DIA

2024 Singapore Annual Meeting

Cultivating Synergies in Clinical Research and the Regulatory Environment to Innovate Healthcare

16-17, July 2024
Voco Orchard Road, Singapore

Overview

The rapid evolution of drug development and technology, coupled with regulatory advances have created new opportunities and challenges in healthcare. It is critical for regulators, academia, patients, and industries to collaborate closely to ensure an evolving and robust regulatory ecosystem that enables accelerated and cost-effective access to innovative healthcare solutions. This year, DIA Singapore Annual Meeting aims to bring regulators, patient representatives and industries to share and discuss ways in cultivating synergies in clinical research and the regulatory environment to innovate healthcare in APAC. Come join us and be a part of the discussions to explore the challenges and actions that stakeholders in APAC can adopt to ensure transformations in the healthcare evolution.

Objective

- Receive updates from senior regulators how healthcare products are regulated, what actions/ plans they have for regulating innovative products and clinical trials, and their collaborations with key stakeholders.
- Hear the dialogues between regulators, patient representatives and industries on Clinical Research and the Product Registration topics.
- Receive the information on hot regulatory topics, such as ICH guidelines, AI, and new technologies adopted in R&D.
- ASEAN Townhall: Hear deliberation about the topics discussed at this DIA Singapore from the ASEAN countries regulators.
- Network with regulators, patient representatives, clinical development, pharmacovigilance and regulatory affairs professionals from industries.

Program Chair

Chair. Finny Liu, MSc, RPh
APAC Regional Regulatory Policy Lead, Roche

Co-Chair. Helene Sou, MSc, RAC
Global Regulatory Policy and Innovation, Takeda Pharmaceutical Company Limited

Program Committee

Audrey Ooi, MSc
Head of Business Development, Clinical Research Malaysia

Ellyne Setiawan, MPharm
Head of Research & Development Quality (Asia Pacific), Daiichi Sankyo Singapore Pte. Ltd.

Jack Wong
Founder, Asia Regulatory Professionals Association (ARPA)

Martin Lim, MBA
CEO, ONWARD

Sannie Chong, Ph.D.
Senior Director of AP Regulatory Policy, MSD

Senthil Sockalingam
Head of Medical Affairs, APAC, BeiGene

Thean Soo Lo, BPharm, MSc
Regulatory Affairs Management Consultant, TS Consulting

Vicky Hsu
Senior Vice President, Head of Project leadership and Biotech Operations Asia Parexel International

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SVP&MD, Japan, Korea, Singapore, and Southeast Asia, DIA

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DIAglobal.org

AGENDA | July 16, 2024 | Day 1 | ALL TIMINGS IN SGT

8.00 – 8.30 am	Registration
8.30 – 8.45 am	**Opening Remarks**
8.45 am – 10.15 am	**Plenary Session -** **Senior Regulator's Perspectives : What Should the Future Regulatory Ecosystem Look Like?**
	In this session, senior regulators will provide an update on their current regulatory system, initiatives and plan to reflect the changing regulatory landscape. They will also share their thoughts and challenges on hot topics, such as - reliance and working toward regulatory convergence - adopting digital technologies, such as DCT, RWD/RWE, eCTD and e-labeling In the Plenary Panel Discussion, Regulators, Patient and Industry Representative will discuss and make recommendations on new ways of working to ensure that the regulatory system is efficient, sustainable and fit-for-purpose to enable faster approval of innovative healthcare products, as well as what should be considered regarding regulatory agility, alignment and harmonisation.
Session Chairs	**Finny Liu, MSc, RPh** APAC Regional Regulatory Policy Lead Roche, Singapore **Martin Lim, MBA** Co-Founder and CEO ONWARD Health Research, Singapore
8.45 – 9.15 am	PMDA's vision in New(Fifth) Mid-term Targets
	Yuriko Takemura Coordinator, Division of Asia II, Office of International Programs, PMDA JAPAN
9.15 – 9.45 am	The recent regulatory updates on MFDS,Korea
	Heesung Kim, PhD, Director of Biologics Division National Institute of Food and Drug Safety Evaluation (NIFDS), Ministry of Food and Drug Safety (MFDS)
9.45 – 10.15 am	Presentation 3 (BPOM)
	Tri Asti Isnariani, Director of Drug, Narcotics, Psychotropics, Precursors and Addictive Substances Standardization, Badan Pengawas Obat dan Makanan (BPOM)
10.15 – 10.45 am	Tea / Coffee Break
10.45 – 11.45 am	**Panel Discussion + Q&A**
	Moderator : **John C W Lim,** Duke-NUS Medical School Panellists: **Yuriko Takemura,** PMDA **Heesung Kim**, MFDS **Tri Asti Isnariani,** BPOM Industry representatives : **Wassim Nashabeh, Ph.D.** Pharma Technical Regulatory Genentech Patient advocacy: **Nidhi Swarup, M.Sc.,** Founding Chair, Alliance of Patients' Organisations Singapore
11.45 – 12.45 pm	**Lunch & Network**
12.45 – 1.35 pm	**Innovation Hub**
12.45 – 1.00 pm	Revolutionizing CTD with LLMs: One-Click Translation and Writing
	Xing Li, Msc, Founder, DEEP INTELLIGENT PHARMA (SG) PRIVATE LIMITED
1.00 – 1.15 pm	Fast-track clinical trials with leading generative AI-powered digital
	Alice Hsu, MHS, MS, SVP of Clinical Technology Services & Consulting, Alphalife Sciences
1.15 – 1.25 pm	**Introduction of DIA Asia Meeting 2024**
	Yil-Seob Lee, MD, PhD, Chairperson for DIA Asia Meeting 2024

