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1 -3 March 2011, Raddison Hotel Delhi, New, Delhi, India

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Fomsgaard Chief of Molecular Virology Laboratory, Statens Serum Institut, Denmark



Dr. Niranjan Y. Sardesai Senior Vice President, Research & Development, Inovio Pharmaceuticals



Prof. Rajiv Khanna Director, Australian Centre for Vaccine Development, Australia



Business Development & Partnerships, Novartis Vaccines Institute for Global Health, Italy











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Letter from the Chairman

Dear friends and colleagues,

It's my sincere pleasure to welcome you to Vaccine World Summit 2011, which will be held in New Dehli in India from 1 - 3 March 2011. The event is organized in conjunction with the Developing Countries Vaccine Manufacturers Network and managed by IMAPAC. Over 35 world class speakers will be sharing their experiences and knowledge, together we will have a great opportunity to share ideas and discuss current trends in the rapidly growing vaccine industry.

Being part of the vaccine industry gives each of us the ability to change the lives of many thousands or millions of people we have never met. It is an honour, a responsibility, and a pleasure to help relieve the unnecessary suffering caused by disease and ill health, and to perform a very significant service to the entire world population.

While our work has already transformed many lives, we should not forget that over 9.5 million people die each year due to infectious diseases - nearly all live in developing countries. Together we can improve this situation. Which is why I encourage you to be part of the Vaccine World Summit, we welcome all public health professionals, NGOs, vaccine business leaders, academics and all other related stakeholders to be part of this global vaccine event.

The inaugural conference will focus on the latest success strategies for vaccines in India and the rest of the world, innovative manufacturing technologies, research funding and novel vaccines. The underlying goals are to increase the availability of life saving vaccines, decrease the cost of these vaccines and work together to find a cure for the disease that continue to pose a threat to our health, welfare and happiness.

I am looking forward to seeing each and everyone of you to join us next March in New Dehli. Let's talk, and listen together so we can share exciting new ideas, stimulate growth of the vaccine industry and improve lives of people worldwide.

Sincerely

Dr Reinhard Glück, Zydus Cadila, India

Event at a glance

Advisory Board:



Suresh Jadhav Executive Director, Serum Insitute of India, India



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Prof Nikolai Petrovsky Research Director Vaxine, Australia



Jaques Francois Martin CEO Parteurop, Mymetics, France

Dr V K Srinivas Head of Quality Assurance, Bharat Biotech International, India

March 1st, Tue	March 2	March 3rd, Thur			
nfluenza ndiasumit		cine schology & mondue stid Summit 2011	Antonio Konstantino Konstantin		
Global and Indian influenza market updates & strategies		e leaders panel ion strategies	Vaccine Distribution & cold chain solutions in the developing world		
Networking & Morning Refreshments	Speed Networking & Morning Refreshments		Networking & Morning Refreshments		
Innovations in influenza vaccines	Vaccine regulations		Vaccine Research & Innovation forum		
Networking Lunch	Networking Lunch & Exhibition Visit Manufacturing Stream Adjuvants & delivery stream		Networking Lunch & Exhibition Visit		
Innovations in adjuvants & delivery systems for influenza vaccines	Vaccine Manufacturing & Production I	Adjuvants	Funding for vaccine research, innovation		
Afternoon Refreshments & Exhibition Visit	Afternoon Refreshments & Exhibition Visit		Afternoon Refreshments & Exhibition Visit		
Pandemic & seasonal flu preparedness	Vaccine Manufacturing & Production II	Delivery Systems	Vaccine Research & Innovation forum		
Closing Plenary: Was H1N1/09 the wakeup call for the next pandemic			Closing Plenary: Creating a road map for the next 5-10 years of India's vaccine industry		
	Welcome C	Cocktail Party			
	Exhibition and Showcases				

Influenza India Summit

9.00 Organizer's welcome remarks

Chairman's opening remarks Nikolai Petrovsky, Chairman, Vaxine, Australia 9.05

Indian Influenza Market Update and Strategies

Opening Keynote: The influenza vaccine 9.10 Keynote market of India

- Opportunities and challenges of the Asia flu vaccine market
- Market size, trend, drivers, competitive landscape and market growth dynamics in India
- Status of international players vs. status of local players in India

