11th ARC – Conference Program

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the Singapore Association of Pharmaceutical Industries (SAPI) are pleased to announce the ***11th Asia Regulatory Conference – Asia Paving the Way in a New Regulatory World – What does this mean for patients, regulators, and industry?,*** taking place on 17-21 October 2022. Over 5 days, the conference proposes short topic-specific webinars.

Day 1 – Monday, 17 October

Regulatory agilities and further accelerating patient access to safe and effective medicines and vaccines **Objective(s):** review ongoing activities around use and implementation of regulatory agilities including the potential impact on patients.		
Timing	**Agenda:**	**Speakers:**
7H30 – 7H35 CET, 13H30 – 13H35 SGT	Opening and Introduction to Special Session with HSA	Christina Teo (SAPI)
7H35 – 7H50 CET, 13H35 – 13H50 SGT	Special Session: Regulatory agilities in the time of COVID-19 and beyond- perspectives from Singapore – video presentation	Mimi Choong (HSA)
Short break to transfer to main session		
8H00 – 8H10 CET, 14H00 – 14H10 SGT	Opening and Welcome to the 11th ARC	Session Chair: Janis Bernat (IFPMA)
8H10 – 8H25 CET, 14H10 – 14H25 SGT	Regulatory Agilities & PQ KMS: What does it mean for Asia?	Karl Cogan (HPRA)
8H25 – 8H40 CET, 14H25 – 14H40 SGT	Regulatory Agilities Project & Recommendations	Janis Bernat (IFPMA)
8H40 – 8H45 CET, 14H40 – 14H45 SGT	Brief Introduction of Subsequent Session	Paloma Tejada (IFPMA)
8H45 – 9H15 CET, 14H45 – 15H15 SGT	Fireside Chat: Why are innovative and agile regulatory systems important for patients, and how are patients engaging in regulatory activities?	**Moderator:** Raj Long (BMGF) **Panelist(s):** Anita

		Abu Bakar (MIASA Malaysia), Paul Mendoza (Psoriasis Asia), Marianne Bork Samuelsen (NovoNordisk)
9H15 – 9H30 CET, 15H15 – 15H30 SGT	Break	
9H30 – 9H45 CET, 15H30 – 15H45 SGT	Accelerating Access: Regulatory agilities during the COVID-19 Pandemic in the Asia Pacific	Sannie Chong (MSD/APAC)
9H45 – 10H05 CET, 15H45 – 16H05 SGT	Perspectives on/Use of Regulatory Agilities in Asia	Rosilawati Binti Ahmad (NPRA)
10H05 – 10H55 CET, 16H05 – 16H55 SGT	Panel Session and Audience Q&A	**Moderator:** Adam Hacker (CEPI) **Panelists:** John Lim (Duke-NUS Medical School); Karl Cogan (HPRA); Sannie Chong (MSD/APAC)
10H55 – 11H00 CET, 16H55 – 17H00 SGT	Closing & Wrap up of Day 1	Session Chair: Janis Bernat (IFPMA)

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Day 2 – Tuesday, 18 October

Reliance, Convergence/Harmonization and Risk Based Approaches to Post Approval Changes (PACs) **Objective(s):** **Part I:** Convergence/Harmonization Presenting the perspectives of regulators, industry and regional experts, this session will explore how convergence/harmonization can support PACs **Part II:** Reliance is an important mechanism that supports regulatory acceleration and capacity building of regulatory systems. This session will explore how progress can be made in implementing reliance process to PACS. **Part III:** Risk based approach, ICH Q9,10 and 12 set out principles of risk-based approaches, understanding how these principles are being implemented and applied more broadly.		
Timing:	**Agenda:**	**Speakers:**
8H00 - 8H05 CET, 14H00 - 14H05 SGT	Introduction & Welcome	Session Chair: Thierry Gastineau (Sanofi/IFPMA)
8H05 - 8H10 CET, 14H05 - 14H10 SGT	Introduction to Part I	Session Chair: Thierry Gastineau (Sanofi/IFPMA)
8H10 - 8H25 CET, 14H10-14H25 SGT	Philippines FDA Perspective of convergence and Harmonisation in the context of PACs	Jesusa Joyce N. CIRUNAY (Philippines FDA)
8H25 - 8H40 CET, 14H25 - 14H40 SGT	Realizing the objectives of the ICMRA PAC collaborative assessment pilot	Sau (Larry) Lee (US FDA)
8H40 - 8H55 CET, 14H40 - 14H55 SGT	Lessons learned in context of COVID-19	Diane Wilkinson (AstraZeneca)
8H55 - 9H10 CET, 14H55 - 15H10 SGT	Pfizer Experience with PACMP	Connie Langer (Pfizer)

