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4th Annual

Vaccines

第四届2012中国疫苗会议

China 2012

打造成功合作关系，追求卓越质量 Forging Successful Collaborations and Ensuring Quality & Compliance

23 – 26 April 2012
Grand Hyatt Shanghai, China

2012年4月23-26日
中国上海·金茂君悦大酒店

This conference will be simultaneously translated. 此会议将会有中英同声翻译。

Featuring Presentations from Leading Experts

Government Research Institutions



Dr. Masato Tashiro
MD, PhD, Director, Influenza Virus Research Center,
National Institute of Infectious Diseases, Japan



Dr. Pele Chong
Director and Distinguished Investigator, Vaccines
Research and Development Center, **National Health
Research Institute, Taiwan**



Prof. Sudhanshu Vrat
PhD, FASc, FNAsc, Dean, **Translational Health
Science and Technology Institute & Head,
Vaccine and Infectious Disease Research
Centre & Principal Scientist, National Institute of
Immunology, India**

International Experts



Dr. Alexander Von Gabain
Member of the Supervisory Board and Co-Founder,
**Intercell AG, Chair of the Governing Board, European
Institute of Innovation and Technology & EIT
Professor, Max Perutz Laboratories, University of
Vienna & Karolinska Institute in Stockholm**



Dr. Alain Bouckennooghe
MD, MPH, Clinical R&D and Medical Affairs, Associate
VP, Regional Head Asia/Pacific, **Sanofi Pasteur,
Singapore**



Prof. Nikolai Petrovsky
Director of Endocrinology, **Flinders Medical Centre &
Research Director, Vaxine Pty Ltd, Australia**



Dr. De-chu C. Tang
Ph.D, Founder, VP & CTO, **Vaxin Inc, USA**

China Industry Leaders



Dr. Aihua Zhang
Professor and Deputy Director of R&D Department,
**China National Biotech Group(CNBG), China National
Pharmaceutical Group Corp.(Sinopharm), China**



Jin Yulan
President, **Changchun Institute of Biological
Products, China**



Dr. Li Shi
Ph.D., CEO, **Shanghai Zerun Biotechnology,
Wilson Group, China**



Dr. Gao Qiang
Director of R&D, **Sinovac Biotech Co. Ltd,
China**



Dr. Bin Wang
Ph.D, Professor, Key Laboratory of Medical Molecular
Virology of MOH and MOE, **Fudan University
Shanghai Medical College, China**



Dr. Jean-Denis Shu
MD MBA, Medical Director, **Sanofi Pasteur,
China**



Dr. Tang Haiwen
MD, Ph. D., Director, Clinical Research and Medical
Affairs, **GSK Biologicals China/ Hong Kong, China**

5 Reasons

Why You Must Attend!

- **Assess the latest development** and clinical updates in novel vaccines research
- Identify **prospective research projects** and technologies for strategic collaborations
- **Gain insights** into quality and compliance strategies from international and local vaccine manufacturers
- **Evaluate opportunities** currently present in the vaccines market and their relevant risks
- **Assess future trends** and the next generation of vaccines

Highlights

of Vaccines China 2012

- **Development of Novel Japanese Encephalitis Candidate** by Vaccine and Infectious Disease Research Centre (India)
- **Clinical Development Update on Dengue Vaccine Candidates** from Sanofi Pasteur (Singapore)
- **EV71 Vaccines Development** from Sinovac Biotech (China) and National Health Research Institute (Taiwan)

And many more!

PLUS!

Insightful
Workshops

Pre-Conference Workshop A: 23 April 2012
**Expression Systems for Antibody and
Vaccine Biomanufacturing**

Led by Dr. Guy de Martynoff, Ph.D, Managing Director,
DMS Biotechnology, Belgium

Post-Conference Workshop B: 26 April 2012
**Next Generation of Vaccine Facilities with
Focus on Design and Containment**

Led by Klaus Hermansen, Senior Technology Partner, & Niels
Guldager, Senior Technology Partner, NNE Pharmaplan, Denmark

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Vaccines

第四届2012中国疫苗会议

China 2012

打造成功合作关系，追求卓越质量 Forging Successful Collaborations and Ensuring Quality & Compliance

Part of **Drug Discovery & Development Week**
药物创制与开发周

23 – 26 April 2012
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“The global vaccines market is expected to reach US\$56.7 billion by 2017 with double-digit growth annually.”

全球疫苗市场预计将于2017年达到567亿美元，每年增长率均达到两位数。

About Vaccines China 2012

Of all major vaccines-producing countries, development is highly anticipated from China, fuelled by WHO's March announcement enabling manufacturers to apply for pre-qualifications and subsequent eligibility under the UN procurement program. This opens the door to a significant market, driving China vaccines manufacturers to upgrade production to meet stricter quality requirements. Further collaboration with international organizations is predicted, in efforts to strengthen vaccines development.

