diagnostics in developed and developing world will be covered.

Speakers:

Subhash Dhawan, Ph.D. US-FDA, USA – “United States FDA Regulations for In Vitro Diagnostics to Detect Blood-borne Agents and Requirements for Various Types of Product Submissions”

Hemant Vaidya, Ph.D. VP, Dade-Behring, USA – “Emerging Antimicrobial Resistance: Prevalence & Laboratory Detection”

Vijay Tavkar, Ph.D., Thornwood, NY, USA - “Past, Present & Future of Clinical Laboratory Diagnostics: Focus on Clinical Chemistry & Laboratory Automation”.

Ravi Pottathil, Ph.D. CEO, Accudx, USA – “Economics in Clinical Laboratory & Field based Diagnostics in Developed and Developing world”

Rick Tullis, Ph.D. Chief Scientific Officer, Aethlon Medical, USA – “Affinity Hemodialysis as a Treatment for Infectious Diseases”

Executive Business Forum: Panel discussion Biopharmaceutical Ventures – Investing & Partnering in Asia

In this session, you will hear from successful entrepreneurs about the process of starting R&D based biopharmaceutical companies and taking them public in the industrialized countries. Speakers will highlight the significant opportunities for start-up companies in the

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West to develop partnerships with companies in the developing world. You will also get the inside view from venture capitalists on challenges for seeking funding for start-up biopharmaceutical companies in Asia.

Featured Panel Speakers:

Eric Patzer, Ph.D. President, Aridis Pharmaceuticals –
“Starting a Company in Partnership with the Developing World”

Stan Yakatan, Katan Associates, USA
‘From Bench top to Boardroom’

Sanjay Sehgal, Partner, Schroder Capital Partners, Singapore, “Venture Funding in Biopharmaceuticals in Asia: Myth or Reality”

Rick Tullis, Ph.D. Chief Scientific Officer, Aethlon Medical, USA, “From R&D to IPO”

Additional experts will join in panel discussion.

For one-on-one business opportunities, session sponsorship, and exhibiting, contact:

Dr. Madhavan P. Nair, Professor, Dept. of Medicine, SUNY @ Buffalo

Email: mnair@buffalo.edu

Phone: 716-859-2215 Fax: 716-859-2999

Dr. Gopakumar Nair, Ex. President, IDMA

E-mail: gopanair@гнаipr.net, гнаipr@vsnl.net

Phone: 022-28872058, 022-28850805, 022-30926169, 022-30926170

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Registration

20% discount before 31 August, 2004!!

US \$ 450 or Rs 18,000 after 31 August 2004

One day Registration - US \$ 225 or Rs 9000

Academic Registration - US \$ 225 or Rs 5000

Student Registration - US \$ 100 or Rs 2000

Fees include Lunches and Tea/Coffee Breaks

You can use the registration form attached below and send to either of the two addresses (US, India) shown below.

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Mumbai-400101, India

For enquiry in India, contact:

Dr. Gopakumar Nair, Ex. President, IDMA

E-mail: gopanair@gnaipr.net, gnaipr@vsnl.net

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For enquiry in USA and elsewhere, contact:

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Fax: 716-859-2999

Dr. Prof. Madhavan P. Nair, Chair, GBPCG. Professor of Medicine, State University Of New York, NY, USA
Telephone: 716-859-2215
Fax: 716-859-2999

Email: mnair@buffalo.edu

TRAVEL

Travel visa information: All US citizens and foreign nationals require travel visa. Please contact the nearest Indian embassy or consulate or GBPCG US office for details.

Express Travel Agency has been selected as the official travel agency for this conference. Please call 914-237-3252 (24 hours), Fax 914-776-7661, E-mail: exptvltrs@hotmail.com

A travel booth is also available for all domestic travel & local tours within India. Please contact GBPCG, USA.

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Please contact the hotel directly and mention GBPCG 2004 for special rates only for this conference. Check In: Sept. 14, 2004, Out: Sept. 17, 2004.

Single Occupancy Rate		Double/Twin Occupancy Rate	
INR	US\$	INR	US\$
4100	100	4400	110

The above per night conference package rates include: Room charges per night, buffet breakfast, and all currently applicable taxes. However, any subsequent government levies will be charged accordingly.

Taj Lands End overlooks the Arabian Sea at Lands End, the tip of the historic Bandstand area of Bandra in Mumbai, India's premier financial and commercial city.

Registration Form

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DAY 2, WEDNESDAY, SEPTEMBER 15, 2004	DAY 4, FRIDAY, SEPTEMBER 17, 2004
Session 1: Plenary Session Session 2: Opportunities & Challenges in Global Outsourcing of Biologics & Pharmaceuticals Panel discussion and Business Forum on Outsourcing Session 3: Advances in the R & D of Small Molecule Pharmaceuticals	Session 8: Opportunities & Challenges in Global Clinical Development of Biopharmaceuticals Session 9: The Past, Present and Future of Clinical Laboratory Diagnostics Executive Business Forum: Panel discussion Biopharmaceutical Ventures – Investing & Partnering in Asia