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## 3 - 6 November 2014 Grand Hyatt Shanghai China

## 2014 年 11月3日-6日 上海金茂君悦大酒店, 中国

A High Level Conference Focusing on Growth & Investment in Animal Health in Asia

### Practical Case Studies on the Ground in China



Jim McAllister Director, Global Strategic Marketing, Swine Asia, Merial, China

IBC

LIFE SCIENCES



Li Zeng Head of Greater China R&D Hub, Elanco Animal Health, China

动物保健会议

HEALTH



Jianfei Wang Director & Head, Laboratory Animal Sciences, GlaxoSmithKline, China



- Regulation, Trends & Market Opportunities in Asia Pacific
- Animal Health Business Models & Collaboration
- Prevention & Control of Animal Diseases
- Zoonoses, Human-Animal Interaction & Risk Mitigation
- Product Development & Marketing
- Animal Health Vaccines

**Lisa Conte** CEO, **Jaguar Animal Health**, USA



Mark Micallef, Director, International Business Unit, Zenoaq, Japan



**International Keynote Speakers** 

Philip Lehrbach Director, Regulatory Affairs Asia Pacific, Zoetis, Australia



Kishore Motwani Head, Technical & Regulatory, Zydus Animal Health, India



KV Balasubramaniam, Managing Director, Indian Immunologicals, India



Octavio Eckhardt Asia Swine Marketing Manager, Virbac, Thailand



Animal Drug Approvals, cGMP & Quality
 Epidemiology in Animal Vaccines
 Quality Risk Management in Animal Vaccines





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## **CONFERENCE DAY ONE 4 NOVEMBER 2014** TUESDAY

- 8:00 **Registration Opens & Morning Coffee**
- 8:50 Welcome Address from IBC Asia & Ice Breaker
- 9:00 **Chairperson's Opening Remarks**

#### **Regulation, Trends & Market Opportunities in Asia Pacific**

- 9:10 The Animal Health Market in Asia Pacific - Opportunities & Challenges What are the opportunities and threats? PANEL DISCUSS Challenges of bringing animal health products to market
  - Commercialization trends backyard farming to commercial ventures
  - Opportunities for generic products
  - Scope for recombinant products

#### Moderator:

Johnson Chiang, President, Federation of Asian Veterinary Associations; Vice President, World Veterinary Association & President, Veterinary Alumni Foundation of National Taiwan University, Taiwan

Panelists: KV Balasubramaniam, Managing Director, Indian Immunologicals, India

Lisa Conte, CEO, Jaguar Animal Health, USA

#### 9:50 **Understanding Animal Health Regulation in Asia Pacific**

- Harmonizing regulations
- Product development
- Clinical trials and approval •
- Manufacturing facility and licensure
- Post marketing aspects

#### Panelists:

PANEL DISCUSSION

Philip Lehrbach, Director, Regulatory Affairs Asia Pacific, Zoetis, Australia

Kishore Motwani, Head, Technical & Regulatory, Zydus Animal Health, India

Mukesh Khamar, Director, Rannim Pharmaceuticals, India

#### 10:30 Morning Networking & Refreshment Break

#### Animal Health Business Models & Collaboration

11:00	The Emerging	Contours of	f the Animal	Health B	usiness

- The way forward on markets
- Emerging new technologies
- New arenas in manufacturing
- **Regulatory developments**

KV Balasubramaniam, Managing Director, Indian Immunologicals, India

#### 11:40 What do Investors Look For?

- How attractive is the animal health business in Asia? What does a company need to demonstrate to attract investors?
- What are the most attractive areas of investment products, services or contract research?

Panelists:

PANEL DISCUSSION

Peter Fuhrman, Chairman & CEO, China First Capital, China Zhi Yang, Managing Partner, BVCF, China

Vijay Karwal, Managing Director & Head of Industrials, Consumer and Healthcare - Asia Pacific, CIMB Investment Bank, Hong Kong



**Roundtable Discussions** 2:30

#### Table1 Table2 Swine Livestock **Rungtip Chuanchuen** Associate Professor & Director, Center for Antimicrobial **Jim McAllister** Resistance Monitoring, Department of Veterinary Public Director, Global Strategic Marketing, Swine Asia, Health, Faculty of Veterinary Merial, China ciénce, Chulalongkorn University, Thailand Table3 Table4 Companion Avian Animal **Munir Iqbal Mark Micallef** Head of Avian Director, International Influenza Group, Business Unit, The Pirbright Institute, Zenoaq, Japan United Kingdon

Each Roundtable will have a designated leader who will facilitate the discussion for 45 minutes. After which, the leader will share the key takeaways on stage for 5 minutes.

