11TH ANNUAL
PHARMACEUTICAL REGULATORY AFFAIRS ASIA
18 - 21 September 2018 • One Farrer Hotel & Spa, Singapore

PLENARY SESSION THOUGHT LEADERS

HO WENG SI
Director, Biomedical Sciences Group, Economic Development Board, Singapore

NIK LEIST
Senior Director, Ingestible Sensor Manufacturing / Site Leader, Proteus Digital Health, USA

ENVER ERKAN
Country Manager, Pfizer, Singapore

ALEXIS SERLIN
Asia Cluster Head, Novartis, Singapore

MIGUEL ANGEL RIVERA TAPIA
Global Digital Innovation Lead, Ferring Pharmaceuticals, Switzerland

FEATURING DISTINGUISHED REGULATORS & REGIONAL PHARMA LEADERS

CHY-N-LIANG (CINDY) HUANG
Section Chief, Division of Medicinal Products, Taiwan Food & Drug Administration, Taiwan

CHUA HUI MING, Senior Principal Assistant Director, Biologics Section, Centre of Product Registration, National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health, Malaysia

SHERRY WANG
Assistant Director, Public Policy & Regulatory Affairs - Southeast Asia, Global External Affairs, United States Pharmacopoeia (USP), Singapore

YEO JING PING
Director, Research Integrity, Compliance & Ethics, Singapore Health Services, Singapore

JAMES CAI
Vice President, Global Regulatory Affairs, Value, Access & Policy, Amgen, China

KOICHI MIYAZAKI
Senior Director, Clinical Development Group, Asia Development Department, R&D Division, Daiichi Sankyo, Japan

BRUCE SUN
Publishing Team Lead (Established Markets), Worldwide Regulatory Operations, Pfizer, China

FINNY LIU
Lead of APAC Regional Regulatory Policy, PDR ROCHE, Singapore

SHWETA UPPAL
Director, Clinical, Medical, Regulatory, Quality & Pharmacovigilance (Singapore, Malaysia, Brunei), Novo Nordisk, Malaysia

CO-LOCATED WITH:
PRODUCED BY:
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08:00 Registration Starts & Morning Coffee
08:55 Chairperson’s Opening Remarks

OPENING KEYNOTE SESSIONS
Joint Plenary Sessions with Accelerating Clinical Trials in Asia, Pharma Market Access & Pricing Summit Asia, Digital Pharma - Asia Conferences

09:00 Keynote Address: Singapore - a Leading Innovation and Commercialization Hub in Asia
Addressing on skilled talent, strong manufacturing capabilities and thriving research ecosystem in pharmaceutical firms to set up to serve patients and connect with the growing Asian market.
Ho Weng Si, Director, Biomedical Sciences Group, Economic Development Board, Singapore

09:20 Industry Address: Integrating Silicon with Drugs: Pushing the Boundaries of Pharma Manufacturing with Digital Medicines
Nik Leist, Senior Director, Ingestible Sensor Manufacturing / Site Leader, Proteus Digital Health, USA

09:40 INNOVATION TALK: Innovation and Digitalisation – The Impact and Where Do We Go Next?
Scott Bales, Managing Director - Innovation & Digital Transformation | Fintech Asia, Asia, Singapore
Scott is a TEDx global thought leader and bestselling author, armed with a raw enthusiasm for technology and a fascination with people. A technology & innovation guru, a global leader in the cutting edge arena known as ‘The Digital Shift’, encompassing innovation, culture, design, and mobility in a world gone digital. As a thought leader, he thrives on the intersection between cultural and behavioural changes in the face of technology innovations.
Aspiring to transform mainstream thought processing around conventional business practices, he has spoken at at TEDx, Social Media Week, Google Think, Fund Forum, Asian Banker, Next Money and a long list of private events. His thought leadership pieces on lead market expansion and innovation capability development have appeared in WIRED, Australian Financial Review and E27.