AGENDA | July 16, 2024 | Day 1 | ALL TIMINGS IN SGT

1.45 – 5.30 pm	**Session 1.** **Accelerating and Streamlining Regulatory Processes**

The recent pandemic highlighted an extraordinary global collaboration among regulators. Utilizing digital tools, establishing new regulatory pathways, and implementing regulatory agility have significantly accelerated and streamlined approval processes for the benefits of patients.

In this session, we will provide an update and reflect on various recent innovative regulatory initiatives and pilots, such as reliance, collaborative, and expedited programs. Industry experts will share their experiences and best practices through insightful case studies. The panel discussion with regulators will offer perspectives and explore the potential evolution of these initiatives in the future.

Session Chairs

Helene Sou, MSc, RAC
Global Regulatory Policy and Innovation,
Takeda Pharmaceutical Company Limited, Singapore

Sannie S Foong Chong, Ph.D.
Senior Director, Global Regulatory Policy
MSD International, Singapore

Thean Soo Lo, BPharm, MSc
Regulatory Affairs Management
Consultant, TS Consultung, Singapore

1.45 – 1.55 pm	**Introduction** - Overview of Ways to Accelerate and Streamline Regulatory Processes
	Helene Sou, MSc, RAC Global Regulatory Policy and Innovation, Takeda Pharmaceutical Company Limited, Singapore

Session 1a Focus on New Product Registration

Session Chairs

Helene Sou, MSc, RAC
Global Regulatory Policy and Innovation,
Takeda Pharmaceutical Company Limited, Singapore

Thean Soo Lo, BPharm, MSc
Regulatory Affairs Management Consultant, Singapore

1.55 – 2.10 pm	Industry sharing : Hybrid ACCESS/ORBIS type C pathway: 1st industry experience, process, benefits and considerations
	Mi-Young Park, Senior Regulatory Affairs Director, Growth and Emerging Markets, Takeda
2.10 – 2.25 pm	Industry sharing : ASEAN Country specific requirements in new product registrations: challenges and what can be streamlined/ harmonized to achieve faster registrations
	Edana Loke, Director, Regulatory Policy and Intelligence, Australia, China, Japan, and Asia (JAPAC), Abbvie
2.25 – 2.55 pm	Regulator's sharing : SRA's documents/tools and support to enable or facilitate reliance pathways
2.25 – 2.40 pm	**Paul Huleatt**, Indo-Pacific Regulatory Strengthening Program International Regulatory Branch | TGA
2.40 – 2.55 pm	**Yuriko Takemura** Coordinator, Division of Asia II, Office of International Programs, PMDA JAPAN
2.55 – 3.20 pm	**Panel Discussion + Q&A**
	Moderator : **Helene Sou,** Takeda Panellists : Regulators - **Yee Hoo LOOI**, HSA | **Paul Huleatt**, TGA | **Yuriko Takemura,** PMDA Industry - **Mi-Young Park,**Takeda | **Edana Loke**, Abbvie
3.20 – 3.45 pm	Tea / Coffee Break

Session 1b focus on Post-Approval Changes

Session Chairs

Sannie S Foong Chong, Ph.D.
Senior Director, Global Regulatory Policy
MSD International, Singapore

Helene Sou, MSc, RAC
Global Regulatory Policy and Innovation,
Takeda Pharmaceutical Company Limited, Singapore

