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 IQVIA Biotech, JAPAC, Chief Medical Officer, Singapore

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

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

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APAC regional medical director, Merck

DIA volunteers, members, and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications, and educational materials, throughout the year, all around the world.

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DIA

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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 Chair(s)

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

Martin Lim, MBA
Co-Founder and CEO
ONWARD Health Research, Singapore

8.45 – 9.00 am	Presentation 1 (PMDA)
	Masahiro Takahata, Division Director, Division of Planning and Management, Office of International Programs, Pharmaceuticals and Medical Devices Agency, PMDA, JAPAN
9.00 – 9.45 am	Presentation 2 (MFDS)
	Heesung Kim, Ph.D. 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)
	Lucia Rizka Andalusia, M.Pharm, Apt. Director General, Pharmaceuticals and Medical Devices Ministry of Health, Republic of Indonesia Acting Head of BPOM, National Agency of Drug and Food Control - Badan Pengawas Obat dan Makanan (BPOM)
10.15 – 10.45 am	Tea / Coffee Break
10.45 – 11.45 am	Panel Discussion

Industry representative:
Wassim Nashabeh, Ph.D
Pharma Technical Regulatory Genentech

Patient advocacy:
Nidhi Swarup,
Crohn's & Colitis Society of Singapore

Moderator
John Lim, Duke-NUS Medical School

Panellists:
Masahiro Takahata, PMDA
Heesung Kim, MFDS
Lucia Rizka Andalusia, BPOM

11.45 – 12.45 pm	Lunch & Network
12.45 – 1.45 pm	**Innovation Hub**
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 Chair(s)

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, Singapore

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

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

Session 1a Focus on New Product Registration

Session Chair(s)

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 – 3.00 pm	Regulator's sharing SRA's documents/tools and support to enable or facilitate reliance pathways
	Karen Loft, Indo-Pacific Regulatory Strengthening Program International Regulatory Branch TGA **Masahiro Takahata,** PMDA JAPAN
3.00 – 3.15 pm	**Panel Discussion + Q&A**
	Moderator : **Helene Sou,** Takeda Pharmaceutical Company Limited, Singapore Panellists : Regulators - **Karen Loft**, TGA | **Masahiro Takahata,** PMDA JAPAN Industry - **Mi-Young Park,**Takeda | **Edana Loke**, Abbvie
3.15 – 3.45 pm	Tea / Coffee Break

Session 1b focus on Post-Approval Changes

Session Chair(s)

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

Helene Sou, MSc, RAC
Global Regulatory Policy and Intelligence,
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 – 4.20 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 Regulatory Policy and Intelligence, Emerging Markets/Greater China Intercontinential, GSK
4.20 – 4.55 pm	Regulator's sharing : Recent and Ongoing Improvements and Streamlining of Regulatory Processes for PACs: Philippines , Thailand
	PFDA and Thai FDA
5.25 – 5.30 pm	Closing Remarks & Day 1 End

4.55 – 5.25 pm	Panel discussion + Q&A (1) A panel discussion focused on: i) PAC reliance pilot including regulators and Accumulus. ii) The future of reliance pathways for PACs, what are potential improvements? (2) Q&A
	Moderator : **Sannie S Foong Chong** MSD International, Singapore Panellists / Industry : **Suat Gnoh Por**, International Regulatory, Roche **Jeffrey Schnack,** Accumulus Synergy, Regulatory Policy Lead - Japan & Asia Regulators : **Mei-Ling Chan,** Reviewer, Section of New Drug Division of Medicinal Products, Taiwan Food and Drug Administration
5.25 – 5.30 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 Chair(s) **Audrey Ooi, MSc** Head- Business Development Clinical Research Malaysia, Malaysia **Vicky Hsu** Senior Vice President, Head of Project leadership and Biotech Operations Asia
	2b Session Chair(s) **Senthil Sockalingam** Head of IQVIA Biotech, JAPAC, Chief Medical Officer, Singapore **Ellyne Setiawan, MPharm** Head of Research & Development Quality (Asia Pacific), Daiichi Sankyo Singapore Pte. Ltd.
8.30 – 8.50 am	Key considerations for first-in-human clinical trials / Adaptive Trial design in Phase 1 Trials
	TBD
8.50 – 9.10 am	Opportunities and Challenges in Radioligand Trials in Asia
	HV Bimba Senior Clinical Research Medical Advisor Global Drug Development, Novartis Singapore Pte. Ltd.
9.10 – 9.30 am	Novel functional liquid biopsy: non-invasive circulating tumor cells-derived organoids for anti-cancer drug screening and clinical monitoring
	Shian-Jiun Shih CEO and co-founder, Cellentia, Inc.
9.30 – 9.50 am	The use of RWD in accelerating development of an indication
	Susan Song Director, Real World Evidence Growth, Parexel, Singapore,
9.50 – 10.30 am	Tea / Coffee Break
10.30 – 11.00 am	Patient's voice in the clinical journey
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	Patient Concierge - Clinical trials beyond borders

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 Chair(s)

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
	TBD
8.55 – 9.20 am	Industry case study: how to regulate AI products?
	TBD
9.20 – 9.45 am	Accumulus Synergy & Regulatory Innovation in the Cloud: What Does this Mean for Asia?
	Jeffrey Schnack 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, ALPA (Asia Longevity Professionals Association)
11.30 – 12.00 noon	Continuous manufacturing of Drug Substances and Drug Products: ICH Q13
	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.

Speaker: **Asmaa Asim,** RA/PV Lead, South, East & Southeast Asia, Organon Asia

Session Chair(s)

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

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

2.30 – 3.30 pm	APEC Regulatory Harmonization Steering Committee (RHSC) Special Feature: Advancing Regulatory Convergence

Session Chair(s)

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

	Participants: **Michelle Limoli**, FDA / TFDA, PMDA, HSA, Thai FDA, MFDS
3.30 – 4.00 pm	Tea / Coffee Break
4.00 – 5.15 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 Chair(s)

Senthil Sockalingam
Head of IQVIA Biotech, JAPAC,
Chief Medical Officer, Singapore

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

4.00 – 4.25 pm	ICH E6 R3 Data Governance: Moving the needle to the next level of data stewardship.
	TBD
4.25 – 4.50 pm	ICH E6 R3 DCT – A regulatory odyssey
	Sandy Chan, Associate Director Global Regulatory Policy & Intelligence, Johnson & Johnson
4.50 – 5.15 pm	Panel with regulators
	TBD
5.15 – 5.30 pm	Closing Remarks and Conference end

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Event #24652 • July 16-17, 2024 | Voco Orchard Road, Singapore

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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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