To listen to Scott's talk, click here

10:00 INDUSTRY THINK TANK: Pharma 2030 – Envisioning the Future
- Drug pipeline growth areas
- Regulatory trends
- Innovation in pricing and market access
- The most significant industry trends in the long term, and how should Pharma respond

Panelists:
- Ho Weng Si, Director, Biomedical Sciences Group, Economic Development Board, Singapore
- Enver Erkan, Country Manager, Pfizer, Singapore
- Alexis Serlin, Asia Cluster Head, Novartis, Singapore
- Miguel Angel Rivera Tapia, Global Digital Innovation Lead, Ferring Pharmaceuticals, Switzerland

10:40 Morning Networking & Refreshment Break

GLOBAL REGULATORY AFFAIRS UPDATES

11:20 Updates on Regulatory Harmonization Efforts in Asia for Pharmaceutical Products
- APEC RHSC Meeting
- ASEAN PPWP Meeting
- Other regulatory harmonisation activities
Finny Liu, Lead of APAC Regional Regulatory Policy, PDR, Roche, Singapore

11:50 Navigating the Regulatory Environment in EU with Introduction of New Clinical Trial Regulation (536/2014)
Hye Jin Choi, Principal, Strategic Clinical Development Consulting Asia Pacific, IQVIA, South Korea

12:20 e-Emerging: Global eCTD Transition on the Way
- Global eCTD adoption status, trends, eCTD 4.0
- e-Acceleration in emerging markets and China’s eCTD transition
- Use cases for AI, technological solutions in regulatory submissions, publishing, and accelerating drug development
Panelists: Silke Nolkemper, General Manager, Director Consulting APAC, EXTEDO, China
Bruce Sun, Publishing Team Lead (Established Markets), Worldwide Regulatory Operations, Pfizer, China
More Panellists to be confirmed

13:00 Networking Lunch
14:00 AI, the New Solution to Global Regulatory Operations
- Pharma-AI new “Eco-system”
- Use Cases in Regulatory Operations (esp. eCTD)
- Future Regulatory Operation Model
Bruce Sun, Publishing Team Lead (Established Markets), Worldwide Regulatory Operations, Pfizer, China

DRUG DEVELOPMENT & REGULATORY LANDSCAPES

14:30 Fast-Tracking Approvals & GM Guidelines Updates in Taiwan
- GMP guidelines and updates
- Overview and case studies for expedited approval timelines and procedures
- Frequently-asked questions and regulatory pain points
Chyn-Liang (Cindy) Huang, Section Chief, Division of Medicinal Products, Taiwan Food & Drug Administration, Taiwan

15:00 Biologics Registration & Approvals in Malaysia
- Recent developments in Malaysia’s regulatory landscape
- Updates on NPPA’s CGTP registration & variation guidelines for biologics
- Regulatory pain points and commonly-encountered challenges in drug approval processes
Chua Hui Ming, Senior Principal Assistant Director, Biologics Section, Center for Product Registration, National Pharmaceutical Regulatory Division (NPPA), Ministry of Health Malaysia

15:30 Afternoon Networking & Refreshment Break
16:00 Quality Medicine Regulation from Compendial Standards Usage
- Generics and OTC drug regulation in Southeast Asia, uneven
- Compliant regulation varied from different international and national, ICH, WHO standards
- Challenges in dossier submission and technical variation for regulators
- How to apply compendial standards in this application to help regulators and industry players
Sherry Wang, Associate Director, Public Policy & Regulatory Affairs - Southeast Asia, Global External Affairs, United States Pharmacopeia (USP), Singapore

16:30 Post-Marketing Surveillance & Safety in Philippines
- Post-marketing considerations and differences across biologics, vaccines and generics in Philippines
- Pharmacovigilance and RMP submission requirements in lieu of vaccines post-marketing surveillance
- ASEAN Common Technical Document (ACTD) requirements in safety studies, in line with ICH standards
Catherine Clemente, Associate Drug Regulatory Affairs & Pharmacovigilance Lead, Sandoz, Philippines

17:00 Chairperson’s Summary & End of Main Conference Day One
MAIN CONFERENCE DAY TWO
Thursday, 20 September 2018

08:30 Morning Coffee
08:55 Chairperson’s Opening Remarks

REGULATORY STRATEGY & ACCESS
09:00 Enhancing Launch Excellence: A Regulatory Perspective for Global & Regional Strategies
- Developments in pharma regulatory affairs in Asia against a global outlook, and how it will impact future launch environments
- Strategies and best practices for navigating evolving, complex regulatory environments
- Pain points and drivers of launch excellence and ensuring market adaptability, flexibility
Panellists:
James Cai, Vice President, Global Regulatory Affairs, Value, Access & Policy, Amgen, China
Finny Liu, Lead of APAC Regional Regulatory Policy, PDR, Roche, Singapore
Shweta Uppal, Director, Clinical, Medical, Regulatory, Quality & Pharmacovigilance (Singapore, Malaysia, Brunei), Novo Nordisk, Malaysia
Koichi Miyazaki, Senior Director, Clinical Development, Group, Asia Development Department, R&D Division, Daiichi Sankyo, Japan

