

A Message from the PIC/S Chairman ...

Dear Ladies and Gentleman, and all 7th APAC participants,

Konnichiwa! Ohayogozaimasu!

First and foremost, my apology again for being unable to accept the invitation from Japan Pharmaceutical Manufacturers Association (JPMA) to attend and speak at the 7th Asia Partnership Conference of Pharmaceutical Association (APAC) meeting.

I am happy to learn that you will be discussing / finalizing the draft Site Master File (SMF) template / guidance document, which is an end product jointly “manufactured” and churned out by Japan/PMDA working in co-operation and collaboration with the industry (i.e. APAC and JPMA). This is a positive development and it is an excellent initiative by Japan/PMDA.

Moving on ...

Japan/PMDA will provide an update on this initiative and its outcome at the forthcoming PIC/S Committee Meeting which will be held on 17 & 18 April 2018 in Geneva / Switzerland. The PIC/S Committee will have an opportunity to be informed and discuss this regional initiative for a SMF template, which was developed by Japan / PMDA with input from Korea / MFDS, Chinese Taipei / TFDA, Thailand / Thai FDA and Indonesia / NADFC, based on the existing PIC/S’ SMF guidance document.

GMP harmonization effort – From regional to global...

This is another successful example of closer co-operation and collaboration between regulators and industry, with an end point of a win-win-win outcome to all relevant parties. This is also a case showing how a global PIC/S “mother” guidance document can contribute to GMP harmonization effort at regional level as well as at a global level. Most important, it is also an initiative to support and promote APAC’s initiative on “Access to innovative Medicines” (ATIM) for people in Asia by facilitating faster manufacturing facility and product dossier approval time, which eventually beneficial to patients in term of accessibility, availability and affordability of medicinal product of intended quality, safety and efficacy. In this perspective, I would like to congratulate Japan/PMDA, APAC and JPMA for the excellent work done!

Wishing everyone ...

Last but not least, I wish everyone has an enjoyable, fruitful, interesting generative discussion, a successful 7th APAC Conference and a pleasant stay in Tokyo.

Domo arigatogozaimashita!

Sayonara!