3.45 – 4.00 pm	Industry sharing : Unleashing the Power of Reliance for PACs: Roche's Exciting Journey with 48 NRAs
	Suat Gnoh Por, International Regulatory, Roche
4.00 – 4.15 pm	Industry sharing : ASEAN Country specific requirements for post-approval changes: current challenges and what can be streamlined/ harmonized to achieve more efficiency in regulatory processes for PACs.
	Sia Lee Yoong, PhD, Global Regulatory Policy and Intelligence, GlaxoSmithKline Singapore Pte. Ltd

AGENDA | July 16, 2024 | Day 1 | ALL TIMINGS IN SGT

4.15 – 4.30 pm	Regulator's sharing : Recent and Ongoing Improvements and Streamlining of Regulatory Processes for PACs: Philippines , Thailand
	MA. THERESA PIA C. YAP, Registration Section, Licensing and Registration Division (LRD), Center for Drug Regulation and Research (CDRR), FDA Philippines
4.30 – 4.45 pm	Regulator's sharing : MA and Post Approval Changes Upsate
	Morakot Papassiripan, ATMPs and biological product subdivision, the Medicine Regulation Division of Thai FDA
4.45 - 5.15 pm	**Panel Discussion + Q&A**
	Moderator : **Sannie Chong,** MSD Panellists : **Suat Gnoh Por**, Roche, **Sia Lee Yoong,** GSK, **Jeffrey Schnack, MBA**, Accumulus Synergy Regulators : **Mei-Ling Chan, PhD**, Taiwan FDA, **MA. THERESA PIA C. YAP**, PFDA, **Paul Huleatt**, TGA **Morakot Papassiripan**, Thai FDA
5.15 – 5.20 pm	Closing Remarks & Day 1 End

8.30 am – 1.00 pm	**Session 2. (Parallel Session)** **Drug Development and Innovation in Clinical Research.**

Transformative approaches to drug development have the potential to improve efficiency in R&D, bringing new therapies and innovations to market earlier as well as provide better prediction and outcome of patient response. In this session, industry speakers will delve into the use of innovative approaches in drug development, the potential of radiopharmaceuticals in oncology trials, advances in liquid biopsy technology, integration of real-world evidence and the impact of patients' voice in accelerating drug development. Finally, in our dynamic healthcare ecosystem, patient involvement and engagement are no longer optional, they are essential drivers of safer, more effective care. We will explore how patients are at the heart of this transformative journey.

2a Session Chairs

Audrey Ooi, MSc
Head- Business Development
Clinical Research Malaysia, Malaysia

Vicky Han
Senior Director, Head of Regulatory Policy for Asia Pacific,
Johnson & Johnson Pte. Ltd.

2b Session Chairs

Senthil Sockalingam
Head of Medical Affairs, APAC, BeiGene

Ellyne Setiawan, MPharm
Head of Research & Development Quality (Asia Pacific),
Daiichi Sankyo Singapore Pte. Ltd.

Session 2a	
8.30 – 8.50 am	Innovations in the conduct of early phase clinical trials
	Aaron Tan, Medical Oncologist, National Cancer Centre Singapore
8.50 – 9.10 am	Opportunities & Challenges in Radioligand trials
	HV Bimba, Senior Clinical Research Medical Advisor Global Drug Development, Novartis Singapore Pte. Ltd.
9.10 – 9.30 am	Revolutionizing Oncology Drug Development with Circulating Tumor Cells-Derived Organoids from Solid Tumors
	Shian-Jiun Shih, CEO and co-founder, Cellentia, Inc.
9.30 – 9.50 am	The use of Real-World Data (RWD) in accelerating development of an indication
	Susan Song, Director, Real World Evidence Growth, Parexel, Singapore,
Session 2b	
9.50 – 10.30 am	Tea / Coffee Break
10.30 – 11.00 am	Patient's voice in the clinical journey
	Nidhi Swarup, M.Sc., Founding Chair, Alliance of Patients' Organisations Singapore
11.00 – 11.30 am	Patient's access to clinical trials: What we can do differently?
	Kate Lawrey, Director and Head of APAC Patient Recruitment, IQVIA RDS East Asia, Singapore
11.30 – 12.00 pm	Clinical trials beyond borders: Patient Concierge and other modalities
	Siew Lee Goh, Director, Patient Recruitment and Retention Management, Syneos Health
12.00 – 1.00 pm	**Lunch & Network**

AGENDA | July 17, 2024 | Day 2 | ALL TIMINGS IN SGT

8.30 am – 1.00 pm	**Session 3. (Parallel Session)** **New Regulatory Fields and Trends**