关于2012年中国疫苗大会

在所有主要疫苗生产国中，中国的发展拥有最大潜力，而 WHO 在三月发表的声明使得生产商可以在联合国采购计划下申请资格预审，进一步推动了中国的发展。借由这一重要市场开放的机会，中国的疫苗生产商将提升产品质量，以满足更为严格的质量要求。预计中国与国际组织将会展开更加深入的合作，加速疫苗开发的脚步。

IBC's 4th Vaccines China 2012 is timely and has been researched with the industry to provide the most comprehensive event focused on vaccines development through to manufacturing. Good manufacturing practices and strategies will be reviewed, alongside potential block-buster technologies and R&D projects. This conference is co-located with the 7th annual China Pharmaceutical R&D Summit and 3rd annual Biosimilars Asia conference to maximize cross-learning, partnering and networking opportunities with biopharma and related industries.

2012年IBC第4届中国疫苗大会适时举办，在行业内作了充分调研，是一项综合性很高的会议，其中包含从疫苗开发到生产等各类业内重点。会议中将探讨优秀的生产规范和策略，以及重大突破性技术和研发项目。本次会议与第7届年度中国药物研发峰会和第3届亚洲生物仿制药会议在同一地点举办，是疫苗行业与生物制药及关联行业相互学习、合作和联系的良机。



Drug Discovery & Development Week

23-26 April 2012, Grand Hyatt Shanghai, China

As world attention continues to shift towards Asia, increasing and ongoing investment into the pharmaceutical industry has come to fruition, matched by rapidly growing demand from the region. Funded by mostly private and emerging government supported initiatives, China is leading efforts as the future source of innovation and producer of quality medicines. Whether in new drug and vaccines discovery and development or in biosimilars, the time is ripe in China! Vaccines China is co-located with:



7th Annual China Pharma R&D Summit 2012
Advancing R&D through Innovation and Collaborations
www.chinapharmard.com

China's first and longest running international conference has brought together world-renowned thought-leadership from the West to Asia, to expedite and develop collaborations in pharma R&D. While global MNCs are firmly established in the region, increasing focus is on Asian enterprises, led by overseas returnee-led and China-supported companies emerging to research and develop new molecules. As the industry globally moves towards biologic medicines and the race to deliver affordable post-patent treatments intensifies, this annual meeting will highlight the winning pathways to successful Asian R&D and commercialization for the region and beyond.

Combining the best of the West and East, traditional and biopharma, from discovery to clinical development and approvals, international, regional and Chinese pharma leaders will address the future of innovation and map the future growth potential for the industry in Asia as well as Asia's contribution to global R&D.



3rd Annual Biosimilars Asia 2012
Partnership & Commercialisation Strategies for Increased Market Uptake
www.biosimilarsasia.com

Asia's first and largest forum on Biosimilars continues to bring key innovator and biosimilars stakeholders for lively discussions and updates. The agenda will highlight strategies to tackle future challenges including regulatory and legal issues, commercial viability, market acceptance, collaborations to further biosimilars development and expansion into pharmerging markets.

Co-located with shared exhibition and networking breaks, providing a unique opportunity for participants to maximize cross-learning, partnering and networking opportunities with biopharma and related industries.

Exhibit Floorplan



DRUG DISCOVERY & DEVELOPMENT WEEK EVENT AT A GLANCE

	MON 23 APRIL	TUE 24 APRIL	WED 25 APRIL	THU 26 APRIL
AM	Pre-Conference Workshops: US Market Entry: A Regulatory, Legal, and Medical Communication Perspective (Full Day) Expression Systems for Antibody and Vaccine Biomanufacturing (Full Day)	China Pharma R&D, Vaccines & Biosimilars JOINT PLENARY SESSION Global and Regional Keynote Presentations On Pharma R&D	China Pharmaceutical R&D Summit <ul style="list-style-type: none"> Drug Development & Partnering Strategies Emerging Business Models in R&D Discovery & Early Stage Devt Role of Academia in Drug Discovery & Development 	Vaccines China <ul style="list-style-type: none"> Novel Vaccine Candidates for Tropical Diseases Research and Clinical Updates for EV71 vaccines
	LUNCH, AM & PM BREAKS	EXHIBITION & POSTER SESSION DISCUSSION DEN CRO Clinic / Onsite 'Lab' & Demonstrations China Technology & Services Pavilion		
PM	US Market Entry: A Regulatory, Legal, and Medical Communication Perspective Expression Systems for Antibody and Vaccine Biomanufacturing Meet the Speakers Reception (by invitation only)	China Pharmaceutical R&D Summit <ul style="list-style-type: none"> Regulatory Snapshots R&D Leaders Panel Investment & Funding 'Pharma Idol': Innovation Showcase CXO Panel Discussion Funding for Innovation 	Vaccines China <ul style="list-style-type: none"> Market Trends & Outlook Vaccines Quality Control & Compliance Novel Development of Vaccines Regulatory Snapshots Visionary Panel Discussion 	Biosimilars Asia <ul style="list-style-type: none"> Market Entry & Opportunities Commercial Viability Regulatory Snapshots Visionary Panel Discussion
		Discussion Den: In depth roundtable discussions on Regulatory and Collaborations in Key Asian Countries		
		NETWORKING RECEPTION EVENING DINNER (Optional)		
			China Pharmaceutical R&D Summit <ul style="list-style-type: none"> 'Pharma Idol': Innovation Showcase and Awarding Clinical Development & Partnerships in Asia Future Opportunities in Biosimilars & Biobetters Closing Visionary Panel Discussion 	Vaccines China <ul style="list-style-type: none"> Innovations & Technological Advancements Future Opportunities for Sustainable Return on Investment
			Biosimilars Asia <ul style="list-style-type: none"> Mad about mAbs Developing Biosimilars & Biobetters Winning Buy-in Closing Panel Debate 	Post-Conference Workshops: Next Generation of Vaccine Facilities with Focus on Design & Containment Turning Strategies into Tactical Plans to Optimize Market Entry – Balancing Commercial, Regulatory and Investments to Deliver Successful Business Models