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9H10 - 9H15 CET, 15H10 - 15H15 SGT	Introduction to Part II	Session Chair: Andrew Deavin (GSK/IFPMA)
9H15 - 9H35 CET, 15H15 - 15H35 SGT	Good reliance practice and the link with post approval changes (PAC)	Marie Valentin (WHO)
9H35 - 9H50 CET, 15H35 - 15H500 SGT	Illustration of a reliance pilot of a PAC	Lyne LE PALAIRE (Sanofi)
9H50 - 9H55 CET, 15H50 - 15H55 SGT	Break	
09H55 - 10H00 CET, 15H55-16H00 SGT	Introduction to Part III	Session Chair: Thierry Gastineau (Sanofi/IFPMA)
10H001 - 10H20 CET, 16H00-16H20 SGT	What are PIC/S' recommendations to demonstrate what an effective PQS is for PACs	Kevin O'Donnell (HPRA) and Lyndall Brennan (TGA)
10H20 - 10H35 CET, 16H20 - 16H35 SGT	Industry experience of using risk-based approaches for PACs	Parag Nagarkar (Serum Institute of India)
10H35 - 10H55 CET, 16H35 - 16H55 SGT	Panel Discussion	Moderator: Andrew Deavin (GSK/IFPMA)
10H55 - 11H00 CET, 16H55 - 17H00 SGT	Concluding Remarks	Session Chair: Andrew Deavin (GSK/IFPMA)

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Day 3 – Wednesday, 19 October

Delivering products with the same quality standards to patients everywhere		
Objective(s): Explain how companies create and maintain complex global supply chains, which ensure global quality standards and efficient product delivery. Showcase different national strategies for quality control of pharmaceutical products. **PART I:** • Describe the global pharmaceutical supply chain, its complexity and systems in place to ensure its robustness. • Highlight the importance of reliance and work-sharing in global efforts towards more efficient regulatory frameworks. • Discuss how companies ensure "product sameness" around the world and deconstruct misconceptions on the topic. **PART II:** • Overview of NRAs quality control strategy for therapeutical products (registration testing, import testing, post market monitoring, etc…) • How quality control testing strategies are set up in a way that optimizes time and resources without compromising patient safety. • Collaboration and work-sharing in the area of quality control.		
Timing	**Proposed Agenda/Topics:**	**Speaker**
8H00 – 8H05 CET, 14H00 – 14H05 SGT	Welcome remarks & Introduction	**Session Chair:** Dinesh Khokal (Amgen)
8H05 – 8H20 CET, 14H05 – 14H20 SGT	Global pharmaceutical supply chain, its complexity and systems in place to ensure its robustness	Chaitanya Koduri (USP)
8H20 – 8H35 CET, 14H20 – 14H35 SGT	Reliance and collaboration in the area of GMP inspections	Hilde Depraetere (EDQM)
8H35 – 8H45 CET, 14H35 – 14H45 SGT	WHO's Good Reliance Practices Discussion on the sameness of medical product	Marie Valentin (WHO)

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8H45 – 8H55 CET, 14H45 – 14H55 SGT	The importance of product sameness in the context of Regulatory Reliance	Mike Saleh (Pfizer, IFPMA)
8H55 – 9H30 CET, 14H55 – 15H30 SGT	Panel discussion and Q&A session with the audience	**Moderator:** Mike Saleh (Pfizer, IFPMA)
15min	Break	
9H45 – 10H00 CET, 15H45 – 16H00 SGT	National QC strategy - TGA	Lisa Kerr (TGA)
10H00 – 10H15 CET, 16H00 – 16H15 SGT	National QC Strategy - NPRA	Puan Wan Nurul Aina Mior Abdullah (NPRA)
10H15 – 10H25 2ET, 16H15 – 16H25 SGT	Industry perspective on in-country testing	Joerg Garbe (Roche, IFPMA)
10H25 - 10H50 CET, 16H25 – 16H50 SGT	Panel discussion	**Moderator:** Joerg Garbe (Roche, IFPMA)
10H50 – 11H00 CET, 16H50 – 17H00 SGT	Closing remarks	**Session Chair:** Dinesh Khokal (Amgen/IFPMA)

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Day 4 – Thursday, 20 October

ICH – The Foundations of Success **Objective(s):** **PART I:** Set the scene and focus on developing outputs for sharing with the ICH Management Committee, including efficiency of the organization, ways of working and training. Followed/enriched by polls to screen audience's opinion on/experience with topics discussed. **PART II:** Delve deeper into clinical topics E6, E8 and E17 as a good example of ICH-piloted harmonization in Asian countries.		
Timing:	**Agenda:**	**Speakers:**
8H00 – 8H05 CET, 14H00 – 14H05 SGT	Welcome & Audience Polling	Session Chair: Julie O'Brien (Pfizer/IFPMA)
8H05 – 8H25 CET, 14H05 – 14H25 SGT	Setting the Scene: ICH and where it is headed for the future (Keynote)	Nobumasa Nakashima (PMDA)
8H25 – 8H40 CET, 14H25 – 14H40 SGT	Setting the Scene: ICH and Training	Masafumi Yokota (Daiichi Sankyo/JPMA)
8H40 – 8H55 CET, 14H40 – 14H55 SGT	The Road to ICH membership	Jeewon Joung (MFDS)
8H55 – 9H10 CET, 14H55 – 15H10 SGT	The role of industry in working with NRA to implement ICH/Experience of experts	Xiaoti Lu (China Pharmaceutical Innovation and Research Development Association)
9H10 – 9H40 CET, 15H10 – 15H40 SGT	Panel discussion and Audience Q&A	Moderator: Judith MacDonald (Pfizer/IFPMA) Panelists: Nobumasa Nakashima (PMDA); Isabelle