Regulatory Affairs has always been an exciting and evolving field, exacerbated with rapid advances in technology. In this session, we will start with exploring AI products regulatory frameworks. Through insightful case studies, we will uncover the intersection of innovation and regulation, offering valuable insights for navigating this dynamic terrain. Then, we will dive into a cloud web-based dossier technology and its fascinating impact on expediting regulatory approval processes in an era where time is of the essence. Next, we will look at creative regulatory pathways and unique strategies employed in Hong Kong and the Greater Bay Area. By embracing unconventional approaches, these regions have carved out distinctive regulatory landscapes, fostering innovation and driving economic growth. Next, we will delve into the regulatory environment for longevity products. Longevity products hold immense promise for improving health and well-being. Our discussions will shed light on the unique challenges and opportunities and essential regulatory considerations for responsibly bringing these transformative products to market. Finally, we will discuss the flexible and innovative regulatory approaches applied in continuous manufacturing of drug substances and products as outlined in the latest ICH Q13. Embracing continuous manufacturing offers unprecedented opportunities for enhancing efficiency, reducing costs, and ensuring product quality.

Session Chairs

Jack Wong
Founder, Asia Regulatory Professionals Association (ARPA), Singapore

Finny Liu, MSc, RPh
APAC Regional Regulatory Policy Lead
Roche, Singapore

8.30 – 8.55 am	Regulatory framework for AI products
	Kwan Ling TAN , Senior Regulatory Specialist, Medical Devices Cluster, HSA
8.55 – 9.20 am	Industry case study: AI in Action : Real-World Regulation
	Greg Michels, CEO, PV.app
9.20 – 9.45 am	Accumulus Synergy & Regulatory Innovation in the Cloud: What Does this Mean for Asia?
	Jeffrey Schnack, MBA Accumulus Synergy, Regulatory Policy Lead - Japan & Asia
9.45 – 10.30 am	Tea / Coffee Break
10.30 – 11.00 am	Hong-Kong and Greater Bay Area (GBA) Innovative Regulatory Pathway
	Jack Wong, Founder, Asia Regulatory Professionals Association (ARPA), Singapore
11.00 – 11.30 am	Longevity Regulatory: how to regulate anti-aging health supplements?
	Christine Yuan HUANG, MD, PhD, Co-founder, Asia Longevity Professionals Association (ALPA)
11.30 – 12.00 noon	Continuous Manufacturing Overview, Current Regulatory Landscape and Future Considerations
	Kai Yin Po, Associate Principle Scientist, Regulatory Affairs, MSD
12.00 – 1.00 pm	**Lunch & Network**

AGENDA | July 17, 2024 | Day 2 | ALL TIMINGS IN SGT

1.00 – 2.30 pm	**Session 4.** **ASEAN Townhall : What is the Influence of Emerging Regulatory Strategies and Trends on the Surveillance of Medicines after They Have Been Approved?**

The ASEAN Town Hall is a key session of DIA Singapore that brings together ASEAN regulators and important industry players such as Clinical Research, Regulatory and Pharmacovigilance professionals. The ASEAN townhall serves as a valuable platform for discussing the current "hot topics" in the evolving regulatory landscape with a key area of focus on addressing operational issues and policy barriers that impact the healthcare sector in the ASEAN region. This collaborative approach is crucial for enhancing the overall quality and accessibility of healthcare services for our patients in need.

This year, the dialogue will revolve around how the current changes or trends in the regulatory landscape (such as risk-based reviews, RWD, use of digital tools etc.) not only bring opportunities for an accelerated development and/or approval timeline for a medicine but also may have an impact on the post-approval monitoring, and pharmacovigilance approaches. We will hear perspectives from ASEAN regulators as well as industry experts.

Session Chairs

Thean Soo Lo, BPharm, MSc
Regulatory Affairs Management Consultant,
TS Consulting, Singapore

Helene Sou, MSc, RAC
Global Regulatory Policy and Innovation,
Takeda Pharmaceutical Company Limited, Singapore