REGISTER NOW! Online www.vaccineschina.com or call our Customer Service Hotline: +65 6508 2401 / +86 21 2326 3680

Conference Day One Tuesday 24 April, 2012

0800 Registration & Morning Coffee

0830 Chairman's Opening Remarks

Li Chen, President and CEO, **Hua Medicine**, China

PLENARY KEYNOTE SESSIONS: GLOBAL AND REGIONAL PHARMA R&D

0840 **Keynote Address: Takeda's R&D Collaboration Model for Targeted Medicine for Unmet Needs**
Mary Haak-Frendscho, President and Chief Scientific Officer, **Takeda San Francisco**, USA

0910 **Global Keynote Address: Global Trends in Pharma R&D Partnering**
Joe McCracken, Global Head of Business Development and Licensing, **Roche**, USA

0940 **Industry Keynote Address: Effectively Tackling R&D Productivity Challenge: Integration of External Research**

- Open innovation models
- Improving innovation for sustainability
- Innovation in China
- Industry-Academia and Industry-Biotech partnerships
- Effectively managing the integration of external research
- Abandoned R&D assets: value or burden?

Dr Helmut Haning, Senior Vice President and Head Global Innovation Outsourcing, **Bayer Healthcare Pharmaceuticals**, Germany

1010 Is China Ready to Lead in Global Drug Development?

- Is ROCE-led innovation transforming China's pharma industry onto the world stage?
- Partnering with China in vaccines research & development
- Opportunities and challenges from biosimilars and biobetters from/for pharmerging markets

Moderator: Carl Firth, Chief Executive Officer, **Aslan Pharmaceuticals**, Singapore

Panelists:

Frank Shen, Vice President Global Data Management and Statistics, **Global Pharmaceutical R&D, Abbott**, USA

Ling Chen, Vice President of R&D China Operations, **GlaxoSmithKline**, China

Ming Wang, Executive Director and Head of Diabetes Research, **Amgen**, USA

Youling Wu, Chief Executive Officer, **ZheJiang Teruisi**, China

End of Plenary Session

1100 Morning Refreshments

VACCINES INDUSTRY OUTLOOK

1130 Vaccines China Chairperson's Opening Remarks

Dr. Pele Chong, Director and Distinguished Investigator, Vaccines Research and Development Center, **National Health Research Institute**, Taiwan

1140 Overview of the Chinese Vaccines Market

- Public and private sector programmes driving key trends and developments in vaccine development
- Areas of greatest need and limitations currently existing in the vaccines market
- Competitive landscape and how it can expedite R&D efforts

Dr. Li Shi, Ph.D., CEO, **Shanghai Zerun Biotechnology**, **Wison Group**, China

1220 CNBG Report of Vaccine Development

- Industry outlook
- Findings and initiatives in research & development
- Preparing for future challenges

Dr. Aihua Zhang, Professor and Deputy Director of R&D, **China National Biotech Group (CNBG)**, **China National Pharmaceutical Group Corp.(Sinopharm)**, China

1300 Networking Lunch

VACCINES QUALITY CONTROL & COMPLIANCE

1400 Achieving WHO – Compliant QA and QC

- Implementing efficient QA and QC controls
- Examples of and applying global best practices
- Changchun's QA and QC strategies

Jin Yulan, President, **Changchun Institute of Biological Products**, China

1430 Quality & Regulatory Requisites for WHO-Prequalification of Vaccines

- Quality requirements (QC/QA) for WHO-prequalification
 - Importance of QC and QA
 - Case studies (issues related Pre-qualification)
 - Clinical requirements
- WHO Pre-Qualification process/procedure

Giridhar Rao, Manager of Global Regulatory Affairs and Compliance, **Indian Immunologicals**, India

1500 Afternoon Refreshments

1530 Preparing for WHO Vaccines Pre-qualifications

- What are the weaknesses of local manufacturers and what are the challenges ahead?
- How should China vaccines manufacturers prepare for Pre-qualifications?
- What are the current strategies adopted by local vaccines manufacturers?
- What should they expect in the transition process?

