

AAPS/FIP/APSTJ/FPTI and IPA Conference

Global Perspectives of

Biotechnology based Therapeutics

January 19-20, 2006, Hyatt Regency, Mumbai, India.

Workshop Co-Chairs

Dr. Rao V.S.V. Vadlamudi, Dr. Vinod Shah and Dr. Daan Crommelin

AAPS/FIP Outreach Programs

American Association of Pharmaceutical Scientists (AAPS) is the premier organization of all scientists dedicated to the discovery, development and manufacture of pharmaceutical products and therapies through advances in science and technology.

AAPS provides a dynamic international forum for the exchange of knowledge among scientists to enhance their contributions to health. AAPS offers timely scientific programs, ongoing education opportunities for networking and professional development.

International Pharmaceutical Federation (FIP) is the worldwide organization of national pharmaceutical professional and scientific associations, with its mission to represent and serve pharmacy and pharmaceutical sciences around the globe.

The Board of Pharmaceutical Sciences (BPS) of FIP provides the infrastructure for scientists to communicate and develop their expertise and knowledge in the areas of interest through the formulation of Special Interest Groups (SIG).

FIP closely collaborates with the World Health Organisation (WHO) to implement a global health agenda. With the status of Non-Governmental Organisation in Official Relations with WHO, FIP provides professional and scientific input to WHO projects and expert groups.

As a part of outreach program initiatives, AAPS & FIP co-sponsor Regulatory Science Workshops in developing countries and Educational Tutorial Workshops in rapidly developing countries with the aim of improving drug product quality in the country.

Biotechnology Based Therapeutics

The biotechnology sector in India is among the fastest growing business sectors. At present, India has more than 200 corporates involved in the biotechnology business and the biotechnology industry ranks third behind Australia and China in the Asia Pacific region in terms of annual net revenues. The pharmaceutical biotechnology industry is a significant part of this sector and is comprised of both dedicated biotech ventures and intelligent alliances between conventional small molecule-based business houses and companies with expertise in niche biotechnology areas. However, the Indian pharmaceutical biotechnology sector is relatively new and small and has the potential for extensive development and growth when compared to the global biotechnology industry. The major

areas of improvement that are necessary to achieve this potential are in development of regulatory frameworks, an increase in the education/training and availability of skilled manpower in certain areas of biotechnology, an overall increase in research and development budgets, and an understanding of biotechnology related IPR issues.

This conference will address these issues with the aim of both understanding the present global biotechnology scenario and to chart the future path of this extremely fast paced pharmaceutical biotechnology industry in relation to Indian progressing to be a major player in the global biotechnology industry.

Programme

Day 1, Thursday, January 19, 2006

| Time | Topic | Speakers |
|-----------------|---|---|
| 9.00 – 9.15 am | Welcome / Introduction | Subodh Priolkar, President, IPA |
| 9.15 – 10.00 am | Key Note address : Global perspectives of Biotechnology-based therapeutic products: Role of India | Dr. G. Padmanaban, Distinguished Biotechnologist, Indian Institute of Science |
| 10.00– 10.45 am | Overview of Biotech Industry in India | Nitin Deshmukh, ABLE & Kotak Mahindra |
| 10.45– 11.15 am | Tea Break | |
| 11.15– 11.45 am | Analytical techniques for analyzing biotech products | Dr. Daan Crommelin, Utrecht Institute of Pharmaceutical Sciences, The Netherlands |
| 11.45– 12.15 pm | Issues related to Gene therapy and recombinant DNA technologies | Dr. Hideyoshi Harashima, Hokkaido University, Japan |
| 12.15– 1.00 pm | Panel discussion- Q and A | |
| 1.00 – 2.30 pm | Lunch | |
| 2.30 – 3.00 pm | Immunogenicity | Dr. Hubb Schellekens, Utrecht University, The Netherlands |
| 3.00 – 3.30 pm | Success story: Case studies | Dr. K. I. Varaprasad Reddy MD, Shanta Biotechnics Ltd. |
| 3.30 – 4.00 pm | Case study: Monoclonal Antibody drug products | Dr. Steven J. Shire, Genentech Inc. |
| 4.00 – 4.30 pm | Tea | |
| 4.30 – 5.30 pm | Q and A | |

