

Minutes of Meeting of 6th APAC held on April 5, 2017

Closing Remarks H. Naito, JPMA

I am very pleased to see that this APAC meeting has come to a successful ending. Thanks to all of you on behalf of JPMA. Thanks again to our special guests, Mr. T. Cueni (IFPM), Mr. Boon M. H (PIC/S (HAS)) and to all of our speakers. Around 330 participants are attended in this APAC meeting, including 60 government officials, 25 researchers from academia and 60 decision-makers from Thailand, Taiwan, Indonesia and Korea. The composition of participants at this meeting is changed comparing to our first meeting. The number of delegates from authorities has increased, and members from industry and research institution have been able to enjoy having the chance to associate and communicate closely with each other. Well, let's look back over this APAC meeting, and I would like to share my personal impressions.

First of all, in the ATIM (Access To Innovative Medicine) session, Dr. Boon gave a wonderful discussion. His point was that "We need to kindly think of the GMP inspectors. They are making their best efforts but are not perfect. We need to kindly understand the limits of GMP inspector's abilities." I am grateful to the speakers as well. Differences among respective countries about Inspection, SMF (Site Master File) / PMF (Plant Master File) came out and we had a fruitful discussion toward the promotion of inspection efficiency. As the move toward the promotion of efficiency of actual inspections will be very important than ever, I am looking forward to talking between Asian countries will advance.

In the DA (Drug Discovery Alliances) session, drug discover/development using natural resources was discussed. As shown in the slide, there are various drugs originated from natural products. However, it has become difficult to find a seed compound originating in natural resources such as using lizard saliva because countless studies were made already to the extent of researching poisonous snakes and poisonous spiders. However, there remain the chances to build valuable compound library if we apply new innovation into it. Also, regarding target diseases, starting with infectious diseases such as NTD, TB and Zika fever, there are more targeting area that millions of people are waiting for new methods of treatment. To develop opportunities for drug discovery for those area, a PPP (Public-Private-Partnership) has started a drug development project targeting malaria working together with GHIT.

In the final RA (Regulations and Approvals) session, many excellent results have been shared on what we had been through in past APAC meeting. All members were able to share the concept that GSubP (Good Submission Practice) doesn't work without GRevP

(Good Review Practice). Also, delivering innovative drugs has been advancing quickly due to acceleration of the examination processes in Asian countries. To achieve this , Capacity Building and Regulatory Convergence were our main agenda to be solved and considered as a big dream no one believed to come true six years ago,. However, we have collaborated this agenda six years in a row in the APAC meetings and we made this happen in the end. I am truly obliged to all of you from authorities, organizations, institutions, and companies, that have participated, worked together, and supported us for those years. Lastly regarding Europe, we are concerned about the EMA's future due to UK's exit from the EU which bring about great instability for EMA. Meanwhile, in Asia with Regulatory Convergence, regulatory authorities in respective countries have been coming together. Thank you again for your participation today.