Giridhar Rao, Manager of Global Regulatory Affairs and Compliance, **Indian Immunologicals**, India
Jin Yulan, President, **Changchun Institute of Biological Products**, China

NOVEL DEVELOPMENT OF VACCINES

1600 Review on Recent Development of Influenza Vaccines

With the looming threat of a devastating global pandemic derived from avian H5N1 virus circulating with diverse antigenic properties, pre-pandemic vaccines capable of inducing wide-spectrum and long acting strong immunity are required. For seasonal influenza, as antigenic drift occurs frequently, changes of vaccine viruses is often required to catch-up vaccine match. Young children and the elderly are high risk groups of influenza but they respond poorly to traditional flu shots. To overcome these problems, new technologies have been applied to develop better vaccines with safety and efficacy.

Dr. Masato Tashiro, MD, PhD, Director, **Influenza Virus Research Center**, **National Institute of Infectious Diseases**, Japan

1630 Development of Tolerogenic Vaccination against Autoimmune Diseases

Type 1 diabetes (T1D) in both humans and nonobese diabetic (NOD) mice is a T cell-mediated autoimmune disease characterized by lymphocytic infiltration of pancreatic islets with subsequent destruction of the insulin-producing cells. The T regulatory (Treg) cell has been suggested to play an important role in controlling T cell-mediated inflammatory T1D. We previously demonstrated that induction of antigen-specific Treg cells in vivo by coimmunization with a DNA vaccine and its encoded protein can effectively inhibit T cell-mediated inflammatory diseases. A strategy based on coimmunization to induce an antigen specific tolerogenic responses against the onset of diabetes in mice may lead to the development of an immunotherapeutic/preventive protocol against T1D or other similar autoimmune diseases in humans.

Dr. Bin Wang, Ph.D., Professor, Key Laboratory of Medical Molecular Virology of MOH and MOE, **Fudan University Shanghai Medical College**, China

1700 Adenovirus-Vectored Drug-Vaccine Duo as a Broad Platform for Conferring Rapid/Sustained Protection against Viral and Bacterial Infections

Vaccine's disease-fighting power has been a public health bonanza credited with the worldwide reduction of mortality and morbidity. The goal to further amplify its power by boosting vaccine coverage requires the development of a new generation of rapid-response vaccines that can be mass-produced at low cost and mass-administered by non-medical personnel. The non-replicating adenovirus-vectored vaccine holds promise in boosting vaccine coverage because the vector can be rapidly manufactured in serum-free suspension cells and noninvasively administered by nasal spray. In contrast to parenteral injection, nasal vaccination minimizes systemic inflammation.

Dr. De-chu C. Tang, Ph.D., Founder, VP & CTO, **Vaxin Inc.**, USA

1730 Chairperson's Remarks and End of Conference Day One followed by Networking Reception

Conference Day Two Wednesday 25 April, 2012

0900 **Chairperson's Remarks**

NOVEL VACCINE CANDIDATES FOR TROPICAL DISEASES

0910 Japanese Encephalitis: Development of Novel Vaccine Candidates

Translational Health Science and Technology Institute (THSTI) has a number of JE vaccine candidates at various stages of development. Technology for a tissue culture derived JE vaccine has been transferred to industry. A DNA vaccine candidate was shown to induce high titers of JEV neutralizing antibodies in rhesus monkeys. A recombinant human adenovirus 5 based JE vaccine showed great potential in the mouse model of disease. These and recent results from THSTI on immunogenicity of a non-human adenovirus recombinant expressing JEV proteins will be presented.

Prof. Sudhanshu Vratil, PhD, FASc, FNAsc, Dean, **Translational Health Science and Technology Institute & Head, Vaccine and Infectious Disease Research Centre & Principal Scientist, National Institute of Immunology**, India

0940 Clinical Development Update on the Sanofi Pasteur Dengue Vaccine Candidate

The Sanofi Pasteur tetravalent dengue vaccine candidate is composed of 4 recombinant live attenuated vaccine viral candidates each expressing the prM and envelope genes of one of the four respective dengue virus serotypes.

- Results of in-vitro and in-vivo preclinical studies
- Adverse events, observed safety and immunogenicity of the vaccine
- Challenges inherent to the development of tetravalent dengue vaccines

Dr. Alain Bouckennooghe, MD, MPH, Clinical R&D and Medical Affairs, Associate VP, Regional Head Asia/Pacific, **Sanofi Pasteur**, Singapore

RESEARCH AND CLINICAL UPDATES FOR EV71 VACCINES

1010 EV71 Vaccine Development: From Research to Human Phase 1 Clinical Trials

In this study, using the standardized viral antigens and immunological assays we report the immunogenicity results obtained from animals immunized with different vaccine candidates produced from various platform technologies. These include synthetic peptides containing virus neutralization epitopes, virus-like particles, recombinant EV71 antigen, and formalin-inactivated EV71 virus grown in culture medium with and without animal serum. An IND for human phase 1 clinical trial was submitted to and approved by Taiwan FDA. The trial began in December 2010 and has been progressing well.