#### 3:30 **Afternoon Networking & Refreshment Break**

### Prevention & Control of Animal Diseases

- 4:00 **Addressing Antimicrobial Resistance (AMR) From Food** Animals in Asia
  - Dynamics and situation of AMR in Asia's livestock industry
  - Antimicrobial use and AMR surveillance and control programs
  - Developing an action plan to mitigate AMR

Alternatives to antimicrobials in animal feed Rungtip Chuanchuen, Associate Professor & Director, Center for Antimicrobial Resistance Monitoring, Department of Veterinary Public Health, Faculty of Veterinary Science, Chulalongkorn University, Thailand

### **Judicious Use of Antibiotics in Animal Health Industry** CASE

4:40

- Antimicrobial resistance risk management
- Therapeutic use and growth promotion
- Future of antibiotics innovation
  - Impact of ban on antibiotics used in animal feed industry

Li Zeng, Head of Greater China R&D Hub, Elanco Animal Health, China

#### 5:20 **Driving Improvement & Excellence in Preventing Swine** Diseases CASE

- Identifying strategies for preventing diseases
- Prevention of diseases through innovative management practices
- Managing extensive collaboration

Jim McAllister, Director, Global Strategic Marketing, Swine Asia, Merial, China

6:00 **Chairperson's Summary & End of Conference Day One** 





## CONFERENCE DAY TWO 5 NOVEMBER 2014 WEDNESDAY

#### 8:50 Chairperson's Opening Remarks

## Zoonoses, Human — Animal Interaction & Risk Mitigation

#### 9:00 Minimizing Risk to Human Health

- Quality of life of companion animal owners
- Livelihood of production animal business owners
- Threat of transmission of diseases through animal meat
- Societal impact of food security/safety issues

Lisa Conte, CEO, Jaguar Animal Health, USA

#### 9:40 Examining the Global Importance of Zoonotic Disease Awareness

- Understanding Zoonotic diseases and its risk to human health
- Emerging zoonotic diseases
- Zoonosis emergence with proximity to animals
- Role of companion animals in zoonosis

G.S. Reddy, Chief General Manager, Indian Immunologicals, India

#### 10:20 Morning Networking & Refreshment Break

#### 10:50 Emergent Rodent Infectious Diseases Globally

- Biomedicine research and drug discovery need
- Zoonotic diseases and other emergent rodent diseases
  How to control disease spread and give animal care
  Jianfei Wang, Director & Head, Laboratory Animal Sciences,
  GlaxoSmithKline, China

Jiaqi Lu, Clinical Veterinarian & Scientist, Laboratory Animal Sciences, GlaxoSmithKline, China

### **Product Development & Marketing**



CAST

#### Providing Animal Health Products & Services to Farmers

- Role of animal health suppliers in swine production
- Comprehensive animal health services to farmers
- Animal health companies providing valuable farmer support
- Improving pig farming: ways and means to optimize productivity

Octavio Eckhardt, Asia Swine Marketing Manager, Virbac, Thailand

## 12:10 Allermmune HDM for Canine Atopic Dermatitis: From

## Concept to Reality

- Canine Atopic Dermatitis
- Discussing the Immunotherapy concept
- Examining the efficacy and safety issues
  Mark Micallef, Director, International Business Unit,
  Zenoaq, Japan

12:50 Networking Lunch

### **Animal Health Vaccines**



- Vaccine Manufacturing & Technology Innovation
  - Different applications in animal health
- Application of single use products in vaccine manufacturing
  - Application difficulties, limits and uncertainties
- Current and future diagnostics methodology Haresh Racha, Head of Vaccine Manufacturing, Zydus Animal Health, India

#### 3:10 Developing High Quality Poultry & Swine Vaccines

- Introduction to an innovative Swine vaccine APM777
- TUDY
- Success story from partners

Shoichiro Hirata, Overseas Operation Leader, Nisseiken, Japan

Technology and quality issues

**Nobuyuki Tsutsumi**, *Chief Scientist & Assistant Manager*, **Nisseiken**, Japan

#### 3:50 Afternoon Networking & Refreshment Break

#### 4:20 Developing Novel Vaccines against Avian Influenza

- Understanding how avian influenza viruses evade the early anti-viral defense mechanisms
- Putting the HA gene into vaccine strains of other viruses already used for poultry
- Applying vaccines to chicks before they hatch
- Contributing to the development of reagents and robust assays for rapid diagnosis
- Munir lqbal, Head of Avian Influenza Group, The Pirbright Institute, United Kingdom

#### 5:00 Recombinant Vaccines & their Application in Veterinary Practice

- Product development of animal health vaccines
- Recent vaccine and immunization strategies
- Increasing demand of vaccines
- Evaluating protective efficacy

