

# Asia Pacific Regional Chapter



## Convention

### USP Convention Asia Pacific Regional Chapter Meeting Agenda 9<sup>th</sup> Sept 2024 Iino Hall & Conference Centre Tokyo, Japan

8:30 AM	Master of Ceremony	<ul style="list-style-type: none"><li>▪ <b>Ruth Lee</b>, Associate Director, Public Policy and Regulatory Affairs, USP APAC</li></ul>
8:35 – 8:45 AM	Introduction	<ul style="list-style-type: none"><li>▪ <b>Prof. John CW Lim</b>, Executive Director, Duke-National University of Singapore Centre of Regulatory Excellence; Chairman of Consortium for Clinical Research &amp; Innovation Singapore; Chair, USP Asia Pacific Regional Chapter</li></ul>
8:45 – 9:00 AM	Opening & Welcome Remarks	<ul style="list-style-type: none"><li>▪ <b>Dr. Ronald Piervincenzi</b>, Chief Executive Officer, U.S. Pharmacopeia</li></ul>
9:00 – 9:45AM	New 5-year cycle, resolutions/priorities: <i>Introduction of new 5-year cycle, resolutions/priorities – implication to APAC; share about benefits of being USP Convention member</i>  <i>[Desired Outcome: Call for more Expert Volunteers from APAC]</i>	<ul style="list-style-type: none"><li>▪ <b>Mr. Anthony P. Lakavage</b>, Senior Vice President, Global External Affairs</li></ul>
9:45 – 10:00AM	Tea Break	
10:00 – 11:00AM	Presentation followed by Panel Discussion: Quality Revolution <i>Share on latest developments by USP and how these innovative approaches impact on quality assurance of pharmaceuticals (What USP is doing) – Get insights/ feedback from participants/convention members</i>  ➤ <b>Complex Generics</b>	<ul style="list-style-type: none"><li>▪ <b>Moderator: Minkyung Kim</b>, Scientific Affairs Manager, USP APAC</li><li>▪ <b>Introduction: Amanda Cowley</b></li><li>• <b>Dr. Prabhakar Gruddanti</b>, Director, Pharmaceutical Science, Science- General Chapters (confirmed)(virtual)</li></ul>

- Digital standards – change in conventional use of standards
- Updates on Advanced Therapy/Biologics
- Updates by ATCC
- **Michael S. Levy**, Senior Vice President, Digital & Innovation, USP (confirmed)
- **Dr. Fouad Atouf**, Senior Vice President, Science – Global Biologics, USP (confirmed)
- **Dr. Ruth Cheng**, ATCC

11:00AM – 13:00 PM

**Presentation followed by Panel Discussion: Quality Imperatives- Impact of poor quality medicines on supply chain integrity:**  
**Using DEG/EG as case study to emphasize the importance and value of having proactive and timely quality testing**

- **Sharing DEG/EG crisis by BPOM and learnings and regulatory challenges**
- **Excipients: Testing of Ethylene Glycol and Diethylene Glycol in High-risk Excipients – Overview of FDA Guidance, WHO Alerts, and USP Activities**
- **Sharing of works done in mitigation of risks - Value of doing proactive testing in ingredients before production**
- **Panel discussion**
- **Moderator: Ramesh Raj**, Regional Director, Pharmaceutical Security Institute, APAC
- **MOH Indonesia/BPOM**, Ibu Rizka, Chairman, BPOM (tbc)
- **Dr. Jenny Liu**, Principal Scientist, Science, Excipients, U.S. Pharmacopeia (confirmed)(virtual)
- **Dr. Paul Huleatt**, Regional Advisor, RSP, TGA, Australia (confirmed)
- **Dr. Thinh/ Dr Hanh**, IDQC, HCM, Vietnam
- **Dr. Tamaki Miyazai**, NIHS, Japan
- 4<sup>th</sup> speaker (tbc)
- **All speakers**

13:00 – 14:00PM

Lunch Break

14:00 – 15:00 PM

**Panel Discussion: Quality in Action: Sharing by industry stakeholders on how quality standards help mitigate risk and drive market access**

**Fireside Chat with CEOs with Anthony T.**

- **Ensuring quality compliance to maintain quality assurance**
- **3 speakers from industry each 15mins \_ panel discussion 45mins (CEOs, CQO, CSOs, owners)**
- **E.g. SPG, Dexta, KR, JP rep (3-4 industry reps)**

- Value of standards

15:00 – 15:15pm

Concluding Remarks

- Prof. John Lim, Chairperson, Regional Chapter

15:15-15.45pm

Tea Break (Room set up- partition)

### Post Meeting Session

Regulatory DG's Forum

15:45 – 17:00pm

Regulators' perspectives (90mins) with panel discussion

- Moderator: Tony Lakavage/John Lim

(room A)

Challenges faced by regulators in ensuring quality compliance of medical products in legal supply chain

- Regulators: from Aus, Viet, Japan, Korea (confirmed); Indonesia (tbc)

Importance of quality medicines in supply chain integrity

- USP team

15:45 – 17:00 PM

Head of Key Industry leaders roundtable session with USP ET cum dinner:

- ET members + Industry leaders
- AT, SCDs , Amanda Cowley

(room B)

- CEO Ron to provide USP Strategic direction in new Cycle
- What are industry views on future of pharmaceutical market / industry future
- What are the challenges face now and future
- Explore ways on how USP can be strategic partner; assist in the development on the new pipeline

18:00pm

End of Regional Chapter meeting

*[Venue name and address: Iino Hall & Conference Centre, 4F IINO Building, 2-1-1, Uchisaiwaicho, Chiyoda-Ku, Tokyo, Japan 100-8506]*