Dr. Pele Chong, Director and Distinguished Investigator, Vaccines Research and Development Center, **National Health Research Institute**, Taiwan

1040 Morning Refreshments

1110 The Preclinical and Clinical Development of an Inactivated EV71 Vaccine

Enterovirus 71 (EV71) is a major etiological agent of hand, foot and mouth disease (HFMD). In recent years, several outbreaks in East Asian and China, resulted in neurological complications and numerous deaths in infants. A new inactivated EV71 vaccine is being developed and the efficacy is currently under evaluation in a multicenter trial in China. In this presentation, the manufacturing process and analytical methods are reported as well as the safety and immunogenicity results from the phase I and phase II clinical trials.

Dr. Gao Qiang, Director of R&D, **Sinovac Biotech Co. Ltd**, China

INNOVATIONS AND TECHNOLOGICAL ADVANCEMENTS

1140 The Particularities of Development of Pentavalent Combination Vaccine and International and Chinese Clinical Studies and Experiences of Practice

The successful development and launch of several acellular DTP (DTaP) vaccines is an important milestone in the last decade of the 20th century, inspiring the development of DTaP based combination vaccines for children, such as DTaP combined with Haemophilus Influenza Type B (HIB), inactivated polio (IPV), Hepatitis B Vaccine (HepB), etc. Since 2007, China began to expand the scope of national immunization programme, replacing whole-cell DTP with DTaP vaccines. It also meant that a child needs 20 doses to complete the immunization program in their first 2 years. With more doses, the cost of services and risk of adverse events following immunization increased as well. The urgent need for a reasonable immunization schedule, while promoting the use of combination vaccines is an important strategy to reduce the number of injections and improve vaccination rates in children.

Dr. Jean-Denis Shu, MD MBA, Medical Director, **Sanofi Pasteur**, China

1210 Insights into Mechanisms of Action of Vaccine Adjuvants

In recent years, the need for more effective vaccines to counter lethal new infections such as pandemic influenza, HIV, and SARS has driven a hunt for new adjuvants. Development of these has not proved to be an easy task, with increased potency being at odds with safety and tolerability. Recent improved understanding of how adjuvants are actually working opens the door to development of new adjuvants that do not share the reactogenicity or toxicity of past adjuvants. These new adjuvants will facilitate development of vaccines against hitherto untreatable infections and cancers.

Prof. Nikolai Petrovsky, Director of Endocrinology, **Flinders Medical Centre & Research Director, Vaxine Pty Ltd**, Australia

1240 Networking Lunch

1400 Recent Progress in Adjuvant Research

In modern vaccinology, the main challenges for scientists include developing effective vaccines against complex pathogens, rapid identification and response to new emerging diseases and providing a better immune response in target groups in which age, chronic conditions or other factors make current vaccine prevention sub-optimal. Adjuvant Systems (AS) are at the heart of a new generation of vaccines as the optimal combination of adjuvant(s) and antigen(s) allows tailoring the immune response to the disease and to the target population. Novel AS technology is fundamental to the development of new or more effective vaccines for very challenging diseases or for subjects with immunologically challenging conditions where classical approaches have proven less effective or have failed.

Dr. Tang Haiwen, MD. Ph. D., Director, Clinical Research & Medical Affairs, **GSK Biologicals China/ Hong Kong**, China

1430 Production of Fast and Efficient Vaccines in Transgenic Animal & Plant Systems

Expression of recombinant antigens in transgenic systems has potential to offer advantages of speed and cost over competitive vaccine technologies. We will review recent advances in transgenic animals or plants demonstrating them potentially as valuable vaccine commodities to the world's health system.

Dr. Guy de Martynoff, Ph.D, Managing Director, **DMS Biotechnology**, Belgium

1500 Afternoon refreshments

1530 The Biotech Facility of the Future

MAB titres increase – SU technology is booming – Bio-similar facilities is trendy – The demand for domestic manufacturing of vaccines goes up and the biotech/vaccine market is growing dramatically! All these factors impact the design of new manufacturing facilities. This presentation provides an overview of the trends and challenges we see in the market and the impact it will have on the facility design, along with a number of cases of how the facility of the future will look.

