

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

Rockville, Maryland, U.S.A., September 12-13, 2017

The meeting of the Pharmacopoeial Discussion Group (PDG) [European Pharmacopoeia (Ph.Eur.), Japanese Pharmacopoeia (JP), and the United States Pharmacopoeia (USP)] was hosted by USP in Rockville, Maryland, U.S.A., September 12 – 13 2017.

PDG has agreed to the implementation of significant changes to the work structure, including:

- Eliminating two stages of PDG harmonization process to streamline and reduce the level of complexity.
- Restructuring meeting format to engage more effectively at the technical level with regards to resolving issues on specific topics.
- Maintaining a twice-yearly meeting frequency with a focus on strategic direction setting.

Under the new structure, harmonization of several PDG topics will be continued in other collaborative venues, such as bilateral discussion or adopt/adapt mechanisms as mentioned in the Good Pharmacopoeial Practices (GPhP). These topics will not be part of the trilateral work program until further notice. Ph.Eur., JP, and USP will continue to closely share information and progress on these topics external to PDG.

Sign-offs at this meeting includes a new General Chapter “Conductivity” and revisions to four monographs, including Microcrystalline Cellulose, Hypromellose, Methylcellulose and Calcium Phosphate Dibasic Anhydrous. In-depth discussions on a number of additional items currently on the revised work programme took place with a view to resolving outstanding issues and advancing the items toward sign-off.

The meeting highlights of this meeting can be found at:

<http://www.pmda.go.jp/english/rs-sb-std/standards-development/jp/0008.html>

Excipients Council

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation was held on September 13, 2017. Topics discussed included elemental impurities as well as monographs for ethylcellulose, hydroxyethylcellulose, polyethylene glycol, povidone, pregelatinized starch, colloidal silicon dioxide and silicon dioxide.

Next Meeting The next PDG meeting will take place via videoconference in April 2018 and the next face-to-face PDG meeting will be hosted by Ph.Eur. and is tentatively set for October 2-3, 2018 in Strasbourg, France.

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