10th Asia Regulatory Conference
Webinar Series

8H30-10H30 CET/15H30–17H30 MYT: 3-6 November 2020
Agenda (Website Version)

Regulatory Reliance (Tuesday, 3 November)

Co-Chairs: *Datin Dr. Farida Aryani Md. Yusofh, Senior Director of Pharmaceutical Services, Ministry of Health, Malaysia & Dr. David Jefferys, Senior Vice President for Global Regulatory, Healthcare Policy and Corporate Affairs, Eisai Europe and Chair of IFPMA's Regulatory Science Committee*

Session 1: Presentations & Panel Discussion

- WHO Activities: focus on reliance – Samvel Azatyan, Team Lead - Regulatory Convergence and Networks [RCN], Regulation and Safety [REG], Regulation and Prequalification [RPQ], WHO
- Worksharing on Medicines Evaluation: the ACSS experience – John Skerritt, Adjunct Prof John Skerritt, Deputy Secretary for Health Products Regulation, Department of Health, Australia
- Industry Perspectives on Regulatory Reliance – Nevena Miletic (Roche) on behalf of IFPMA
- Interactive Q&A Session

Session 2: Moderated Panel Discussion

Moderator: *Greg Perry, Assistant Director General, IFPMA*

- Patients Perspectives on Regulatory Reliance and Why Patient Engagement is Important - Ratna Devi, IAPO Board Member & Ranjit Kaur, Breast Cancer Welfare Association Malaysia

Session 3: Final Interactive Q&A for all Panellists

Regulatory Reliance in Asia (Wednesday, 4 November)

Keynote: Role of ICMRA in Regulatory Strengthening and Convergence & Asia Training Center for Pharmaceutical and Medical Devices Regulatory Affairs – Yasuhiro Fujiwara, Chief Executive, PMDA

Session 1: Presentations & Panel Discussion

Co-chairs: *Yasuhiro Fujiwara, Chief Executive, PMDA & Dr. Hasenah Ali, Director of NPRA, JUSA B*

- Regulatory System Strengthening for Health Products in Asia – John Lim, Founding Executive Director of the Centre of Regulatory Excellence (CoRE) Duke-NUS
- Progressing regulatory reliance in the Asia region by identifying efficient regulatory processes (OpERA Initiative) – Neil McAuslane, Director of the Center for Innovation in Regulatory Science (CIRS)
- Best Practices – How Can the Pharmaceutical Industry Engage & Establish Dialogue with Various Coalitions and Collaborations – Dora Lau (Pfizer) on behalf of IFPMA

Session 2: Final Interactive Q&A for all Panellists

Moderator: *Professor John CW Lim, Executive Director of the Centre of Regulatory Excellence (CoRE) at the Duke-National University of Singapore Medical School (Duke-NUS)*

ICH in Asia (Thursday, 5 November)

Objective: Discuss future direction of ICH and highlight implementation activities, experience and perspectives of newer ICH Members in Asia.

Presentation: ICH at 30 – implementing reforms to build the future – Junko Sato, Office Director, PMDA

Moderated Panel Discussion

Moderator: Angelika Joos – (MSD), IFPMA representative on ICH Management Committee, on behalf of IFPMA

Junko Sato - Office Director of Office of International Cooperation, MHLW/PMDA, MHLW/PMDA representative on ICH Management Committee

Hironobu Hiyoshi – Chair, Drug Evaluation Committee, Japan Pharmaceutical Manufacturers Association (JPMA), JPMA Delegate to ICH Management Committee

Nihan Burul Bozkurt – Head of Clinical Trials Department, ICH Coordinator of TITCK, Turkey

David Jefferys - (Eisai), IFPMA Regulatory Science Committee Chair, on behalf of IFPMA

Pär Tellner - Director, Regulatory, Drug development and Manufacturing, EFPIA, EFPIA representative on ICH Management Committee

Audience Q&A

Agile Regulation for Supply Chain Management (Friday, 6 November)

Chair: *Greg Perry, Assistant Director General, IFPMA*

Presentations (15min each)

- Supply chain management during COVID-19: Triggers for disruption – Anthony McDonnell, Senior Policy Analyst, Center for Global Development
- The Importance of Agile In-country Quality Control Requirements – Barbara Allen (Sr. Director Global Quality External Engagementm Eli Lilly) on behalf of IFPMA
- Vaccine Registration Harmonization proposals & impact to other products in Asia – Samir Desai (President & Head, BU Biologics, Zydus Cadila) on behalf of DCVMN
- COVID-19 Vaccines & Batch Release: Building on existing platforms to facilitate reliance during a pandemic – Ute Anna Rosskopf, WHO

Moderated Panel Discussion (25min)

- Shain post-COVID – what "new normal" could look like (e.g. implementation of digital solutions)

Final Interactive Q&A for all Panellists (15min)

Wrap Up & Final Remarks (15min) – David Jefferys (Eisai) as Chair of IFPMA Regulatory Science Committee

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