Klaus Hermansen, Senior Technology Partner, **NNE Pharmaplan**, Denmark

Niels Guldager, Senior Technology Partner, **NNE Pharmaplan**, Denmark

FUTURE OPPORTUNITIES FOR SUSTAINABLE RETURN ON INVESTMENTS

1600 Next Gen Vaccines R&D: Prospects and Challenges

- New vaccines for unmet medical needs
- Novel vaccine technologies - opportunities and challenges ahead
- Proven technologies for improvement of existing vaccines
- From vaccination to immunization

Dr. Alexander Von Gabain, Member of the Supervisory Board and Co-Founder, **InterCell AG**, Chair of the Governing Board, **European Institute of Innovation and Technology & EIT Professor**, **Max Perutz Laboratories**, **University of Vienna & Karolinska Institute in Stockholm**

1630 Creating Win-Win Vaccine Partnerships: How can Chinese and Overseas Vaccines Organisations Collaborate?

- What are the synergies and what is the best collaboration format?
- Risks and challenges: What to expect when entering a partnership?
- Where are the partnership opportunities?

Dr. Alexander Von Gabain, Member of the Supervisory Board and Co-Founder, **InterCell AG**, Chair of the Governing Board, **European Institute of Innovation and Technology & EIT Professor**, **Max Perutz Laboratories**, **University of Vienna & Karolinska Institute in Stockholm**

Dr. De-chu C. Tang, Ph.D, Founder, VP & CTO, **Vaxin Inc.**, USA

Dr. Bin Wang, Ph.D, Professor, Key Laboratory of Medical Molecular Virology of MOH and MOE, **Fudan University Shanghai Medical College**, China

1710 Chairperson's Closing Remarks & End of Conference

REGISTER TODAY!

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Pre-Conference Workshop A Monday 23 April, 2012 (9-5pm)

This full day workshop includes breaks and lunch. Registration begins 30 minutes prior to starting.

Expression Systems for Antibody and Vaccine Biomanufacturing

The production of vaccines and monoclonal antibodies is a topic of great importance in the biopharmaceutical industry as these products have the highest rate of growth in terms of sales and applications in the pharmaceutical industry. The demand for higher production volume and lower cost motivates the development of diverse expression systems to improve their yield and quality and at the same time provide economic efficiency. This workshop provides an overview of antibody-related products and the various expression systems available for their production. It will focus on the newest technologies and methods for expressing antibodies and vaccines in order to enable improved process optimization and quality control while reducing cost.

Who Should Attend

This workshop is recommended for those working with monoclonal antibodies and vaccines, for anyone who is new to the biopharmaceutical industry, or for those with an interest in understanding the role of antibodies or vaccines in providing novel diagnostic and therapeutic products for cancer, inflammation and infectious diseases.

Workshop Agenda

- Antibodies and Vaccines Already Market Approved - Future Products in Clinical Pipelines
 - Oncology, Inflammation, Infection, Organ Transplantation, Prophylaxis Agents
 - Parameters Influencing Selection of Antibody Format, Isotype and Glycoform
 - Mouse isotype; chimeric; humanised/human - HAMA/HACA/HAHA response
 - Antibody-receptor/toxin/radioisotope fusion proteins - Antibody fragments
 - Immunocytokines (ICK) > Bispecific antibodies (strategies)
 - Glycoform - ADCC/CDC/PK effects > how to enhance ADCC activity of your antibodies?
- Mammalian Expression Systems
 - Relevant cell lines (GS, DHFR and other selections)
 - New improvements in transient CHO production (preGMP batches)
 - Vectors: modifications, improvements, comparing and contrasting different technologies
 - Stability of cell lines and selection of the best producers
- Animal Transgenic Systems
 - Overview of the products already on the market + future prospects
 - Biopharmaceuticals and vaccines
 - Monoclonal antibodies from milk - Human polyclonal antibodies from cattle and rabbit
- Bacteria- Fungi Fermentation Systems
 - Fusion protein with anti-infective peptides
 - Full-length antibodies in E. Coli, antibody fusion proteins
 - Fragments: Fab, biospecific antibodies and bispecific single chain antibodies
 - Full-length mAbs in yeast (Saccharomyces, Pichia) and aspergillus
- Plant Transgenic Systems
 - Monoclonal antibodies from seeds
 - Secretory antibodies from foliage
 - Fast and flexible productions of Flu vaccines in transgenic tobacco

Workshop Leader

Dr. Guy de Martynoff, Ph.D., Managing Director, DMS Biotechnology, Belgium
Guy has over twenty years' experience in the biopharmaceutical industry. His areas of expertise include R&D in molecular biology, immunology, virology as well as scale-up in various expression systems and protein purification processes. He started his industrial career in 1991 for a diagnostic/vaccine project on hepatitis C virus, joining 4C Biotech (now Novasep Process) in 1997 as Manager of the Biochemistry Department and then as Scientific Coordinator. He developed thereafter more "exotic" industrial and business processes, first as CEO for BioProtein Technologies (France), a company producing therapeutics proteins in the milk of transgenic animals (rabbits), and, as Executive Vice President for Meristem Therapeutics, one of the world leaders in production of Plant-Made Pharmaceuticals (corn and tobacco).