09:40 Regulatory Environment on Botanical Drug Development
- Regulatory Environment of Asia Pacific
- FDA and EMA opinions
- Challenges and opportunity on Botanical Drug Development
May Wei, Vice President, Head of Regulatory, CMC & Production, Moleac, Singapore

10:10 Globalisation & Digitalisation – Impacts & Opportunities for IP Strategies in Regulatory Affairs
- What are the considerations and influences on intellectual property protection with the rise of internationalisation, harmonisation and digitalisation?
- Emerging approaches for IP strategies and its regulatory implications
Yoshihito Daimon, Director, IP Legal, Mylan Seiyaku, Japan*

10:40 Morning Networking & Refreshment Break

11:00 Cross-functional Connections for Better Regulatory Outcomes
- Eliminate silos to develop a proactive cross-functionally interacting team leading to integration of functional expertise and business goals
- Practice timely and effective communication for a successful cross-functional integration
- Leverage cross-functional expertise to strengthen relationships with regulatory agencies
Shweta Uppal, Director, Clinical, Medical, Regulatory, Quality & Pharmacovigilance (Singapore, Malaysia, Brunei), Novo Nordisk, Malaysia

11:30 The Impact of ICH–E17 on Drug Development Strategy in Asia
- Impacts of ICH E17 and considerations for regulatory decision-making in the evolving landscape of clinical development
- Best practices and industry perspectives on meeting different requirements
- Managing clinical studies and regulatory strategies following E17 implementation
Koichi Miyazaki, Senior Director, Clinical Development, Group, Asia Development Department, R&D Division, Daiichi Sankyo, Japan

12:00 China’s Regulatory Reform 2.0
- China’s current regulatory landscape and structure – what’s changed and what else to expect
- IND application procedures and streamlining of clinical trial administration
- Fast-tracking of drug approvals and updated review processes
Lu Bihong, Head, Regulatory Affairs APAC, UCB Pharmaceuticals, China

12:30 Networking Lunch

REGULATORY COMPLIANCE & POST-APPROVAL CONSIDERATIONS
13:30 Developments in GVP – EMA Updates and Strategies for Asia
- Developments in EMA’s GVP guidelines and modules, EudraVigilance monitoring
- GVP practices in Asia, US and best practices for aligning current practices and regulatory strategies
Senior Representative, Eli Lilly & Company

14:00 Improving Compliance in Clinical Research – According to ICH GCP & HBRA
- Challenges in compliance will be discussed
- The importance of QMS and key elements will be reviewed
- The practical steps in ensuring quality and compliance to ICH GCP E6(R2) and Singapore Human Biomedical Research Act will be discussed
Yeo Jing Ping, Director of Research Integrity, Compliance & Ethics, SingHealth, Singapore

14:30 Managing Post-Approval Changes: A Compliance Viewpoint
- GMP guidelines in Asia – what to expect, and what are the key differences
- Quality, lifecycle management
Koo Siang Chuang, Director, Regulatory Compliance, Johnson & Johnson, Singapore

15:00 e-Labelling: A Global & Regional Outlook
- Uptake and progress on drug e-labelling initiatives across US, EU, Japan and Asia
- What are the risks, concerns, and key considerations for implementation in Asia and what are its impacts?
- How can regulatory affairs support the adoption of electronic labelling?
Rie Matsui, Director, Regional Labeling Head for Asia, Pfizer, Japan

15:30 Afternoon Networking & Refreshment Break

CLOSING PLENARY PANEL
Joint Plenary Session with Accelerating Clinical Trials in Asia, Digital Pharma Asia Conferences

16:00 CLOSING PLENARY ROUNDTABLE: Evolving Scenarios for the Asian Pharma Market
- Top line innovation trends and implications
- Drug research and development environment in the long-term Impact of M&A activity and investment on industry
- Emerging pharma business models, broadening value propositions, and sustainable revenue models
Panellists:
Hazel Dy Tioco, Asia Pacific Regional Director, Study Management and Logistics, Sanofi, Philippines
Yaron Turpaz, Chief Data & Technology Officer, Managing Director, Global Gene Corp, Singapore
More panellists to be confirmed

