IBC LIFE SCIENCES

3 - 6 August 2015 | Grand Copthorne Waterfront Hotel, Singapore

PharmaCon

Pharmaceutical Congress Asia

4 Conferences in 1 Location

Clinical Trials 2015 | 8TH ANNUAL PHARMACEUTICAL REGULATORY AFFAIRS ASIA | PHA RMA MARKET ACCESS2015 | 3RD ANNUAL MEDICAL AFFAIRS FORUM ASIA 2015

The leading event that brings together Asia's leading pharmaceutical companies and its suppliers in one place!

Distinguished Global & Regional Speakers Include:

Carl Firth
Chief Executive Officer,
Aslan Pharmaceutical, Singapore

Churn-Shiouh Gau
Executive Director, Center for Drug Evaluation,
Taiwan Food and Drug Administration (FDA), Taiwan

Jimmy Zhang
Vice President, Transactions,
Johnson & Johnson Innovation, China

Stewart Geary
Chief Medical Officer, Senior Vice President, General Manager, Corporate Medical Affairs Headquarters, Global Safety Board Chair,
Eisai, Japan

Eva Kopecna
Head, Regulatory Affairs-Global OTC,
Teva, UK

Tadashi Fujisawa
Chief Executive Officer,
Mebiopharm, Japan

James Garner
Head, Unit Development Operations, Asia R&D,
Sanofi, Singapore

Maggie Lim
Director, Asia Pacific Clinical Development Quality Assurance, R&D Global Quality & Compliance,
GlaxoSmithKline, Singapore

Robert Braithwaite
Founder & CEO,
Luqa Pharmaceuticals, China

Jin-San Yoo
President & CEO,
PharmAbcine, South Korea

Talita Hilse
Senior Director, Global Clinical Operations,
Takeda Pharmaceuticals, Switzerland

Anirban Roy Chowdhury
Senior Director, Global Clinical Operations,
Merck & Co., India

Ajay Tiku
Vice President Medical, Asia Pacific, North & South Asia,
GlaxoSmithKline, Singapore

Andrew Eggleston
JAPAC Market Access & Policy Director,
Abbvie, Singapore

R. Byron Sigel
Director, Patient Innovation Policy,
Baxalta, Japan

Dominique Milea
Director Health Economics & Epidemiology Asia,
Lundbeck, Singapore

What's New for 2015:

- **Latest country-focused updates** on regulation and market trends
- **Real-life case studies** from **18+ countries**
- **80+ renowned speakers** from leading pharmaceutical companies
- **1 shared exhibition room** to showcase latest technology and services
- **4 days** of expert knowledge sharing
- **180+ attendees** to network with

Optimize your Time & Money with a GOLD PASS

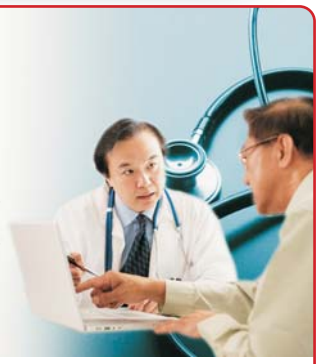
www.pharmaconasia.com

PharmaCon
Pharmaceutical Congress Asia

3 - 6 August 2015
Grand Copthorne Waterfront Hotel, Singapore

4 Conferences in 1 Location

Clinical Trials 2015



Designed for professionals in clinical trial value chain, Clinical Trials Asia zeroes in on the latest new trial markets in Asia and the newest trends in operational excellence for Asia. This event aims to accelerate cost-efficient clinical development that meets global trial standards for big pharma, local pharma and biotech in Asia. It discusses how to achieve the quality requirements for meeting global clinical standards, accelerating trial timelines in Asia Pacific, examining the individual clinical capabilities in Asia Pacific and most cost-effective ways to conduct trial operations in Asia. Find out how to smoothly integrate Asia Pacific into global clinical trials with a focus on enhancing trial quality, improved research outcomes and accelerated timelines for drug approvals at the ONLY senior platform for Clinical Research Excellence in Singapore for 2015.

WHO SHOULD ATTEND?

VPs, Directors, Heads, Managers, Team Leaders of:

- Clinical Operations
- Clinical Development
- R&D
- Drug Development
- R&D business operations
- Clinical Trial Co-ordination
- Clinical Quality Assurance
- Clinical Compliance
- Inspection Readiness
- Clinical Supply Chain Management
- R&D Outsourcing
- Procurement
- Strategic Partnerships and Alliances
- Business Development
- Partnership Strategies
- Medical Affairs
- Project Management
- Project Leadership
- Trial Site Management
- Onsite-monitoring
- Clinical Resourcing
- Global/regional APAC Monitoring
- Biometrics and Medical Writing
- Data Management
- Clinical Research Associate (CRA)
- Strategic Outsourcing
- Clinical Trial Monitoring
- Project / Trial Start-up

8TH ANNUAL PHARMACEUTICAL REGULATORY AFFAIRS ASIA

The leading platform for regulatory experts to be updated with latest country updates and strategies to navigate the complex and ever changing regulations in the region. Good depth & breadth of discussions include both country-centered and product- focused regulatory strategies for ease of product access into regional and international markets. Accelerate your approvals to fast-track your drugs to the market.

WHO SHOULD ATTEND?

VPs, Directors, Heads, Managers of:

- Global/ Regional Regulatory affairs
- Regulatory Submissions
- Regulatory Compliance
- Drug Development & Regulatory Affairs
- Medical & Regulatory Affairs
- Regulatory & Government Affairs
- Regulatory Policy
- Regulatory Intelligence
- Regulatory strategy
- Product Development
- Clinical Development
- Regulatory publishing
- Pharmacovigilance
- QA/QC

PHA RMA MARKET ACCESS2015

Designed for regional and country managers and senior executives from marketing, commercial development, Government affairs and business development, the conference pinpoints key success factors in strategizing market entry in Asia's complex diverse, competitive and growing pharmaceutical market. This event is Asia's one and only platform to provide updated and in-depth evaluation on profitable and successful market entries.

WHO SHOULD ATTEND?