Michael Boddington, Managing Director & Lead Consultant, Asian Agribusiness Consulting, China

5:40 Chairperson's Summary of the Day & End of Conference



# **WORKSHOPS**

## Pre-Conference Workshop: 3 November 2014 | Monday Animal Drug Approvals, cGMP & Quality

## WORKSHOP (A) (9:00am - 5:00pm)

#### **Session 1: Preparation of Clinical Trial** Applications

- **CTA and IND applications**
- Guide to preparation of documents
- Key issues and common pitfalls

#### Session 2: Good Record Keeping in Support of **Regulatory Applications**

- Understanding the value of development reports
- Key writing skills for clear communication

#### Session 3: Drug Master Files and Facility Registration

研讨会

- Types of drug master files
- How to prepare and submit a master file

#### How to register your facility

#### **Session 4: Quality Systems**

Key quality systems for international cGMP How to establish and organize your quality

#### program **Session 5: Current Quality Issues**

#### Current topics in quality assurance

Examples and case studies of real problems

#### Session 6: Preparing for Inspections and Audits

- How to prepare your company for foreign inspections and audits
- How to work with inspectors and auditors

#### How to reply to observations

- Session 7: cGMP Facility Design Variations in requirements between different
- regulatory agencies Basic principles for facility
- Review of facility examples

**About Your Workshop Leaders:** 



#### Kishore Motwani, Head, Technical & Regulatory, Zydus Animal Health, India

Rishore indowani, Head, Iechnical & Regulatory, 2yous Animal Health, India Kishore is a post-graduate in Veterinary Science, a graduate diploma holder in Marketing Management and also holds a degree in Law. After being trained at France; Kishore is a post-graduate in Veterinary Science, a graduate diploma holder in Marketing Management and also holds a degree in Law. After being trained at France; Kishore is a cost-graduate in Veterinary in early 90's was instrumental for introducing new products including imported product-for the treatment for theileriosis in crossbreds to the Indian market. Subsequently, at Jubilant Organosys Ltd, Vadodara (Anichem India Ltd) undertook market seeding operations of imported dry Choline chloride-60% and toxin binder (treated HSCAS), prior to the Choline chloride on corn cob plant being set up in technical collaboration with DuCoa, USA. Kishore is also the founder Director of Rannim Pharmaceuticals Pvt Ltd, specializing in poultry products wherein had introduced in late 90's amikacin and lincomycin for poultry. Presently based at Ahmedabad with Cadila Healthcare's Animal Health division, he again has to his credit, a number of new formulations being introduced to the Indian Market, after seeking approvals from federal and state Drug authorities apart from importing and introducing poultry vaccines (including those in tablet form) for the first time in India. He maintains a robust pipeline of new products under varying stages of development for future timely introductions.



#### Mukesh Khamar, Director, Rannim Pharmaceuticals, India

Mukesh worked with Cadila Pharmaceuticals since 1981 as a Sales and Marketing Officer. Had a good exposure of the regulatory procedures such as company registration and new products approval. He is the Co-founder Director of Rannim Pharmaceuticals based in India. He has more than a decade of experience in production, quality controls, regulatory procedures and marketing in India.

## Post-Conference Workshops: 6 November 2014 | Thursday

## **Epidemiology in Animal Health** Vaccines

## WORKSHOP (3) (9:00am - 12:00pm)

The objective of this workshop is to introduce epidemiologic principles needed to estimate the benefit of vaccination at the population level. An example will be used to illustrate the classical approach to estimate this benefit, which may greatly underestimate the true value of the vaccine. A method will be presented, which will estimate the true value of vaccination at the population, which typically is greater than estimates obtained using the individual animal approach.

Session 1: Epidemiologic Concepts Important to Assessing Vaccination Efficacy in a Population

Session 2: Case Study Illustrating How Vaccines are undervalued

Session 3: Illustration of Correct Interpretation of Vaccine Impact at the **Population Level** 

#### **About Your Workshop Leader:**



Tim Carpenter, Professor & Director of the EpiCentre, Gilruth Chair of Animal Health & Leader, World Animal Health Organization's (OIE) Collaborating Centre for Veterinary Epidemiology & Public Health, Massey University, New Zealand

Prior to coming to New Zealand, Professor Carpenter was on the faculty of the School of Veterinary Medicine at the University of California at

Davis, where he taught and conducted research for more than 30 years. His teaching and research were both cross disciplinary and cross species. He has authored or co-authored more than 230 peer-reviewed manuscripts. His animal species and disease focus are equally as diverse as the methods used to study them, including aquatic, wildlife, companion animals and livestock as well as bacterial, viral, protozoan infections and non-infectious diseases, from African swine fever to West Nile virus. Throughout all this, the common thread in his research is a problem-solving approach that provides useful information to an individual pet owner through to decision makers, who are responsible for the wellbeing of large animal populations. Beneficiaries of this work include various agencies, both within the US and abroad, including the US Department of Homeland Security (DHS), the Inter-American Development Bank (IDB), the World Animal Health Organization (OIE), the Food and Agriculture Organization (FAO), several State and Federal Departments of Animal Health, including the US Department of Animal Health (USDA), the US Department of the Interior (USDI), and decision and policy makers around the world, including more than 25 countries from Argentina to Zambia.