		Colmagne-Poulard (Merck KgA); Sara Wang (RDPAC)
9H40 – 9H55 CET, 15H40 – 15H55 SGT	Break	
0955 – 10H00 CET, 15H55 – 16H00 SGT	Harvard MRCT & ICH clinical (E6/E8/E17) training - video	
10H00 – 10H05 CET, 16H00 – 16H05 SGT	Audience Polling	Session Chair: Julie O'Brien (Pfizer/IFPMA)
10H05 – 10H20 CET, 16H05 – 16H15 SGT	How do clinical guidelines link together & what are the challenges (lens on E6/E8/E9/E17)	Yuki Ando (PMDA)
10H20 – 10H30 CET, 16H15 – 16H30 SGT	E17 case studies – industry perspective	Anette Hjelmsmark (NovoNordisk/EFPIA)
10H30 – 10H55 CET, 16H30 – 16H55 SGT	Panel discussion and Audience Q&As	Moderator: Angelika Joos (MSD/IFPMA) Panelists: Sally Zhang (AstraZeneca); Anette Hjelmsmark (NovoNordisk); Yuki Ando (PMDA)
10H55 – 11H00 CET, 16H55 – 17H00	Closing & Wrap up of Day 4	Session Chair: Julie O'Brien (Pfizer/IFPMA)

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Day 5 – Friday, 21 October

Changing regulatory landscape of Biotherapeutics and Advanced Therapy Medical Products (ATMPs) **Objective(s):** **PART I:** Biotherapeutics Landscape • Overview of biotherapeutic regulatory landscape including the revision of WHO GLs for Biosimilars and mAbs and their implementation. • Panel Discussion: Changing landscape of biosimilar regulations including traceability and interchangeability. **PART II:** Advanced Therapy Medical Products (ATMP) Regulatory Convergence & Reliance • Discussion on the WHO GLs for ATMP regulatory convergence and their implementation Panel Discussion: Promoting reliance approaches across the lifecycle of ATMPs (incl key topics such as classification, GMOs)		
Timing:	**Agenda:**	**Speakers:**
8H00 – 8H10 CET, 14H00 – 14H10 SGT	Welcome & Introduction	Mümün Gencoglu (IFPMA)
	Session 1: Biotherapeutics	
8H10 – 8H30 CET, 14H10 – 14H30 SGT	WHO Guideline Updates & Future Plans for biotherapeutics and mAbs	Dr. Hye-na Kang (Scientist, WHO, Norms & Standards for Biologics Unit (NSB))
8H30 – 8H50 CET, 14H30 – 14H50 SGT	Regional trends in regulatory evaluation for Biotherapeutics- regulators perspective	Dr. Azizah Ab Ghani (Head of Biologics, NPRA, Malaysia)
8H50 – 9H10 CET, 14H50 – 15H10 SGT	Overview of Biosimilar regulatory landscape (e.g. Interchangeability, Noncomparable biologics) – industry perspective	Virginia Acha (MSD/IFPMA Biotherapeutics lead)

9H10 – 9H30 CET, 15H10 – 15H30 SGT	Panel discussion and Q&A	Moderator: Virginia Acha (MSD/IFPMA Biotherapeutics lead)
9H30 – 9H40 CET, 15H30 – 15H40 SGT	**Break**	
	Session 2: ATMPs	
9H40 – 10H00 CET, 15H40 – 16H00 SGT	WHO Guideline Updates & Future Plans for ATMPs	Richard Isbrucker (Scientist, WHO, Norms & Standards for Biologics Unit (NSB))
10H00 – 10H20 CET, 16H00 – 16H20 SGT	Overview of ATMPs and key regulatory topics in the region	Dr. Srinivasan Kellathur (Director, Advanced Therapy Products, HSA)
10H20 – 10H40 CET, 16H20 – 16H40 SGT	Importance of regulatory reliance for ATMPs: Global perspective	Kowid Ho (Roche/IFPMA, ATMP topic lead)
10H40 – 11H00 CET, 16H40 – 17H00 SGT	Panel discussion and Q&A	Moderator: Kowid Ho (Roche/IFPMA, ATMP topic lead)
11H00 – 11H10 CET, 17H00 – 17H10 SGT	Wrap up and close of conference	Mümün Gencoglu & Janis Bernat (IFPMA)