Jacques Cholat, Vice President, Commercial Operations- International, Sanofi Pasteur, France

9.40 Getting ahead of the competition: Keynote What it takes to be the first domestic player to launch H1N1 vaccine?

- Speed to market: Streamline the decision making and development process to successfully deliver VaxiFlu-S to the market
- Innovative marketing strategy: Targeting the corporate market niche

Reinhard Gluck, CSO, Zydus Cadila, India

- 10.10 Opening debate: Indian Influenza market: Here today, gone tomorrow or not?
 - Is seasonal flu vaccine a permanent cultural shift or a fad?
 - Potential market segmentations & forecasted demand for influenza vaccines in the long term
 - National influenza pandemic surveillance program for the recent pandemic: lessons learnt and actions forward
 - Live vote from the audience: India's influenza vaccine demand will go up or down in the near future?

Panelists:

Reinhard Gluck, CSO, Zydus Cadila, India **B.G. Rhee**, President, Green Cross Corporation, Korea

Jacques Cholat, Vice President, Commercial Operations- International, Sanofi Pasteur, France Nagendra Hegde, Group leader of Virology, Ella Foundation, India

10.50 Morning refreshment

Influenza Vaccine Innovation

11.20 The promises and challenges of developing a DNA based influenza

- Advantages of DNA technology vs. traditional approach
- Challenges in designing and developing a viable delivery system
- Latest clinical results

Anders Fomsgaard, Department of Virology, Statens Serum Institut, Denmark

11.50 Clinical progress towards development of a universal flu vaccine

- Possible approaches that could be taken to create a universal flu vaccine
- Strategic and regulatory considerations for the development and ultimate commercialization of the universal flu vaccine

• Implications of universal vaccines for infections infections diseases and their impact on global health

Niranjan Sardesai, SVP R&D, Inovio, USA

12.20 Networking luncheon and themed roundtable discussions

Innovation in Adjuvants and Delivery Systems

14.00 Using adjuvants to boost global vaccine capacity as well as the immune response

- What adjuvants are readily available to developing world manufacturers during a pandemic situation
- How much extra capacity do adjuvants really
- give us, is it enough for a global pandemic? Case study of using a novel adjuvant to boost the efficacy of a H1N1 vaccine

Nikolai Petrovsky, Chairman, Vaxine, Australia

- 14.30 The way to successful intranasal vaccine delivery -What's important for intranasal vaccine delivery?
 - Cost implications Vs health implications of needle borne diseases, and how this comparison fairs in the developing world
 - Selecting an appropriate delivery device

Degenhard Marx, Associate Director Business Development, Prescription Division, Aptar Pharma, Germany

15.00 Afternoon refreshment

Pandemic Flu and Seasonal Flu Preparedness

15.30 Pandemic preparedness challenges for India Panel and the rest of world in 2011 Discussion

- Lessons learned from H1N1/09
- Immediate and long-term challenges which need to be addressed in order to combat a future pandemic
- Should H1N1/09 have been declared a pandemic
- Ensuring surveillance and accurately identifying strains
- To stock pile or pre-emptive vaccination what is the best route

Panelists:

L. S. Chauhan, Director, National Centre for Disease Control, India Nihal Abeysinghe, Regional Advisor, Vaccine Preventable Diseases , World Health Organization, South-East Asia Region, India

16.10 Innovative, localized and portable manufacturing solutions to be pandemic ready whenever and wherever

- Is there adequate global capacity;
- if not is it a viable business proposal to build it?
- Making facilities more flexible in order to cope with pandemics

Manufacturing pandemic flu vaccines in cell 16.40 culture vs. egg in developing countries: Which system provides more promises in the long run?

- Pros and cons of cell culture vs. eggs
- Which system best suits India?