Post-Conference Workshop B Thursday 26 April, 2012 (9-1230pm)

This half day workshop includes a mid-morning break. Registration begins 30 minutes prior to starting

Next Generation of Vaccine Facilities with Focus on Design and Containment

Workshop Agenda

- This workshop will provide a deep insight into the following topics:
- Next generation of vaccine facilities (modular design, standardization, flexibility etc)
 - Containment for vaccine facilities – the risk based approach
 - SU (single use) technology for vaccine development and vaccine manufacturing – trends, benefits and challenges

Workshop Leaders

Klaus Hermansen, Senior Technology Partner, NNE Pharmaplan, Denmark
Klaus currently heads the Vaccine Design group and has been engaged in several biotech projects regarding multi-product facilities and the use of single use technology. He is an expert within the area of vaccine manufacturing, containment and SU technology.

Niels Guldager, Senior Technology Partner, NNE Pharmaplan, Denmark
Niels has over 16 years' experience with biotech and pharmaceutical processes including both operations and design. Recent projects include early design and consulting roles in projects for MAb-production facilities, vaccine facilities and in general multi product facilities. He is currently engaged in single use technology community work for industry organisations PDA and ISPE where he is heading collaborative writing efforts for task force and baseline guide groups.

Past Participating Companies at Vaccines Conferences

Beijing Tiantan Biological Products Co Ltd • Beijing Vaccines Biomedicine Co Ltd • Berna Biotech Korea Corp • Biopharmaceuticals • CCM Duopharma (M) Sdn Bhd • Chengdu Institute of Biologic Products • China National Biotech Group • Crucell • Dalian Hissen Bio-Pharm Co Ltd • Defense Science & Technology Center-Far East • Foster Wheeler Asia Pacific Pte Ltd • GE Healthcare Life Sciences • Gland Pharma Ltd • GSK Biologicals • Glavax • Green Signal Bio Pharma Private Ltd • Hangzhou Msd Pharmaceutical Co Ltd • Hualan Biological Engineering Inc • Intercell Ag • Kerry Bio-Science • Liaoning Biological Medicine Engineering Institute • Liaoning Yisheng Bio Pharma Co • National Health Research Institute • NNE Pharmaplan • Novartis Corporation (Malaysia) Sdn Bhd • Pall Biopharm Shanghai • Pall Life Science • Panacea Biotech Ltd • Path • Roche Diagnostics (Shanghai) Ltd • Sanofi Pasteur • Sartorius Stedim Biotech GmbH • Shanghai Wilson Bioengineering Co Ltd • Shenzhen Sanofi Pasteur Biological Products Co Ltd • Singvax • Sichuan Kelun Pharma Co Ltd • Sinovac Biotech Co Ltd • SK Chemicals • Square Pharmaceuticals Ltd • Swinburne University Of Technology • Wuhan Institute of Biological Products • Wyeth • Zhejiang Tianyuan Bio-Pharmaceutical Co Ltd

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会议第一天 2012年4月24日, 星期二

- 0800 签到及早茶
0830 主席开场白
Li Chen, President and CEO, Hua Medicine, China

大会主题演讲：全球药物研发与区域合作发展现状

- 0840 主题演讲: 武田制药的研发合作模式创新 - 贴近医患需求, 积极推进靶向药物开发
Mary Haak-Frendscho, President and Chief Scientific Officer, Takeda San Francisco
- 0910 全球主题演讲: 全球医药研发合作伙伴的趋势
Joe McCracken, Global Head of Business Development and Licensing, Roche, USA
- 0940 全球主题演讲: 有效应对研发生产力挑战: 整合外部研究
Dr Helmut Haning, Senior Vice President and Head Global Innovation Outsourcing, Bayer Healthcare Pharmaceuticals, Germany
- 1010 全体小组讨论: 中国是否做好准备, 领导全球药品创新与发展?
Carl Firth, Chief Executive Officer, Aslan Pharmaceuticals, Singapore
Frank Shen, Vice President Global Data Management and Statistics, Global Pharmaceutical R&D, Abbott, USA
Ling Chen, Vice President of R&D China Operations, GlaxoSmithKline, China
Ming Wang, Executive Director and Head of Diabetes Research, Amgen, USA
Youling Wu, Chief Executive Officer, ZheJiang Teruishi, China
- 1100 上午茶歇
药物创制和开发周联合会议时段结束
- 1130 大会主席致词
庄再成博士, 特聘研究员兼疫苗研发中心主任, 台湾国家卫生研究院

疫苗市场趋势和前景

- 1140 中国疫苗市场和行业概览
史力博士, 首席执行官, 惠生集团上海泽润生物医药技术有限公司
- 1220 中生集团的疫苗发展报告
张爱华研究员及医学博士, 科研管理中心副部长, 中国生物技术集团公司
- 1300 联谊午餐

