独立行政法人
医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Press Release

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

Tokyo, Japan, 30 June-1 July 2015

The meeting of the Pharmacopoeial Discussion Group (PDG) [European Pharmacopoeia (Ph.Eur.), Japanese Pharmacopoeia (JP), and the United States Pharmacopeia (USP)] was hosted by JP in Tokyo, Japan, 30 June – 1 July, 2015.

At present, 29 of the 36 General Chapters and 48 of the 62 excipient monographs on the current work programme have been harmonised. Sign-offs at this meeting included a revised monograph on “Povidone” in order to refine conditions for impurity testing of monomers (1-vinyl-2-pyrrolidone and 2-pyrrolidone) and to add identity testing by infrared spectroscopy as a harmonised attribute. In-depth discussions on a number of additional items currently on the work programme took place with a view to resolving outstanding issues and advancing the items toward sign-off.

With regard to “Chromatography chapter”, as a follow-up from recent PDG decisions on PDG process improvement, a teleconference with experts from the 3 regions had taken place in May and allowing significant progress to be made in the resolution of major sticking points. The coordinating pharmacopoeia will work on the resolution of a number of other items with the aim of finalising a Stage 4 draft for public inquiry for the next PDG meeting.

With regard to “Copovidone”, the coordinating pharmacopoeia will send out a draft for public consultation in July for the three pharmacopoeias to publish according to their respective schedules.

The three pharmacopoeias exchanged information on their respective approaches for the implementation of the ICH Q3D guideline. In addition, PDG confirmed their commitment to harmonise the general chapter on testing procedures for elemental impurities.

Furthermore, the PDG meeting participants had a meeting with Dr. Tatsuya Kondo, Chief Executive of Pharmaceuticals and Medical Devices Agency (PMDA) on 30 June, who expressed his appreciation for the three pharmacopoeias’ efforts and achievements and emphasised the importance of harmonisation.

The meeting highlights for the June-July 2015 meeting can be found:
http://www.pmda.go.jp/files/000206332.pdf

Next Meeting

The next face-to-face PDG meeting will be hosted by USP on 3-4 November, 2015 in Rockville, Maryland, USA.

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