- CEO
- President/Managing Director/Vice President of Asia
- Country Manager
- Regional Marketing Director
- Head of Corporate Planning
- Head of Government Affairs
- Head of Marketing & Sales
- Head of Market Access & Pricing
- Head of Health Economics
- Head of Business Development
- Head of Commercial
- Head of Product Development
- Head of Procurement & Sourcing
- Head of Compliance

4TH ANNUAL MEDICAL AFFAIRS FORUM ASIA 2015

Join us at IBC Asia's 4th Medical Affairs Forum 2015 – the region's longest running strategy forum where leading medical affairs professionals share best practices, discuss common issues and learn from industry experts to enhance scientific reputation, sustain collaboration, build their brand names and achieve success. Gain insights into how to balance both scientific and commercial roles, engage in effective cross-functional team collaborations, and form mutually beneficial partnerships with KOLs to get ahead and drive success.

WHO SHOULD ATTEND?

- Chief Medical Officers
- Vice President/Director, Medical Affairs
- Head, Medical and Regulatory Affairs
- Medical and Scientific Affairs
- Medical and Clinical Affairs
- Medical Directors
- Medical Affairs Managers
- Medical Advisors
- Medical Affairs Associates
- Medical Science Liaisons
- Medical Writers

PharmaCon
Pharmaceutical Congress Asia

CONFERENCE DAY ONE
4 August 2015
Tuesday

8.00	**Registration Opens & Morning Coffee**
8.45	**Welcome Address from IBC Asia & Speed Networking**
8.50	**Chairperson's Opening Remarks**

ASIA PHARMA MARKET OUTLOOK

9.00 **Keynote Big Pharma Panel: What are the Key Commercial Considerations for Successful Drug Research, Investment & Development in Asia?**
Panelists:
Yariv Hefez, *Vice President, Strategic Development, Business Development, Portfolio Management and Partnering, Biosimilars*, **Merck Serono**, Switzerland
Stewart Geary, *Chief Medical Officer, Senior Vice President, General Manager, Corporate Medical Affairs Headquarters, Global Safety Board Chair*, **Eisai**, Japan
James Garner, *Head, Unit Development Operations, Asia R&D*, **Sanofi**, Singapore
Jimmy Zhang, *Vice President, Transactions*, **Johnson & Johnson Innovation**, China

9.30 **Keynote Regional CEO Panel: What is the Impact of Globalization on Drug Development for Biotech and Local Pharma?**
Panelists:
Tadashi Fujisawa, *Chief Executive Officer*, **Mebiopharm**, Japan
Robert Braithwaite, *Founder & CEO*, **Luqa Pharmaceuticals**, China
Jin-San Yoo, *President & CEO*, **PharmAbcine**, South Korea
Carl Firth, *Chief Executive Officer*, **Aslan Pharmaceutical**, Singapore

10.00 **Special Government Panel: Regulatory Convergence, Drug Development Pathways and Access in Asia**
Panelists:
Churn-Shiouh Gau, *Executive Director, Center for Drug Evaluation*, **Taiwan Food and Drug Administration (FDA)**, Taiwan
Maria Victoria Calub, *Food-Drug Regulation Officer IV*, **Food and Drug Administration (FDA),** Philippines
Andrea Laslop, *Head of Scientific Office, Austrian Agency for Health and Food Safety (AGES) PharmMed & Member, Committee for Medicinal Products for Human Use (CHMP)*, **European Medicines Agency (EMA)**, Austria
Nguyen Ngo Quang, *Deputy Director*, **Administration of Science, Technology and Training (ASTT), Vietnam Ministry of Health**, Vietnam

10.30 **Morning Networking & Refreshment Break**

Choose Your Own Sessions From 3 Different Tracks

Clinical Trials 2015

11.15 **Chairperson's Opening Remarks**

11.20 **Clinical Trial Market Opportunities in Asia Pacific**

Keynote Panel Discussion:
Where are Big Pharma and Biotech Looking for Clinical Trials in Asia Pacific?
Panelists:
Stewart Geary, *Chief Medical Officer, Senior Vice President, General Manager, Corporate Medical Affairs Headquarters, Global Safety Board Chair*, **Eisai**, Japan
Jason Yang, *Senior Vice President and Head of Clinical Development*, **BeiGene**, China
Anirban Roy Chowdhury, *Senior Director, Global Clinical Operations*, **Merck & Co.**, India
James Garner, *Head, Unit Development Operations, Asia R&D*, **Sanofi**, Singapore

12.00 **Case Study:**
Regulatory Update Relating to Clinical Trial Conduct in Vietnam
Nguyen Ngo Quang, *Deputy Director*, **Administration of Science, Technology and Training (ASTT), Vietnam Ministry of Health**, Vietnam
Tran Thi Minh Nguyet, *Co-founder, General Manger*, **Smart Research**, Vietnam

8TH ANNUAL PHARMACEUTICAL REGULATORY AFFAIRS ASIA

11.15 **Chairperson's Opening Remarks**
Michel Mikhail, *Expert in International Global Regulatory Affairs*, Germany

11.20 **Country-Focused Regulatory Updates & Clarification of Guidelines**

Latest Country Updates & Regulatory Environment Overviews

Taiwan
Churn-Shiouh Gau, *Executive Director/Center for Drug Evaluation*, **Taiwan FDA**

Philippines
Maria Victoria P. Calub, *Food-Drug Regulation Officer IV*, **FDA Philippines**

Vietnam
Thao Nguyen, *Regulatory and Government Affairs Director*, **Roche Vietnam**

PHARMA MARKET ACCESS 2015

11.15 **Chairman's Opening Remarks**
Rafael Mendoza, *Regional Therapeutic Lead – Global Innovative Pharma*, **Pfizer**, USA

11.20 **Country Updates, Investments & Expansion**

Keynote Panel:
Challenges in Asia's Changing Healthcare Economics and Improving the Commercial Success of New and Established Products in Asia
Moderator:
Dr Allan Lai, *Vice President*, **International Society of Pharmacoeconomics and Outcome Research**, Singapore
Panelists:
R. Byron Sigel, *Director, Patient Innovation Policy*, **Baxalta**, Japan
Marcelina 'Ace' Itchon, *President and CEO*, **Aspen Philippines, Inc**, Philippines
Jittrakul Leartsakulpanitch, *Head, Market Access, Asia Pacific*, **Janssen**, Singapore
Nathan Kothandaraman, *Lead, Government Affairs*, **Johnson & Johnson**, Malaysia

