International Harmonization in the Field of Pharmaceuticals: Where are we and where will we go ?

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The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was organized in 1990 by regulatory authorities and pharmaceutical industries associations of three regions (USA, EU, and Japan) to eliminate differences in their regulation of drugs. More than 50 guidelines in the field of quality, safety, and efficacy have been successfully prepared by the ICH and implemented in the regulations in the three regions. Consequently, the development of new drugs and review of registration applications are being done on the basis of global standards (such as ICH guidelines). The Pharmacopoeial Discussion Group (PDG) has made efforts to harmonize general methods and excipient monographs among the United States Pharmacopeia, European Pharmacopoeia and Japanese Pharmacopoeia in cooperation with the ICH.

The Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH) has tried to harmonize crude drug monographs in the pharmacopoeias of six Asian countries (Japan, China, Korea, Singapore, Vietnam, and Hong Kong). The Global Harmonization Task Force (GHTF), which has a similar mechanism as the ICH, has also made efforts to harmonize standards for medical devices.

In this mini-symposium, we will hear six presentations on the current status of harmonization in the above fields, covering: 1) the standpoint from which harmonization efforts have been made; 2) the impact of harmonization on the field; 3) whether the primary aims have been attained by harmonization; and 4) whether any unexpected results have occurred with harmonization. We will also have a panel discussion based on the presentations.