1.00 – 1.20 pm	A comprehensive approach to the Benefit-Risk Assessment of new drugs throughout its lifecycle
	Muzzaffar Halli, Senior Manager RA/PV, South East Asia, Novo Nordisk
1.20 – 1.40 pm	Transformative Impact of AI and the Social Media Challenge in Post-Marketing Surveillance
	Asmaa Asim, MBA, RA/PV Lead, South, East & Southeast Asia, Organon Asia
1.40 – 2.00 pm	A New Era of Pharmacovigilance – Learnings and Opportunities (Singapore's Perspective)
	Sreemanee DORAJOO, **BSc(Pharm) Hons, PhD**, Senior Data Analyst, HSA
2.00 – 2.30 pm	**Panel Discussion + Q&A**
	Moderators : **Thean Soo Lo, BPharm, MSc,** TS Consulting, **Helene Sou, MSc, RAC**, Takeda Panellists : **Sreemanee DORAJOO**, **BSc(Pharm) Hons, PhD**, HSA **Morakot Papassiripan**, Thai FDA **MA. THERESA PIA C. YAP**, PFDA **Tri Asti Isnariani,** BPOM **Asmaa Asim, MBA,** Organon Asia **Muzzaffar Halli**, Novo Nordisk
2.30 – 3.30 pm	APEC Regulatory Harmonization Steering Committee (RHSC) Special Feature: Advancing Regulatory Convergence

Session Chairs

Sannie S Foong Chong, Ph.D.
Senior Director, Global Regulatory Policy
MSD International, Singapore

Kum Cheun Wong, PharmD
Head Asia Pacific Regulatory & Development Policy,
Novartis Asia Pacific Pharmaceuticals Pte. Ltd., Singapore

2.30 - 2.35	Welcome and Introductions
	Sannie Chong, MSD **& Kum Chuen Wong,** Novartis
2.35 - 2.45	Overview of the RHSC
	Michelle Limoli, USFDA
2.45 - 2.50	MRCT/GCP
	Naoyuki Yasuda, PMDA
2.50 - 2.55	Global Supply Chain Integrity
	Leigh Verbois, USFDA
2.55 - 3.00	Good Registration Management
	Kuo-Teng Hung, TFDA
3.00 - 3.05	Biotherapeutics and Advanced Therapies
	Judith Arcidiacono, USFDA

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3.05 - 3.10	Pharmacovigilance
	Sunim Park, MFDS
3.10 - 3.15	RHSC Centers of Excellence Overview & Operations
	Jared Auclair, Associate Teaching Professor, Chemistry & Chemical Biology Northeastern University
3.15 - 3.25	Q&A
3.25 - 3.30	Concluding Remarks & Adjourn
	Chairs
3.30 – 4.00 pm	Tea / Coffee Break
4.00 – 5.30 pm	**Session 5.** **Clinical Research Regulations : Critical Aspects that Impacts Clinical Research Practices**
	Dive deep into the intricacies of ICH E6 R3 at the final session of DIA Singapore, where we dissect the updated guidelines with precision, focusing on the critical aspects that impacts clinical research practices. Explore strategies for navigating regulatory landscapes, ensuring compliance, and optimizing clinical research practices. Gain invaluable insights into how the highest standards of quality are maintained through the evolving role of technology and its advances.

Session Chairs

Senthil Sockalingam
Head of Medical Affairs, APAC, BeiGene

Ellyne Setiawan, MPharm
Head of Research & Development Quality (Asia Pacific),
Daiichi Sankyo Singapore Pte. Ltd.

4.00 – 4.20 pm	Overview of ICH GCP E6 (R3) Renovation
	Peter Twomey, Head of Inspections, Quality and Safet of Medicines Department, EMA
4.20 – 4.40 pm	ICH E6 R3 Decentralized Clinical Trial – A clinical trial odyssey.
	Cathy Dove, Director Quality and Risk Management, Dove Quality Solutions
4.40 – 5.00 pm	Regulatory landscape of Decentralised Clinical Trials in Asia Pacific
	Sandy Chan, Associate Director Global Regulatory Policy & Intelligence, Johnson & Johnson
5.00 – 5.15 pm	**Panel Discussion + Q&A**
	Moderators : **Senthil Sockalingam**, APAC, BeiGene, **Ellyne Setiawan, MPharm,** Daiichi Sankyo Singapore Panellists : **Rosemarie Corrigan**, Worldwide Clinical Trials **Peter Twomey,** EMA **Cathy Dove**, Dove Quality Solutions **Sandy Chan**, Johnson & Johnson **Xing Li, Msc,** Deep Intelligent Pharma **Sharon Chen,** Alphalife Sciences
5.15 – 5.30 pm	Closing Remarks and Conference end

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2024 Singapore Annual Meeting

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MEMBER	Academic	Early Bird (until July. 2, 2024)	❑ 320
		After July. 3, 2024	❑ 420
	Government	Early Bird (until July. 2, 2024)	❑ 270
		After July. 3, 2024	❑ 370
	Industry	Early Bird (until July. 2, 2024)	❑ 700
		After July. 3, 2024	❑ 900
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		After July. 3, 2024	❑ 530
	Government	Early Bird (until July. 2, 2024)	❑ 370
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Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but **membership is not transferable**. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

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