12.00 **Investment & Market Updates in Asia**
Vijay P. Karwal, *Managing Director, Co-Head of Mergers & Acquisitions, Head of Industrials, Consumer & Healthcare*, **CIMB Investment Bank**, Hong Kong

PharmaCon
Pharmaceutical Congress Asia

CONFERENCE DAY ONE
4 August 2015
Tuesday

Clinical Trials 2015 | 8TH ANNUAL PHARMACEUTICAL REGULATORY AFFAIRS ASIA | PHARMA MARKET ACCESS 2015

12.50 Networking Lunch & VIP Tables

Bring your questions and get to know industry experts whilst having lunch

VIP Table 1: **Nguyen Ngo Quang**, *Deputy Director, Administration of Science, Technology and Training (ASTT)*, **Vietnam Ministry of Health**, Vietnam
VIP Table 2: **Stewart Geary**, *Chief Medical Officer, Senior Vice President, General Manager, Corporate Medical Affairs Headquarters, Global Safety Board Chair*, **Eisai**, Japan
VIP Table 3: **Feng Guo**, *Head, R&D*, **Merck Serono**, China
VIP Table 4: **Churn-Shiouh Gau**, *Executive Director, Center for Drug Evaluation*, **Taiwan Food and Drug Administration (FDA)**, Taiwan
VIP Table 5: **Maria Victoria Calub**, *Food-Drug Regulation Officer IV*, **Food and Drug Administration (FDA)**, Philippines
VIP Table 6: **Andrea Laslop**, *Head of Scientific Office*, **Austrian Agency for Health and Food Safety (AGES) PharmMed** & *Member, Committee for Medicinal Products for Human Use (CHMP)*, **European Medicines Agency (EMA)**, Austria
VIP Table 7: **Andrew Eggleston**, *JAPAC Market Access & Policy Director*, **Abbvie**, Singapore
VIP Table 8: **Irene Chen**, *Regional Market Access and Pricing Lead, Asia Oceania*, **Astellas Pharma**, Singapore
VIP Table 9: **Bruno Rossi**, *Senior Advisor, Market Access and Health Policy*, **Bayer HealthCare,** Japan

2.00

Early Phase Clinical Development for Niche Biologics in Asia Pacific

The Ecosystem for Early Phase and Translational Clinical Research in Singapore: Where are the Gaps and Opportunities?
Danny Soon, *Former Managing Director, Lilly-NUS, Medical Director*, **Drug Discovery and Development (D3), A*Star**, Singapore

2.40

Case Study:
Early-Phase Clinical Development Pathway for mAb Biologics in Korea
Jin-San Yoo, *Chief Executive Officer, President*, **PharmAbcine**, Korea

Country-Focused Regulatory Updates & Clarification of Guidelines (continued)

Indonesia
Ikhsan Rambia, *Head of International Regulatory Affairs*, **Sanbe Farma**, Indonesia

Thailand
Noppadon Adjimatera, *SEA Regional Regulatory and Medical Affairs Director*, **Reckitt Benckiser**, Thailand

Japan
Koichi Miyazaki, *Senior Director, Regulatory Affairs Group, Asia Development Department*, **Daiichi Sankyo,** Japan

China Case Study:
Creating a Successful Specialty Pharma Company in China – Opportunities & Challenges
Robert Braithwaite, *Founder & CEO*, **Luqa Pharmaceuticals**, China

Philippines Case Study:
Realizing the Full Potential of Philippines' Unique Market
Marcelina 'Ace' Itchon, *President and CEO*, **Aspen Philippines, Inc**, Philippines

Indonesia Case Study:
Indonesia's Universal Healthcare Coverage: How can Foreign Pharma Companies Leverage & Remain Profitable in the Market?
Dr. Luthfi Mardiansyah, *Chairman*, **International Pharmaceutical Manufacturer Group (IPMG)**, *President Director*, **Novartis**, Indonesia

3.20 Afternoon Networking & Refreshment Break

3.50

Designing an Effective Corrective Action Preventive Action (CAPA) Management System for Conducting Clinical Trials in Asia
Maggie Lim, *Director, Asia Pacific Clinical Development Quality Assurance, R&D Global Quality & Compliance*, **GlaxoSmithKline**, Singapore

China
Victoria Elegant, *Vice President, Medical & Regulatory Affairs*, **Baxter,** China

India
Premnath Shenoy, *Regulatory Affairs Director*, **AstraZeneca**, India

Thailand Case Study:
Maintaining Profit Margins under Universal Healthcare in Thailand
Paul Uthaichalanond, *Director, Vaccine Sub-Cluster Lead - Thailand, Indonesia and Vietnam*, **Pfizer,** Thailand

4.30

Case Study:
Quality Assurance Measures and Compliance in Asia Trials: Ensuring Readiness for FDA Inspections
Seema Gaonkar, *Global Clinical Quality Assurance Manager*, **Lundbeck**, Singapore

Accelerating Patient Access to Medicines via Adaptive Licensing and Approval Pathways
Andrea Laslop, *Head of Scientific Office*, **AGES, PharmMed**, Austria and *Austrian member, CHMP*, **EMA (European Medicines Agency)**

Panel Discussion:
Biosimilars – Where is it Heading & How to Access the Asian Market Profitably?
Panelists:
Yariv Hefez, *Vice President, Strategic Development, Business Development, Portfolio Management and Partnering, Biosimilars*, **Merck Serono**, Switzerland
Sreeraj Roy, *Business Director*, **Pfizer**, Indonesia

5.10 Roundtable Discussions

Role of Academic Research Institutes in Global Clinical Trial Operations
Isabelle Lee, *Head, Research Operations & Project Management*, **Singapore Clinical Research Institute**, Singapore

Comparisons of CMC Variations in the Region & Managing Complications
Tong-Lay Crystal Lau, *Senior Technical Regulatory Specialist (Global)*, **GlaxoSmithKline**, Singapore

Current Compliance Issues for Pharma Companies
Redentor Romero, *Regional Compliance Officer*, **Teva Pharmaceuticals**, Singapore

Monitoring Trip Reports in Asia: Balance Between Optimization Time, Dynamic Trip Reports and Recording of Critical Information
Juliana Wang, *Onsite Monitoring and Resourcing Manager, South East Asia*, **Boehringer Ingelheim Pharmaceuticals**, Singapore

