

## Minutes of Meeting of 6<sup>th</sup> APAC held on April 5, 2017

### Keynote Lecture Mr. Boon, Vice Chairman, PIC/S

PIC/S GMP systems are composed of the intergovernmental MRA (PIC) and the collaborative inspection scheme MOU (PIC Scheme). PIC has legal binding power, whereas the PIC Scheme does not. The initial objective was the harmonization of GMP. However, given the difficulties associated with this, we are moving towards convergence rather than harmonization. Our activities include issuing guidance, providing implementation methods and training opportunities, and evaluating operations by inspection authorities. As of August 2016, Thailand's FDA has become the 49<sup>th</sup> affiliated member, with five other authorities currently applying and one authority in the pre-applicant stage. Authorities associated with the EU account for about half of this number.

We anticipate that PIC/S can reduce redundant inspections and contain costs. Operations are composed of committees, executive offices, and formulation of guidelines. In 2014, we set up a new system, consisting of seven sub-committees to promote affiliation to PIC/S: Sub-Committee on Compliance, Sub-Committee on Strategic Development, Sub-Committee on Harmonization of GM(D)P, Sub-Committee on Gadget, Risk & Audit, Sub-Committee on Expert Circles, Sub-Committee on Training. The chair of the executive committee is UK MHRA.

Training is carried out so that trainees can understand the guidance. In addition to the yearly seminar and joint inspection program, training is conducted from various perspectives. The next seminar is scheduled for September 2017, to be hosted by Thailand's FDA. The US FDA will host the following seminar in 2018. The host of the 2019 seminar has yet to be decided – possibly Japan, Korea, or Thailand, but Indonesia seems unlikely.

For the joint inspection program, member countries are divided into groups of three, with the role of inspector rotating among them (1 host, 2 observers). This is understood to be an effective method of calibrating inspection among authorities. Generally, prior to inspections, companies provide authorities with information regarding production sites via an SMF (site master file; of 25 to 30 pages) and authorities draw up inspection plans based on that. In inspection reports, definitions of Majors or Minors are given, with judgments of Non-compliance based on the number of Majors. After that, in the joint re-evaluation program, the said evaluation or judgment is made by different staff.

It has been 47 years since PIC/S was cross certified with PIC in 1970, and its objectives remain the same. We are continuously working on agreements with EU GMP and issuing guidance and revisions. As for coordination with international organizations, we are trying to harmonize with OECD, WHO, and the industry. Our activities cover five specialized areas and 12 WGs. It is difficult for PIC/S to be compatible with the EU's ATMP GMP guidelines, so the EC's proposal may exert influence on EU GMP Annex 2.13. Although the PIC/S side has asked to participate in the drafting of this proposal, our request has been refused time and again by the EC. We have submitted letters and posted messages to them on our web site.

WGs cover data security, CCCISF (Controlling Cross-Contamination In Shared Facilities), medicines for animals, and GCP/GPvP. A new WG includes inspector travel safety. Please see the

materials for details.

The expert circle for active pharmaceutical ingredients is currently active in Australia.

With regard to PIA, training harmonization is being conducted in three steps (at the educational training center). At the end, explanations about guidance revision are given.

(No questions and answers.)