Nagendra Hegde, Group leader of Virology, Ella Foundation, India

17.10 Chairman closing remarks: Nikolai Petrovsky, Chairman, Vaxine, Australia

Vaccine World Summit, Day 1

- 9.00 Guest of honor: Sri P.K.Pradhan, Additional Secretary and Mission Director, National Rural Health Mission, India
- 9.05 Chairman's opening remarks, Reinhard Gluck, CSO, Zydus Cadila, India

India vaccine leaders panel & immunization strategies

9.10 Chair - Dr. V. K. Vinayak, Chief Scientific Officer, Panacea Biotec

9.50 Strategising the best fit Universal Immunisation Guest Program for India speaker

- The challenges of co-ordinating on the world's biggest immunisation program
- The challenges of selecting the optimal vaccination schedule and which diseases to target
- Strategising future developments in the Universal Immunisation Program

Sri P.K.Pradhan, Additional Secretary and Mission Director, National Rural Health Mission, India

10.20 Speed Networking and Refreshment

Vaccine Regulations

10.50 Painting a clearer picture for vaccine regulatory pathway

- Examine the existing vaccine approval
- procedure in India
- Roles and responsibilities of Kasauli and CDSCO

Arun Bharadwaj, Director, National Control laboratory Kasauli, India

11.20 International regulations and WHO pre-qualifiaction

- Preparing a vaccine for FDA, EMEA licensure
- WHO prequalification and the challenges of maintaining prequalification
- Case studies of recent successes and failures

12.00 Networking Lunch

Breakout Stream A

Vaccine Manufacturing & Production I

- 13.30 Vaccine Security: Building Technologies to Ensure Health Autonomy for All Nations
 - Ensuring that all nations have access to cheap and abundant vaccines
 - Review of new low cost vaccine manufacturing technologies
 - Subunit vaccine expression technologies

Michael Callahan MD, Director, Emergency Vaccine Manufacturing, DARPA, USA

14.00 Trends in Vaccine Development

- Conventional vaccine lack immunogenicity & acceptable levels of protection. These have several adverse reactions & require cold chain for storage
- Easy vaccine targets have been exploited and conventional/classical vaccines have been employed as a part of childhood immunization that has resulted in prevention of several fatal infections
- Newer vaccines are being developed for infections by utilizing molecular strategies, understanding host: pathogen infections and exploitation genomic informations

- 2 March 2011, Wednesday
- Challenge: revolutionary vaccines are needed to combat life threatening infections that are emerging & assuming pandemic dimensions and to control deadly bio-weapon pathogens
- Way Forward: use of genomic information for better/efficacious vaccines

Dr. V. K. Vinayak, Chief Scientific Officer, Panacea Biotec

14.30 Evaluating Platform Technologies for Vaccine Purification Processes

- How standardising the manufacturing processes can reduce the time-to-market of a vaccine
- Recombinant viruses and VLPs and how they effect the upstream and downstream processes
- Single use technology and the flexibility it provides for vaccine manufacturing

Annelies Onraedt, Global Market Manager Vaccine, Pall Life Sciences, Switzerland

15.00 Afternoon refreshment

Vaccine Manufacturing & Production II

15.30 Managing cost-of-goods: secrets of manufacturing affordable vaccines for developing countries

- Working with trusted partners
- Key work practices
- Choosing the right technologies

Mahima Datla, SVP Biotechnology and projects, Biological E, India

Case study: Planning, constructing and 16.00 validating a new VLP vaccine facility in India

- Design layout and operating philosophy
- Site and equipment selection
- Technology transfer
- Validation and commissioning

Sudeep Srivastava, General Manager -Biotechnology, CPL Biologicals, India

16.30 Media Supplementation for Vaccine Production - Lessons Learned and a Look Ahead

Matthias Brand, Market Development Manager, Advanced Bioprocessing, BD, Singapore

17.00 Management of Bio-containment Facilities for the safe manufacture and testing of 'Foot and Mouth Disease' Cattle vaccine

- Legal requirements
- Containment strategies
- Disinfection and Effluent Treatment methods

P. R. Ramdas , Head – Plant Engineering & HSE, Intervet, India

17.30 Chairman's Closing Remarks

18.00 Welcome networking cocktail party

Breakout Stream B

Adjuvants and Delivery Systems

Developing and understanding the effects 13.30 of novel Adjuvants

- Adjuvants theory and do we really know the whole story
- Does the preclinical data back up the clinical and long term studies
- Can we develop adjuvants which are suitable for both the developed and developing world

Lakshmi Khandke, Director, Formulation Development, Pfizer Vaccine Research, USA

Improving prophylactic vaccines using 14.00 adjuvants

- The need for adjuvants
- Evaluating adjuvants in animals
- Selection of adjuvants