Strategies for Handling Products in Multiple Countries
Jack Wong, *Director, Regulatory Affairs Asia Pacific*, **Terumo BCT**, Singapore, *Founder of* **Asia Regulatory Professional Association (ARPA)**

Opportunities under Universal Healthcare Coverage in Indonesia
Bernardus Sidharta, *former COO/Director Commercial Operation & Development*, **Merck**, *President & Managing Director*, **PT Rama Emerald Multi Sukses**, Indonesia

Trial Site Selection in Asia Pacific: The Right Country, the Right Site and the Right Partner
Prabhuram Krishnan, *Medical Director*, **Eli Lilly and Company**, Philippines

Regulatory Intelligence when Developing Regulatory Strategies for a Global Market
Michel Mikhail, *Expert in International Global Regulatory Affairs*, Germany

Market Entry for Established Pharma Products
Rafael Mendoza, *Regional Therapeutic Lead – Global Innovative Pharma*, **Pfizer**, USA

6.00 Chairperson's Summary & End of Conference Day One

PharmaCon
Pharmaceutical Congress Asia

CONFERENCE DAY TWO
5 August 2015
Wednesday

	Clinical Trials 2015	8TH ANNUAL PHARMACEUTICAL REGULATORY AFFAIRS ASIA	PHARMA MARKET ACCESS 2015
9.00	**Chairperson's Opening Remarks**	**Chairperson's Opening Remarks** **Premnath Shenoy**, *Regulatory Affairs Director*, **AstraZeneca**, India	**Chairperson's Opening Remarks** **Salman Bokhari**, *Managing Director*, **Sidrapex**, Singapore
9.10	**Partnerships and Outsourcing Strategies** **Examining Innovative R&D Collaboration Strategies for Asia** **Yariv Hefez**, *Vice President, Strategic Development, Business Development, Portfolio Management and Partnering, Biosimlars*, **Merck Serono**, Switzerland	**Identifying Regulatory Pathways & Crafting Regulatory Strategies for Key Products** **Panel Discussion:** **Comparison of Regulatory Trends and Impacts on Business Strategy: APAC vs International Regulatory Models FDA/EMA** Moderator: **Ng Cheng Tiang**,*Asia Regulatory Affairs Regional Director*, **Teva**, Singapore Panelists: **Michel Mikhail,** *Expert in International Global Regulatory Affairs*, Germany **Chau Giang Le**, *Vice President, Regulatory Affairs and Scientific Engagement APAC*, **Johnson and Johnson**, *Singapore*	**Real World Evidence and Health Economic Outcome Research** **Staying Ahead of Your Competitors in Evidence-Based World – Models for Success** **Seng Chuen Tan**, *Regional Director, HEOR and Real-World Evidence*, **IMS Health**, Singapore
9.50	**Panel Discussion:** **Key Considerations in CRO Selection for Trials in Asia** Panelists: **Talita Hilse**, *Senior Director, Global Clinical Operations*, **Takeda Pharmaceuticals**, Switzerland **Seema Gaonkar**, *Global Clinical Quality Assurance Manager*, **Lundbeck**, Singapore **Sachin Pasumamula**, *Regional Global Medical Operations Compliance Head, Region International, Asia Pacific and Middle East*, **Formerly Novartis Vaccines**, **GlaxoSmithKline**, Singapore **Valerie Tan**, *Asia Pacific & South Africa Head, Global Medical Operations*, **Novartis Asia Pacific**, Singapore	**Regulatory Strategies for OTC Drugs** **Eva Kopecna**, *Head, Regulatory Affairs-Global OTC*, **Teva**, UK	**Creating and Using RWE (Real World Evidence) in Support of Market Access** **R. Byron Sigel**, *Director, Patient Innovation Policy*, **Baxalta**, Japan
10.30	**Morning Networking & Refreshment Break**		
11.00	**Efficient and Cost-Effective Trial Operation in Asia** **Critical Considerations in Quality for the Clinical Supply Chain Operations in Asia Pacific** *Senior Representative*, **ALMAC**	**Strategies for: Biosimilars & Vaccines – Key APAC Markets** **Premnath Shenoy**, *Regulatory Affairs Director*, **AstraZeneca**, India	**Creating a Sustainable Health Economics & Outcomes Research Strategy** **Bruno Rossi**, *Senior Advisor, Market Access and Health Policy*, **Bayer HealthCare**, Japan
11.40	**Panel Discussion:** **Understanding the Concepts of Risk-Based Monitoring for Clinical Trials** Moderator: **Seema Gaonkar**, *Global Clinical Quality Assurance Manager*, **Lundbeck**, Singapore Panelists: **Pei Yin Tan**, *Associate Director, Head of Asia Clinical Operations*, **Eisai Clinical Research**, Singapore **Valerie Tan**, *Asia Pacific & South Africa Head, Global Medical Operations*, **Novartis Asia Pacific**, Singapore	**Generics Regulatory Pathways** **Krishna Prasad**, *Associate Director Regulatory Affairs*, **Actavis**, Singapore	**Pricing & Reimbursement** **Case Study:** **Optimal Market Access and Pricing & Reimbursement (P&R) Strategies** **Jittrakul Leartsakulpanitch**, *Head, Market Access, Asia Pacific*, **Janssen**, Singapore **Out-licensing & Partnership** **Is Out-licensing an Efficient Way to Accelerate Market Penetration in New Markets?** **Lalit Baregama**, *General Manager – Global Development*, **Cadila Pharmaceuticals,** India **High Priced Therapeutics** **Building up a Credible Health Economic Database for High Price Therapeutics Drugs** **Dominique Milea**, *Director Health Economics & Epidemiology Asia*, **Lundbeck**, Singapore
12.20	**Accelerating Clinical Trial Timelines Cost-Effectively in Asia Pacific**	**Regulatory Pathways for Medical Device and Combination Products in Asia** **Jack Wong**, *Director, Regulatory Affairs Asia Pacific*, **Terumo BCT**, Singapore, *Founder*, **Asia Regulatory Professional Association (ARPA)**	