17:00 Chairperson’s Summary and End of Conference

WWW.PHARMAREGULATORYASIA.COM
ICH M4 & M8: REQUIREMENTS AND SIGNIFICANCE OF ECTD IMPLEMENTATION

ABOUT THE WORKSHOP LEADERS

HANDSOME JI
APAC Publishing Lead, Worldwide Regulatory Operations
Pfizer, China

Bruce Sun is Pfizer China’s Publishing Team Lead focusing on eCTD submissions of Pfizer Established Markets (US/Canada/EU). Bruce has profound knowledge of eCTD standards, system expertise and regulatory operational experiences across markets and led multiple critical eCTD transition projects within Pfizer in APAC region (Thailand eCTD: 2015; China eCTD: 2017-now).

BRUCE SUN
Publishing Team Lead (Established Markets), Worldwide Regulatory Operations
Pfizer, China

POST-CONFERENCE WORKSHOP • FRIDAY, 21 SEPTEMBER 2018. 9.00AM – 1.00PM:
LIFECYCLE MANAGEMENT & REGULATORY STRATEGIES FOR BETTER POST-APPROVAL OUTCOMES

ABOUT THE WORKSHOP LEADERS

SANNIE CHONG
Head, APAC Technical Regulatory Policy
Genentech / Roche, Singapore

Sannie Chong heads the Roche’s Technical Regulatory Policy of Asia Pacific. Part of the Regulatory Harmonization Steering Committee Meeting, Dr. Chong is active in promoting access to safe medical products, innovation and trade through regulatory convergence and cooperation within the 21 APEC (Asia-Pacific Economic Cooperation) countries.

Prior to joining Roche, Dr. Chong was Deputy Head of the Innovative Therapeutic Group, Deputy Head of the Quality Regulatory Unit and then Director of the Generics and Biosimilars Branch at the Singapore Health Sciences Authority (HSA), where she also represented Singapore as Chair of Process Validation, Co-Chair of Biologics, as well as Co-Chair of Post-Approval Variation in the Association of Southeast Asian Nations (ASEAN) harmonization activities.

CHUA HUI MING
Senior Principal Assistant Director, Biologics Section, Centre of Product Registration
National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia

Mdm. Chua Hui Ming is a pharmacist in practice registered with Malaysia Pharmacy Board, and works under the Biologics Section, Centre of Product Registration in NPRA. She heads the Biotechnology & Blood Product Unit under the Biologics Section. Currently she handles the review and approval of Biotechnology and Biosimilar products, as well as other biotherapeutics which include vaccines, blood or cell-derived products.
The 11th Annual Pharma Regulatory Affairs Summit is 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. With a 10-year track record, IBC Asia brings to market the latest developments and key insights from decision makers.

Part of the 5th Annual PharmaCon Asia, meet and network with industry leaders and implementers, and get up-to-speed on the latest insights and case studies in pharma across 4 co-located events.

5TH PHARMACON ASIA AGENDA AT A GLANCE

- Trends in Digitalisation
- Redefining Pharma – Consumer Interactions
- Regional Trends in Pharma 4.0
- Pharma-HCP Relationships
- Beyond the Pill
- Enabling Digitalisation

WHO YOU WILL MEET:

BY INDUSTRY:

- Pharma/Biopharma/Biotech ....60%
- Government ................... 15%
- Medical Device ............... 10%
- CROs ........................ 10%
- Consultancies/Academia ...... 5%

BY GEOGRAPHY:

- Singapore ............ 45%
- Malaysia / Indonesia / Thailand .... 15%
- Rest of South East Asia .... 10%
- North Asia ............ 20%
- Australia/New Zealand .... 5%
- US/Europe .............. 5%

TOP REASONS TO ATTEND:

- Gain critical advice from government regulators directly and industry experts on regulation matters
- Understand the practical applications of ECTD
- Meet and network 250+ industry leaders and peers, with four (4) co-located events under PharmaCon Asia
- Benchmark your regulatory strategies with other leaders and learn from case studies shared for better regulatory outcomes
- Breadth and depth of key topics on production registration, submission, quality and launch excellence will be addressed
- Gain insights beyond the core functions of regulatory affairs and how to strategically leverage strengths for synergistic, cross-functional efficiencies

Partnership Opportunities Available: For more information about how you can leverage on our events to optimise your marketing budget, and reach your target audience, please contact:

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