Bakulesh Khamar, Executive Director, Research, Cadila Pharmaceuticals, India

Regulatory and scientific considerations when 15.00 using novel adjuvants or immuno-modulators in vaccine manufacture

Afternoon refreshments 15.30

Moving from Vials to Pre-fills and the 16.00 enhanced safety it brings

- Case study of integrating a pre-fill delivery system into an existing facility
- Decreasing needle born diseases and the implications that it has on the welfare and development of developing countries
- Cost comparison of pre-fills vs syringe and vial

Case study of the successful delivery of 16.30 vaccines via novel delivery systems in India

- Assessing and selecting the most appropriate delivery system
- Cost implications- were there any or did the safety benefits outweigh them
- Challenges and changes required to integrate the new delivery systems into the manufacturing process
- Future plans

Rajeev M Dhere, Senior Director Manufacturing, Serum Institute of India, India

Innovations in needle free vaccine delivery 17.00

- Case studies of recent trials of novel systems in India
- Case study of influenza vaccine delivery in the USA and Brazil

Michael Royals, Chief Scientific Officer, Pharmajet, USA

- Chairman closing remarks: 17.30 Reinhard Gluck, CSO, Zydus Cadila, India
- Vaccine Summit World day 1 Closes 17.40
- 18.00 Welcome networking cocktail party

9.00 Chairman's opening remarks: Kevin P Killeen, VP of Research & Development, Matrivax Corp., USA

Innovation Showcase

- 9.05 Presentation on Science Technology and Innovations in HIV Vaccine R&D
 - Endemic Disease barriers to Economic Growth
 - Harnessing India Innovations for Health R&D
 - IAVI and its India programs
 - The benefits and challenges to drive innovations in health

Rajat Goyal, Country Director, IAVI, India

9.30 Sabin-IPV: Challenges and Benefits

- WHO polio eradication programRationale for Sabin-IPV development
- History & current status in Sabin-IPV development
- Clinical/Regulatory aspects

Dr Arani Chatterjee, Vice President, Clinical Research Panačea Biotec, India

- 9.55 Morning refreshments and networking
- Case study: The challenges of developing a 10.20 Chikungunya vaccine.

K Sumathy, Associate director of R&D, Bharat Biotech International Limited , India

10.45 Case study: Advantages of a neonatal dosing schedule and the status of an ongoing Phase II neonatal/infant rotavirus vaccine clinical trial in Ghana

> Leonard P. Ruiz. President, International Medica Foundation, USA

11.10 Case study: The promises of a therapeutic HIV vaccine.

> Anders Fomsgaard, Department of Virology, Statens Serum Institut, Denmark

- 11.35 Case study: Search for the elusive Cholera Vaccine
- 12.00 **Networking Lunch**

Funding Innovation in India

13.00 The challenges of getting vaccines from the lab and into production in the developing world

- Licensing vaccines from not-for-profit research Vs spending on internal research capability
- The challenges of phase 1; funding, partnerships and production

Mae Shieh, Business Development & Partnerships, Novartis Vaccines Institute for Global Health, Italy

- 13.25 The Wellcome Trust's commitment to Indian health care
 - An introduction to the R&D for affordable healthcare in India project
 - MSD Wellcome Trust Hilleman Laboratories, a JV not-for-profit organization focusing on unmet medical needs

Shirshendu Mukherjee, Strategic advisor, Wellcome Trust, India

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Vaccines do they need a new investment 13.50 model or just patience? Panel

- Discussion What can the vaccine industry do to make itself more appealing to venture capital?
 - How can developing world vaccine manufacturers become more effective at applying for grants
 - PPP is it an option?

Leonard P. Ruiz, President, International Medica Foundation, USA Mae Shieh, Business Development & Partnerships, Novartis Vaccines Institute for Global Health, Italy

Rajiv Khanna, Director, Australian Centre for Vaccine Development, Australia Shirshendu Mukherjee, Strategic advisor, Wellcome Trust, India Amit Chander, Head of investments- Healthcare & Pharma, Baring Private Equity Partners India,

India

14.30 Afternoon refreshment

15.00 Case study: Malaria Vaccines: Hopes, Hurdles & Hopes

> Virander S. Chauhan, Director, International Centre for Genetic Engineering and Biotechnology, India

Using the Animal Rule to make extrapolations of 15.25 human immunogenicity, before first in man

- An introduction to 21 CFR 314.600 & 21 CFR 601.90 "Animal Rule"
- Case studies of successful implementation of the Animal Rule and examples of situations during which it would be unethical to determine the efficacy of a vaccine
- Models and methodologies for the Animal Rule

Gurdyal Kalsi, VP Global Clinical Development, Emergent Biosolutions, UK

15.50 Case study: Using polyepitope vaccine technology for chronic viral infection

Rajiv Khanna, Director, Australian Centre for Vaccine Development, Australia

Case study: Clinical progress towards an 16.15 effective dengue vaccine.