疫苗控管和法规要求

- 1400 达到WHO标准的QA及QC
金子兰, 长春生物制品研究所所长兼党委书记
- 1430 获取世界卫生组织预认证的质量和法规要求
Girdhar Rao, Manager of Global Regulatory Affairs and Compliance, Indian Immunologicals, India
- 1500 上午茶歇
- 1530 专题讨论会: 赢取世界卫生组织预认证
Girdhar Rao, Manager of Global Regulatory Affairs and Compliance, Indian Immunologicals, India
金子兰, 长春生物制品研究所所长兼党委书记

新型疫苗的开发

- 1600 探讨流行性感冒疫苗的最新开发进展
Dr. Masato Tashiro, MD, Ph.D, Director, Influenza Virus Research Center, National Institute of Infectious Diseases, Japan
- 1630 研制用于治疗自身免疫性疾病的免疫耐受疫苗
王宾博士, 复旦大学上海医学院特聘教授
- 1700 腺病毒载体疫苗组合物作为快速/持续防止病毒和细菌感染的广阔平台
Dr. De-chu C. Tang, Ph.D, Founder, VP & CTO, Vaxin Inc., USA
- 1730 大会主席致词后第一天的议程结束, 随后是联谊酒会

会议第二天 2012年4月25日, 星期三

- 0900 主持人致开幕词

热带疾病的新型候选疫苗

- 0910 流行性乙型脑炎: 新型候选疫苗的开发
Prof. Sudhanshu Vratil, PhD, FASC, FNASC, Dean, Translational Health Science and Technology Institute & Head, Vaccine and Infectious Disease Research Centre & Principal Scientist, National Institute of Immunology, India
- 0940 赛诺菲巴斯德研制的登革热候选疫苗的临床开发进展
Dr. Alain Bouckenoghe, MD, MPH, Clinical R&D and Medical Affairs, Associate VP, Regional Head Asia/Pacific, Sanofi Pasteur, Singapore

EV71 疫苗的研究和临床进展

- 1010 肠病毒七十一型疫苗之研发
庄再成博士, 特聘研究员兼疫苗研发中心主任, 台湾国家卫生研究院
- 1040 上午茶歇
- 1110 EV71灭活疫苗的临床前研究和临床研究
高强博士, 北京科兴生物制品有限公司研发总监

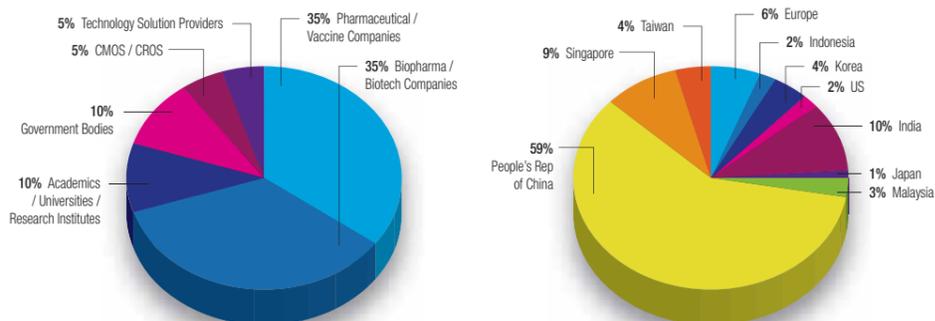
创新和技术进步

- 1140 五联疫苗的研发特性和国内外临床试验和使用经验
舒德博士, 赛诺菲巴斯德中国公司医学总监
- 1210 对疫苗佐剂作用机制的新见解
Prof. Nikolai Petrovsky, Director of Endocrinology, Flinders Medical Centre & Research Director, Vaxine Pty Ltd, Australia
- 1240 联谊午餐
- 1400 佐剂研究新进展
唐海文博士, 中国/香港区GSK疫苗部医学总监
- 1430 在转基因动物系统中生产速效疫苗
Dr. Guy de Martynoff, Ph.D, Managing Director, DMS Biotechnology, Belgium
- 1500 下午茶歇
- 1530 明日之生物技术制药设施
Klaus Hermansen, Senior Technology Partner, NNE Pharmaplan
Niels Guldager, Senior Technology Partner, NNE Pharmaplan

未来投资新机会

- 1600 下一代疫苗研发: 展望与挑战
Dr. Alexander Von Gabain, Member of the Supervisory Board and Co-Founder, Intercell AG, Chair of the Governing Board, European Institute of Innovation and Technology & EIT Professor, Max Perutz Laboratories, University of Vienna & Karolinska Institute in Stockholm
- 1630 专题讨论会: 建立双赢的疫苗合作伙伴关系: 中外疫苗企业如何展开合作?
Dr. Alexander Von Gabain, Member of the Supervisory Board and Co-Founder, Intercell AG, Chair of the Governing Board, European Institute of Innovation and Technology & EIT Professor, Max Perutz Laboratories, University of Vienna & Karolinska Institute in Stockholm
王宾博士, 复旦大学上海医学院特聘教授
Dr. De-chu Tang, Ph.D, Founder, VP & CTO, Vaxin Inc, USA
- 1710 大会主席致词, 会议结束

Who Should Attend



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