PharmaCon
Pharmaceutical Congress Asia

CONFERENCE DAY TWO
5 August 2015
Wednesday

Clinical Trials 2015 | 8TH ANNUAL PHARMACEUTICAL REGULATORY AFFAIRS ASIA | PHARMA MARKET ACCESS2015

1.00 Networking Lunch & VIP Tables

Bring your questions and get to know industry experts whilst having lunch

VIP Table 1: Elaine Wang, *Director, Clinical Development and Medical Affairs, Respiratory,* **Boehringer Ingelheim**, USA
VIP Table 2: Sivabalan Sivanesan, *Director, Medical and Regulatory Affairs*, **Roche Pharmaceuticals**, Malaysia
VIP Table 3: Keisuke Shiroyama, *R&D Procurement Manager*, **Janssen, Johnson & Johnson**, Japan
VIP Table 4: Vo Thi Nhi Ha, *Vice Head, Division of Clinical Trial Management*, **Administration of Science, Technology and Training (ASTT), Vietnam Ministry of Health**, Vietnam
VIP Table 5: Manish Garg, *Medical Director*, **MSD Pharmaceuticals**, Singapore
VIP Table 6: Jeonghoon Han, *Regional Medical Director, APAC*, **Teva Pharmaceuticals**, Singapore
VIP Table 7: R. Byron Sigel, *Director, Patient Innovation Policy*, **Baxalta**, Japan
VIP Table 8: Jackie Tieng, *Head of Marketing*, **Takeda Pharmaceuticals**, Taiwan
VIP Table 9: Jittrakul Leartsakulpanitch, *Head, Market Access, Asia Pacific*, **Janssen**, Thailand

2.00

Modernizing and Transforming Clinical Practices in Asia

Transforming the Landscape of Trial Technology in Asia: Application of ePRO Systems for Clinical Data Management
Senior Representative, **ERT**

Regulatory Considerations for Clinical Development and NDA

Panel Discussion:
Multi Regional Clinical Trials (MRCTs) for Accelerated Drug Development

Panelists:
Shun Jin, *Regulatory Policy & Intelligence Director, JAPAC*, **AbbVie** Singapore

Yuko Kikuchi, *Senior Director Asia Regulatory Affairs*, **Eisai**, Japan

Koichi Miyazaki, *Senior Director, Regulatory Affairs Group, Asia Development Department*, **Daiichi Sankyo**, Japan

Case Study:
Early Access Program and Orphan Indication for Accelerated Approvals
Elaine Wang, *Director, Clinical Development and Medical Affairs – Respiratory*, **Boehringer Ingelheim,** USA

2.40

Bridging Gaps in Meeting Trial Timelines: Effective Communication Between Biometrics and Clinical Trial Operations
Lot Yin Teng, *Director, Biometrics and Medical Writing*, **Lundbeck**, Singapore

Overcoming Challenges in Filing for New Drug Application (NDA) across Asia
Bindoo Chahal, *Regulatory Affairs Director, SEA*, **Lundbeck**, Malaysia

Case Study:
Successful Market Access for Oncology Products in Asia
Jackie Tieng, *Head of Marketing*, **Takeda Pharmaceuticals,** Taiwan

3.30 Afternoon Networking & Refreshment Break

4.00

Creative Strategies for Pharma to Address the Challenges of Patient Recruitment & Retention
Anirban Roy Chowdhury, *Senior Director, Global Clinical Operations,* **Merck & Co.**, India

Achieving Operational Excellence in Delivering Dossier Submissions

Preparing Global Dossiers Effectively – Cross Regional Submission Advice
Ikhsan Rambia, *Head of International Regulatory Affairs*, **Sanbe Farma**, Indonesia

Case Study:
Formulating an Effective Market Access Strategy in Diabetes
Dr Viraj Rajadhyaksha, *Medical Director, Therapy Area Lead, Diabetes Portfolio Asia Area*, **AstraZeneca**, Singapore

4.40

What is Next for Clinical Trials in Asia?

Panel Discussion:
Which is the Next Big Trial Destination in Asia?

Panelist:
Danny Soon, *Former Managing Director,* **Lilly-NUS**, *Medical Director,* **Drug Discovery and Development (D3)**, **A*Star**, Singapore

Post Market Surveillance Essentials & Compliance

CMC Variation Essentials in Lifecycle Management
Tong-Lay Crystal Lau, *Senior Technical Regulatory Specialist (Global),* **GlaxoSmithKline**, Singapore

IP and Legal Issues

Case Study:
IP Litigation and Policy – Highlights and Recent Development in India and Asia
Sandeep Rathod, *Vice President/Head IP Litigation and Policy (India and Emerging Markets)*, **Mylan Laboratories**, India

5.20

Variations in Post Market Surveillance Across the Region

Patent Strategies under Competitive Landscape
Dr Amin Trehan, *Director (Head) – Intellectual Property*, **Novel Laboratories**, USA

6.00 Chairperson's Summary & End of Conference! See You Next Year!

SPONSORSHIP SOLUTIONS CAN BE TAILORED TO YOUR NEEDS!

To position your company as a market leader at this event, and to explore the range of thought leadership, speaking, branding and marketing opportunities available, please contact **Yvonne Leong** • Tel: **+65 6508 2489** • Email: **Yvonne.Leong@ibcasia.com.sg**

PharmaCon FORUMS

Pharmaceutical Congress Asia

PRE Conference Forum: 3 August 2015 | Monday

Leadership in CLINICAL OUTSOURCING

9.00 **Chairperson's Opening Remarks**
Kiran Marthak, *Global Head, Director, Clinical Development, Member of Board of Directors,* **Lambda Therapeutic Research**, India

9.10 **CRO Market Outlook: Past, Present and Future**
OPENING LEADERSHIP PANEL
Panelists:
Anand Tharmaratnam, *Senior Vice President, Head of Asia Markets, Member of Quintiles Executive Committee,* **Quintiles Transnational**, Singapore
Alistair Macdonald, *Chief Operating Officer, Global President,* **INC Research**, UK
Albert Liou, *Vice Chairman for Asia Pacific,* **PAREXEL International**, Taiwan

10.10 **How Does Asia Fit into the Global CRO Strategy?**
Alistair Macdonald, *Chief Operating Officer, Global President,* **INC Research**, UK

11.10 **Morning Networking & Refreshment Break**

11.40 **Evolving CRO Business Models in Asia: 2015 and Beyond**
Alek Safarian, *Chief Executive Officer,* **Novotech**, Australia

12.40 **Managing an Efficient Functional Service Provision Model in Asia**
Rabinder Buttar, *President, Chief Executive Officer and Founder,* **ClinTec International Group**, UK