> Josemund Menezes, Regional Director, Clinical Development (Asia-Pac), Sanofi-Pasteur, India

Shaping the future of India's Vaccine Industry

- 16.35 Hilleman Laboratories: Developing vaccines for resource limited countries
 - Partnerships and technology transfer
 - The challenges of creating a novel vaccine
 - which will have a low unit cost when in production Selecting which diseases to target that afflict resource limited countries

Altaf Lal, CEO, MSD Wellcome Trust Hilleman Laboratories, India

17.00 Closing visionary panel discussion: Creating a 5-10 year roadmap for India's Vaccine Industry

- Which direction should the vaccine industry take innovative research or diversify into biologics?
- Factors limiting India's vaccine industry and how they can be addressed
- Preparing for China's SFDA WHO pre-qualification and the impact Chinese vaccine manufacturers will have on the international market
- Programs and initiatives to encourage the next generation of scientists and engineers to become part of the vaccine industry

Altaf Lal, CEO, MSD Wellcome Trust Hilleman Laboratories, India **K.R.S. Krishnan**, Senior Executive Director, Research and Development and Strategic Planning, HLL Lifecare Limited , India Mahima Datla, SVP Biotechnology and projects, Biological E, India C S Jambaladinni, Associate Director

(Production), Ranbaxy Laboratories Limited, India

- 1740 Chairman's closing remarks
- 17.45 **Conference closes**

Welcome Cocktail Party



Wednesday 6pm, 2 March 2011, Raddison Hotel Delhi

Having fun makes everything easier... and good food, good drink and good company makes it even easier.

Get to know your peers, become friends, network, laugh, do business; we understand that a fun atmosphere can make a difference. Vaccine World Summit's welcome cocktail party is a time to relax, enjoy yourself and get to know people. You never know who you might meet there!



Your Opportunity to Pentrate India's Vaccine Market

Indian vaccine industry has never been playing a more important role than before. It currently caters to 60 to 70 percent of global requirement of basic vaccines procured by U.N. agencies for the children. Furthermore, it is also an important partner in the global initiatives for the development of cost-effective vaccines against emerging threats of swine flu, meningitis, Japanese encephalitis, etc.

On the other hand, are you aware that Indian vaccine manufacturers are looking for new ways to stay competitive and cost effective? Challenges such as "access to new technology", "increasing cost", "inadequate disease burden data in our own country", "funding", "multiple set of regulation and regulators" still remain as major stumbling bocks for Indian vaccine manufacturers to develop more innovative vaccines. It's your ideal opportunity to present your latest technology and product to this market right now!

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Headquartered in Golden, CO, USA, Pharma Jet was founded in 2005 with the mission to enhance developing world healthcare by providing a safe, affordable and less painful means of vaccine and drug delivery to more people in more places.

With clearances in the US, Europe, Brazil and India, the spring-operated PharmaJet needle-free injection system delivers vaccines and medications in a 0.5mL volume, either intramuscularly or subcutaneously by means of a narrow, high velocity fluid jet, which penetrates the skin.

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Coming to the Indian market in 2011 is Pharma Jet's intradermal injector. This system, based on the currently marketed technology, will permit dose-sparing ID delivery of polio, rabies and other vaccines for which ID delivery has been shown efficacious. The system is designed to enable healthcare workers with little or no training in ID delivery to obtain consistent vaccine delivery to the dermal tissues.

PharmaJet's needle-free injection systems benefit the patient, the healthcare worker and the environment by eliminating needles from the process of vaccine administration and eliminating needle sharps from the environment.







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Subtota

The registration fee includes refreshments, lunch and full conference documentation. The conference fee does not include hotel accommodation Special discounts and eligibility:

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