Day 2 : Friday, January 20, 2006

| | |
|-----------------|--|
| 9.00 – 9.45 am | Challenges in drug development of biotech products |
| 9.45 – 10.15 am | Biogenerics – Points to Consider, Regulatory aspects. |
| 10.15– 10.45 am | Scale up issues in biotech based products |
| 10.45– 11.15 am | Tea Break |
| 11.15– 12.45 am | Breakout Sessions |
| Session I | Downstream industrial processing aspects / Upscaling |
| Session II | Analytical aspects |
| Session III | Delivery and formulation aspects including stability, route of administration, specification setting |
| Session IV | Human clinical development / immunogenicity |
| 12.45– 2:00 pm | Lunch |
| 2.00 – 3.30 pm | Breakout Sessions Contd... |
| 3.30 – 4.00 pm | Tea break |
| 4.00 – 4.45 pm | Plenary Lecture : Prospects of Biotechnology Industry : Indian and Global Scenarios |
| 4.45 – 6.00 pm | Summary of breakout session Q & A |

Dr. Daan Crommelin
Dr. Vinod Shah, FIP, Science Secretary
Dr. Hiroshi Kikuchi, Daiichi Pharmaceutical Co., Japan

Dr. Hiroshi Kikuchi
Dr. Steven J. Shire
Dr. Daan Crommelin

Dr. Hubb Schellekens

All the pre-lunch sessions will be repeated for the benefit of participants to attend a different session of their interest

Utkarsh Palnitkar, Ernst & Young

Sponsorship Details

Principal Sponsor (INR. 3,00,000)

- Display of name and logo under the Principal Sponsor Category in the conference sponsor panel and banners
- Inclusion of company brochure in the conference kits
- Delegate fee exemption for 10 persons
- Different colour delegate badges
- Projection of logo on the screen in the conference room during the break

Dinner Sponsor (INR. 2,50,000)

- A separate dinner sponsor panel in the dinner venue
- Delegate fee exemption for 5 persons
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Co-Sponsor (INR. 2,00,000)

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- A separate lunch sponsor panel in the lunch venue
- Logo of the sponsors in the lunch cards
- Delegate fee exemption for 3 persons
- Different colour delegate badges

Conference Kit Sponsor (INR. 75,000)

- Display of name and logo in the conference sponsor panels
- Printed logo on the inside cover of the conference kits
- Delegate fee exemption for 3 persons
- Different colour delegate badges

Session Sponsor (INR. 50,000)

- Display of name and logo under the workshop sponsor category in the workshop sponsor panel and banners
- Inclusion of company brochure in the workshop kits
- Acknowledgement of sponsor in the Media Advertisement
- Delegate fee exemption for 4 persons
- Different colour delegate badges

Associate Sponsor (INR. 1,00,000)

- Display of name and logo under the Associate Sponsor category in the conference sponsor panel and banners
- Inclusion of company brochure in the conference kits
- Delegate fee exemption for 4 person
- Different colour delegate badges

Scientific Committee

Dr. Neelima Khairatkar-Joshi, Dr. M. E. Subramaniam,
Dr. K. G. Rajendran, Dr. Arvind Lali,
Dr. Swati Patankar, Dr. K. Satyamoorthy

Planning Committee

Subodh Priolkar, Gopal Nair, Nitin Deshmukh,
S. D. Joag, T. B. Nair, Narayan Kulkarni

Who should attend

- Policy Makers
- CEOs of Pharma and Biotech Companies
- R&D Scientists
- Regulatory Personnel
- Business Development Personnel
- Consultants
- IPR Managers
- CRO Personnel
- Quality Assurance Team



For more details, please contact : T. B. NAIR

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Registration Information

Date : January 19-20, 2005
Time : Start : 9.00 a.m. Finish : 6.00 p.m.
Registration & Coffee : 8.30 a.m.
Venue : Hyatt Regency
Sahar Airport Road, Andheri (East), Mumbai - 400099.
Tel +91 22 56961234 • Fax : +91 22 56961235
Email: hyattregencymumbai@hyattintl.com
Directions : Near Sahar International Airport
The tariff includes complimentary breakfast, taxes & airport transfer
Registration : Rs. 7000/- for Non-IPA Member per delegate and
Rs. 5500/- for IPA Members
Rs. 4000/- for Faculty & Research Students
US \$ 300 for Foreign delegate

Fee includes convention material, lunch, tea/coffee.

Please send your remittance in favour of "IPA-IPD" payable at Mumbai.

Application to Register

Title _____ First Name _____ Family Name _____
(Dr./Mr./Ms./Mrs.)
Position _____
Company / Institute _____
Address _____
City _____ Post Code _____ Country _____
Tel. No. _____ Fax No. _____
E-mail address _____
Payment Details : Amount : INR _____ USD _____
Cheque / DD No. & Date _____
(Please add Rs. 30/- extra for outstation cheques.)
Issuing Bank & Address _____