2.40 **Leadership Through Operational Excellence: Integrating Asian Operations into Global Clinical Trial Operations for CROs**
Yeo Jing Ping, *Vice President, Project Leadership APAC,* **Parexel International**, Singapore

3.40 **Considerations in Clinical Quality CROs Conducting Clinical Trials in Asia Pacific**
Monelle Payet, *Director, Clinical Quality Assurance,* **ICON Clinical Research**, Singapore

4.40 **Afternoon Networking & Refreshment Break**

5.10 **How Are the Drug-Development Collaboration Models for Pharma and CRO Changing in Asia?**

6.10 **Chairperson's Closing Remarks & End of Forum**

"Good mix of investigators, sites, pharmas and partners... led to lively discussions, good participation"
Takeda Clinical Research

"An excellent conference, very interactive and I certainly learned a lot"
Boehringer Ingelheim Pharmaceuticals

POST Conference Forum: 6 August 2015 | Thursday

4TH ANNUAL MEDICAL AFFAIRS FORUM ASIA 2015

9.00 **Chairperson's Opening Remarks**
Timothy Low, *Vice President, Medical Affairs APAC,* **Medtronic**, Singapore

9.10 **Overcoming Challenges in a Cross Functional Team & Meeting Expectations of All Stakeholders**
PANEL DISCUSSION
Panelists:
Ajay Tiku, *Vice President Medical, Asia Pacific, North & South Asia,* **GlaxoSmithKline**, Singapore
Stewart Geary, *Chief Medical Officer, Senior Vice President,* **Eisai**, Japan
Victoria Elegant, *Vice President, Medical & Regulatory Affairs,* **Baxter**, China

9.50 **Develop a Medical Strategy that Aligns with Business Goals**
Jeonghoon Han, *Regional Medical Director, APAC,* **Teva Pharmaceuticals**, Singapore

10.30 **Morning Networking & Refreshment Break**

11.00 **Creating Synergies between Marketing & Medical Affairs**
Sivabalan Sivanesan, *Medical and Regulatory Affairs Director,* **Roche**, Malaysia

11.40 **Strategic KOL Engagement and Management**
PANEL DISCUSSION
Dr Timothy Low, *Vice President, Medical Affairs APAC,* **Medtronic,** Singapore
Manish Garg, *Medical Director,* **MSD Pharmaceuticals**, Singapore
Prabhuram Krishnan, *Medical Director,* **Eli Lilly and Company**, Philippines

Networking Luncheon

1.30 **Clinical Development and Medical Affairs: Realizing Synergies for Successful Drugs**
Victoria Elegant, *Vice President, Medical & Regulatory Affairs,* **Baxter**, China

2.10 **Effective Management of Observational Studies and Investigator-Initiated Studies (IIS)**
Stewart Geary, *Chief Medical Officer, Senior Vice President,* **Eisai**, Japan

2.50 **High Performing Medical Science Liaisons Teams and Key Success Factors**
Ajay Tiku, *Vice President Medical, Asia Pacific, North & South Asia,* **GlaxoSmithKline**, Singapore

3.30 **Afternoon Networking & Refreshment Break**

4.00 **Addressing Success Factors and Hitting the KPI in Medical Affairs**
Dr Abhishek Bhagat, *Head, Medical Science & Regional Medical Director, Consumer Health Asia,* **Merck Group**, Singapore

4.40 **Resource Allocation & Implementing an Effective Talent Development Program**
Prabhuram Krishnan, *Medical Director,* **Eli Lilly and Company**, Philippines

5.20 **Early Access Program (EAP) for Patients – Oncology**
CASE STUDY
Manish Garg, *Medical Director,* **MSD Pharmaceuticals**, Singapore

6.00 **Chairperson's Closing Remarks & End of Forum**

PharmaCon WORKSHOPS

Pharmaceutical Congress Asia

PRE Conference Workshop: 3 August 2015 | Monday

8TH ANNUAL PHARMACEUTICAL REGULATORY AFFAIRS ASIA

PHARMA MARKET ACCESS2015

Workshop A • 9.00am - 5.00pm

Registration in the ASEAN Region: Overview of Dossier Requirements, Time-Frames and Registration Procedures

Michel Mikhail, *Expert in International Global Regulatory Affairs,* Germany

Workshop B • 9.00am - 12.30pm

Improving Market Access Using Real World Evidence Strategies

Dr Arun Gowda, *Director of Focus Scientific Research Center*, **Pharmax**, India

Networking Luncheon

Registration in the ASEAN Region: Overview of Dossier Requirements, Time-Frames and Registration Procedures (continued)
Michel Mikhail, *Expert in International Global Regulatory Affairs*, Germany

Workshop C • 1.30pm - 5.00pm

Philippines

Lyle Joseph Morrell, *Corporate Development Officer*, **Metro Pacific Investments Corporation**, Philippines

POST Conference Workshop: 6 August 2015 | Thursday

8TH ANNUAL PHARMACEUTICAL REGULATORY AFFAIRS ASIA

PHARMA MARKET ACCESS2015

Workshop D • 9.00am - 5.00pm

Regulatory Strategies for Clinical Trials

9.10 **Chairperson's Opening Address**
Yuko Kikuchi, *Senior Director Asia Regulatory Affairs,* **Eisai**, Japan

Clinical Regulatory Pathways: Timelines, Submissions and Regulatory Challenges of Conducting Local Clinical Trials in Key Regions

9.15 **Japan**
Yuko Kikuchi, *Senior Director Asia Regulatory Affairs,* **Eisai**, Japan

10.00 **Thailand**
Noppadon Adjimatera, *SEA Regional Regulatory and Medical Affairs Director*, **Reckitt Benckiser**, Thailand

11.15 **Philippines**
Julie Anne Odarbe, *Regulatory Affairs Manager,* **Allergan Healthcare**, Philippines

11.55 **Vietnam**
Thao Nguyen, *Regulatory and Government Affairs Director,* **Roche**, Vietnam

Workshop E • 9.00am - 5.00pm

China and IndoChina

John Wong, *Senior Partner & Managing Director*, **Boston Consulting Group**, China

Zarif Munir, *Partner and Managing Director*, **Boston Consulting Group**, Malaysia

Networking Luncheon

Regulatory Strategies for Clinical Trials (continued)

2.00 **India**
Premnath Shenoy, *Regulatory Affairs Director,* **AstraZeneca**, India

