

10th APAC Opening Remarks: 4/13 (Tue.) 10:40-10:45

Good morning everyone. I'm George Nakayama, President of JPMA. Thank you very much for attending today's commemorative 10th APAC. I am delighted that we can welcome all the participants from government bodies, regulatory agencies, academia and Industry throughout Asia.

Although we were hoping to invite you all to Japan, as many people around the world are still fighting against crisis of COVID-19, we set up this conference by online style.

Even we all are facing difficulties through this pandemic in glove, we believe that we should not stop our steps to achieve our mission and goals which is "To expedite the launch of innovative medicines for the people in Asia".

With regard to the acknowledgement by the regulators in Asia to our "APAC letter" that was jointly sent by 13 main industry associations last year, we appreciate their practice of regulatory agility in ensuring patients to receive innovative medicines timely.

APAC is celebrating its 10th anniversary this time. Today, I would like to take some time to share with you our footprints through the past 10 years.

We started APAC as an industry-driven initiative in 2012 by twelve R&D-based pharmaceutical industry associations from eleven economies in Asia. The first meeting was held on Mar 16th, 2012.

We set up two 'Expert Working Groups' as RA-EWG (Regulations & Approvals) and DA-EWG (Drug Discovery Alliances) and started to work with our member associations to meet our missions.

Every year we were holding this conference with the hot topics and reporting our EWG activities as on these slides.

We set up ATIM TF (Access to Innovative Medicine task force) at the 5th APAC and picked up the topics for GMP and post approval change controls. At the 8th APAC conference, we started two taskforces, VBH-TF (Value-based Healthcare) and PMRE-TF (Pharmaceutical Market and Regulatory Environment).

For the 9th APAC, we were not able to hold a conference because of the COVID-19 crisis had happened.

Through the history of APAC, RA-EWG has contributed to build the scheme of GRM (Good registration Management) under the APEC with PMDA and Taiwan FDA,

DA-EWG realized a consortium focusing on natural product. It is proved to be useful for capacity building of young researchers in Asia.

ATIM-TF has provided Site Master File (SMF) template by collaborating with PIC/s and created the position paper for the change controls.

VBH-TF has been elucidating how our industry contributes for sustainability of healthcare system.

PMRE-TF has been creating each area reports every year.

There are lots of other achievements and ongoing discussions too.

For this 10th anniversary meeting, we have set our theme as “Overcoming COVID-19 and taking on new innovative challenges for the next decade in Asia.”

Under the ATIM-TF, a new e-Labeling session will be set up.

I believe that our challenges and activities will continue in the future and provide the people in Asia with further results to meet our goal of mission.

Lastly, taking this opportunity, let me express my sincere thanks for all the support we have been getting from the stakeholders.

Especially I appreciate close collaborations with government and academia.

Wishing we all could meet each in Tokyo next year for this conference by overcoming COVID-19.

Thank you very much for your attention.