



USP International Excipient Workshop

July 20 - 21, 2009

USP Headquarters, Rockville, Maryland

USP Meetings Center

PRESENTATION ABSTRACT

Title: Japanese Pharmacopeial Perspective on International Harmonization and Excipient Performance

Author: Hiroshi Tokunaga, Ph.D.
JP Secretariat, Pharmaceuticals and Medical Devices Agency

Abstract: In this section, JP perspective for international harmonization is presented. The schedule of JP publication is as follows: JP fifteenth edition (JP15) has been published in March 2006. The supplement I to JP15 has been published in September 2007. The supplement II to JP15 will be published in September 2009. The JP sixteenth edition will be published in March 2011. The main policies on the preparation of JP16 are as follows: 1.Addition of monographs important for health care and medical treatment, 2.Active introduction of up-to-date science and technology, 3.Promotion of international harmonization, 4.Swift and time partial revision and 5.Ensuring transparency of the revision process and promotion of JP to public. Drugs to be preferentially adapted in JP are those approved by priority review, those in EP and USP used on worldwide, those widely used in Japan (generic drugs etc.), those re-evaluated on efficacy, safety and quality, and orphan drugs. On the face of active introduction of up-to-date science and technology, JP hopes to introduce the new technologies and new drug forms from harmonization with EP and USP and to adopt test methods wisely used and already introduced in EP and USP. Regarding revision monographs, JP considers the introduction of latest analytical methods, addition of tests for preparations, and introduction of test not using animals. JP hopes to promote the International harmonization under the collaboration with EP and USP through PDG.