2.45 **Bridging Studies and Waivers in Asia**
Shun Jin, *Regulatory Policy & Intelligence Director, JAPAC,* **AbbVie**, Singapore

4.00 **Challenges in Drug Safety and Efficacy Reporting**
Pai Raghavendra, *Regional Pharmacovigilance Manager,* **Lundbeck** Singapore

China and IndoChina (continued)

John Wong, *Senior Partner & Managing Director*, **Boston Consulting Group**, China

Zarif Munir, *Partner and Managing Director*, **Boston Consulting Group**, Malaysia

IBC LIFE SCIENCES

3 - 6 August 2015 | **Grand Copthorne Waterfront Hotel, Singapore**

PharmaCon

Pharmaceutical Congress Asia

4 Conferences in 1 Location

Clinical Trials 2015

8TH ANNUAL PHARMACEUTICAL REGULATORY AFFAIRS ASIA

PHA PMA MARKET ACCESS2015

MEDICAL AFFAIRS FORUM ASIA 2015

IBC's **PharmaCon Asia** will bring together key industry leaders from different regions in Asia Pacific, Europe, Middle East and US to meet, network and exchange ideas to drive innovation, investment and development in Asia's growing pharmaceutical sector.

Multiple Events

1 Unique Business Platform

Gain Insight on Asia's Unique & Complex Pharmaceutical Environment Today!

- Where are the investment opportunities in Asian led research and drug development?
- Who is taking the lead?
- What is the latest progress with clinical development in Asia?
- How are regulations and approval processes evolving?
- How do you access key markets in Asia successfully?
- What are the key considerations to optimize success and profitability in Asia's markets?

"High quality speakers — Strategic inputs valuable for my day today" ***~ AstraZeneca***

"Very interactive with case based learning approaches" ***~ Abbott Healthcare***

"Eye opening event to know and interact with peers" ***~ Pfizer China***

"Learned much on the role of MSL" ***~ Janssen Singapore***

TOP REASONS TO ATTEND!

Official Opening Visionary Sessions – Senior level executives from TOP pharma companies will address the opportunities, issues and challenges for Asian led drug research and development

80+ Top Level Speakers – Meet and hear from renowned global and regional pharma speakers

Customize your Conference Learning & Experience – Choose your Own Sessions Across 3 Special Focused Conferences Addressing Pertinent Issues Faced Today

The Ideal Networking Platform – 1 Location for you to Meet and Network across the Pharmaceutical Value Chain

Don't Miss NEW Interactive Pre & Post Conference Forums – Gain even more insight and value from leading CROs and Pharma Expert Speakers

THE FOLLOWING COMPANIES HAVE ALREADY CONFIRMED THEIR ATTENDANCE

- Merck Serono
- Eisai
- Sanofi
- Johnson & Johnson
- Mebiopharm
- Luqa Pharmaceuticals
- PharmAbcine
- Aslan Pharmaceutical
- Taiwan Food and Drug Administration (FDA)
- Food and Drug Administration (FDA) Philippines
- Novartis Asia Pacific Pharmaceuticals
- Boehringer Ingelheim
- Pharmaceuticals
- Austrian Agency for Health and Food Safety (AGES) PharmMed
- European Medicines Agency (EMA)
- Administration of Science, Technology and Training (ASTT), Vietnam Ministry of Health
- BeiGene
- MSD, India
- Roche Vietnam
- Pfizer
- Janssen
- TEVA UK
- GSK
- Takeda Pharmaceuticals
- Smart Research
- Baxter Limited
- Aspen Philippines
- CIMB Investment Bank
- Bayer Healthcare
- Astellas Pharma
- Merck Serono China
- A*Star
- Reckitt Benckiser
- IPMG
- Novartis Indonesia
- Pfizer Thailand
- Singapore Clinical Research Institute
- ARPA
- PT Rama Emerald Multi Sukses
- AbbVie
- Eli Lilly & Co Philippines
- ALMAC
- Actavis
- Cadila Pharmaceuticals
- ERT
- Daiichi Sankyo
- Boehringer Ingelheim
- Sanbe Farma
- Novel Laboratories
- Fresenus Kabi
- Metro Pacific Investments
- Pharmax India
- Mylan Laboratories
- Novel Laboratories
- Quintiles
- INC Research
- Novotech
- ClinTec International Group
- Allergan Healthcare
- PACRA
- Takeda Development Centre Asia
- Parexel International

Plus Many More...

Produced by: ibc Life Sciences — an informa business

Bronze Sponsor: ALMAC — Partnering to Advance Human Health

Session Spotlight Sponsors: ERT — Getting It Done. Right. | imshealth — INTELLIGENCE APPLIED.

Exhibitors: BIOCAIR — moving science forward | NOVOTECH

Supported Organisation: PACRA | SABPA | ARPA

Media Partners: BioPharma Asia | BioPharm Insight | Pharma China | Pharma Focus Asia | Pharma Marketing News | Technology Networks | Asia Pacific Biotech | Bentham Science | 生物探索 | Bio-Equip | BioSingapore | Kong Posh | 世易 | DMAS | Life Sciences | lingmed | CanBiotech | pharmaphorum | iptechex | ChemLinked

International Marketing Partner: Global Information

REGISTER TODAY! ☎ **+65 6508 2401** **register@ibcasia.com.sg** **www.pharmaconasia.com**

If undelivered, please return to:

IBC ASIA (S) PTE LTD
COMPANY NO: 200108203N
an Informa business

111 Somerset Road,
TripleOne Somerset #10-05, Singapore 238164
Tel: +65 6508 2400 Fax: +65 6508 2408

Register 3 Delegates and The 4th Attends For Free!

PHARMACON ASIA

6 EASY WAYS TO REGISTER

MAIL the attached registration form with your cheque to
IBC Asia (S) Pte Ltd
c/o Informa Regional Business Services
111 Somerset Road,
TripleOne Somerset #10-05,
Singapore 238164

Scan the QR Code with your smartphone and register today

Customer Service Hotline
+65 6508 2401

Email
register@ibcasia.com.sg

Fax
+65 6508 2407

Web
www.pharmaconasia.com

PharmaCon
Pharmaceutical Congress Asia

4 Conferences in 1 Location

Clinical Trials 2015
8th Annual Pharmaceutical Regulatory Affairs Asia
PMA RMA Market Access 2015
Medical Affairs Forum Asia 2015

3 - 6 August 2015
Grand Copthorne Waterfront Hotel, Singapore

RESERVE YOUR PLACE TODAY!