## **Quality Risk Management in** Animal Vaccines



Quality risk management includes risk assessment, control, communication and review. In vaccine production, the risk analysis has to be performed keeping cGMP in view. The risks associated with quality, safety and efficacy have to be addressed holistically. There are different approaches for risk assessment and management. The quality risk assessment and management should be a part of a quality assurance system. The risk evaluation is based on scientific knowledge, experience with the process and ultimately links to protection of the patient. Better understanding of the process and tolerance levels in manufacturing of vaccines will help in designing better quality risk management systems. The workshop will expose the participants to risk identification, analysis, evaluation and control in vaccine manufacturing.

#### **Key Topics to Discuss:**

- Risk assessment perspective in vaccine manufacturing
- Qualitative and quantitative methods risk analysis
- Tools useful in risk management
- Process of risk evaluation and review

#### About Your Workshop Leader:

G.S. Reddy, Chief General Manager, Indian Immunologicals, India



Dr. G.S. Reddy is the Chief General Manager of Indian Immunologicals Limited, a major veterinary and human vaccines manufacturer in India. He obtained basic degree in Veterinary medicine in 1981 from Andhra Pradesh Agricultural University, Hyderabad. He has 30 years of experience

in industry, developing veterinary and human biologicals. Experience encompasses Quality, Research and Development, Manufacturing and Regulatory affairs. He is heading the team which is involved in manufacturing of veterinary and human vaccines. He worked on collaborative vaccine development projects with Georg August University, Gottingen, Germany and Centers for Disease Control and Prevention, Atlanta, USA. He is a co-author of patent on DNA Rabies vaccine. He has coordinated clinical trials of Rabies, Hepatitis B, Measles, DT, TT and DTP vaccines. He has published 43 scientific papers in various journals.



## 3 - 6 November 2014 Grand Hyatt Shanghai China

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IBC's **Animal Health Conference** focuses on the investments, projects, research and partnerships going into the Asian Animal Health Business. With the potential threats associated with outbreaks of animal disease, pharmaceutical companies have been focusing on animal disease prevention and the production of veterinary medicines such as vaccines and other pharmaceuticals for swine, poultry, avian and companion animals. This conference will provide thorough evaluation of the market trends, opportunities and challenges experienced by animal health industry leaders.

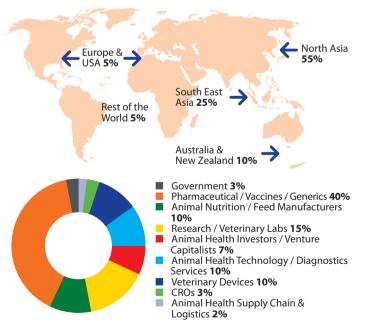
## Agenda at a Glance

Pre-Conference Workshop 3 November   Monday	Conference Day One 4 November   Tuesday	Conference Day Two 5 November   Wednesday	Post Conference Workshops 6 November   Thursday		
Workshop A Animal Drug Approvals, cGMP & Quality	Regulation, Trends & Market Opportunities in Asia Pacific Animal Health Business Models & Collaboration	Zoonoses, Human – Animal Interaction & Risk Mitigation Product Development & Marketing	Workshop B Epidemiology in Animal Health Vaccines		
Networking Lunch					
Workshop A Animal Drug Approvals, cGMP & Quality (Continued)	Prevention & Control of Animal Diseases	Animal Health Vaccines	Workshop C Quality Risk Management in Health Vaccines		



- Examine how key animal health companies such as Elanco, Merial, Zoetis and GSK address animal health diseases and viruses in Asia Pacific
- Gain faster market access by understanding the regulatory pathways, trends and expectations in Asia Pacific
- Evaluate how attractive the animal health business in Asia Pacific is from key investors
- Answer your burning questions during interactive roundtable and panel discussions
- Learn and network with 23+ industry experts from 10 countries
  - Ohina Australia Japan New Zealand
  - USA Sindia Thailand Singapore Taiwan
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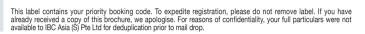
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