☐ Yes! I/We will attend the **PHARMACON ASIA**
3 – 6 August 2015, Grand Copthorne Waterfront Hotel, Singapore
☐ I would like to purchase the conference presentations at SGD1000 + GST (SGD1070) per log in.

FEE PER DELEGATE	Early Bird Rate Register & pay on or before 29 May 2015	Special Rate Register & pay on or before 26 June 2015	Normal Rate Register & pay after 26 June 2015	Group Rate (3 or more delegates)
ALL ACCESS PASS TO PHARMACON				
❑ 4 Day Package	SGD 4,095	SGD 4,295	SGD 4,495	SGD 4,095
❑ 3.5 Day Package	SGD 3,895	SGD 4,095	SGD 4,295	SGD 3,795
❑ 3 Day Package	SGD 3,595	SGD 3,795	SGD 3,995	SGD 3,495
❑ 2.5 Day Package	SGD 3,295	SGD 3,495	SGD 3,695	SGD 3,195
❑ 2 Day Conference only	SGD 2,895	SGD 3,095	SGD 3,295	SGD 2,795

4 - 5 August 2015 • Tick the Main Conference of Interest
❑ Clinical Trials Asia ❑ Pharma Regulatory Affairs
❑ Pharma Market Access

3 and 6 August 2015 • Tick the Workshop(s) You Would Like to Attend

3 August • Pre-Conference 0.5 Day Workshops
❑ Improving Market Access Using Real World Evidence Strategies
❑ Philippines

3 August • Pre-Conference 1 Day Workshop
❑ Registration in the ASEAN Region: Overview of Dossier Requirements, Time-Frames and Registration Procedures

6 August • Post-Conference 1 Day Workshops
❑ China and IndoChina
❑ Regulatory Strategies for Clinical Trials

3 and 6 August 2015 • Tick the Pre or Post Conference Forum

3 August • Pre-Conference 1 Day Forum:
❑ Leadership in Clinical Outsourcing

6 August • Post-Conference 1 Day Forum
❑ Medical Affairs

- Multiple Bookings Discount pricing is applicable to groups of 3 or more delegates from the same organisation registering for the same event, at the same time. Fee stated is the discounted price PER DELEGATE. Only one discount applies; either the early bird rate OR special rate OR group rate.
- All fees stated include luncheons, refreshments and complete set of documentation. It does not include the cost of accommodation and travel.
- Registration fees are subject to the prevailing government tax.

Name: Dr/Mr/Ms

Job Title: Department

Tel: Mobile No.:

Email:

Please photocopy for additional delegates

Who is Head of your Department?

Who is Head of Training?

Company Information

Company Name: Main Business/Activity:

Address: Postal Code:

PAYMENT METHOD
(Please tick)

☐ I enclose my bankers draft / cheque payable to IBC Asia (S) Pte Ltd
☐ I am paying by bank transfer (copy attached)
☐ Payment by Credit Card. (AMEX, VISA or MasterCard accepted)

CREDIT CARD PAYMENTS

The best way to pay by credit card is through our secure on-line registration process, simply log on to the website at **www.pharmaconasia.com** and click "Register On-line". If you would prefer to pay over the phone please complete the contact name and details and our Customer Services Team will call within 24 hours to take payment. As we treat your credit card information in the strictest confidence, please do not send payment details by email.

Credit card contact: Department:

Direct phone number: Email:

P46285

HOTEL INFORMATION

GRAND COPTHORNE WATERFRONT HOTEL, SINGAPORE
392 Havelock Road, Singapore 169663.
Tel: +65 6233 1301 | Fax: +65 6233 1177
International Reservation: +65 6735 7575
Contact: Tan Ai Li, Director of Events
Email: aili.tan@millenniumhotels.com
DID: +65 6233 1301

PAYMENT TERMS

Payment must be received 10 business days prior to the event. To take advantage of discounts with an expiry date, registration and payment must be received by the cut-off date.

- Payment by bankers draft or cheque in S$ or US$ should be made in favour of **"IBC Asia (S) Pte Ltd"** and mailed to:
  IBC Asia (S) Pte Ltd
  c/o Informa Regional Business Services
  111 Somerset Road, TripleOne Somerset #10-06
  Singapore 238164
  Attn: The Accounts Receivable Team
- Payment by bank transfer in S$ or US$ made payable to:
  IBC Asia (S) Pte Ltd
  A/C No.:147-059513-001 (S$)
  A/C No.:260-457866-178 (US$)
  The Hongkong and Shanghai Banking Corporation Limited
  21 Collyer Quay, HSBC Building
  Singapore 049320
  Bank Swift Code: HSBCSGSG
  Bank Code: 7232
- Payment by Credit Card (AMEX, VISA or MasterCard).
  The best way to pay by credit card is through our secure portal built into the website. To pay by phone please indicate the contact name and details below and our Customer Services Team will call within 24 hours to take payment. Please do not send credit card information by email.

CANCELLATIONS / SUBSTITUTION

Should you be unable to attend, a substitute delegate is welcome at no extra charge. Cancellations must be received in writing at least 10 business days before the start of the event, to receive a refund less 10% processing fee per registration. The company regrets that no refund will be made available for cancellation notifications received less than 10 business days before the event.

IMPORTANT NOTE

Please quote the name of the delegate, event title and invoice number on the advice when remitting payment. Bank charges are to be deducted from participating organisations own accounts. Please fax your payment details (copy of remittance advice, cheque or draft to +65 6508 2407).

Attendance will only be permitted upon receipt of full payment. Participants wishing to register at the door are responsible to ensure all details are as published. IBC assumes no further liability or obligation, beyond the refund of the paid registration fee, in the event of postponement or cancellation by IBC.

DATA PROTECTION

The personal information entered during your registration/order, or provided by you, will be held on a database and may be shared with companies in the Informa Group in the UK and internationally. Occasionally, your details may be obtained from or shared with external companies who wish to communicate with you offers related to your business activities. If you do not wish your details to be used for this purpose, please contact our Database Department at Email: database@ibcasia.com.sg, Tel: +65 6508 2400 or Fax: +65 6508 2408.

REG NO. 200108203N