

AHWP WG1 Updates

November 2016

WG1 – Members Update

- **Chair:** Mr. Essam Al Mohandis from Saudi Arabia FDA
- **Co-Chair:** Ms. Kate Kim from Johnson & Johnson Medical Korea succeeding Ms. Ming Hao Tan

Welcome New Members:

- Mr. Sung-In Beak from MFDS Korea
- Mr. Young-Soo Seol from ILOODA Korea
- Ms. Young-Soon Jeon from Bard Korea
- Mr. Jian (Jason) Guo from Abbott Vascular China
- Ms. Mandy Kim from Johnson & Johnson Medical Korea
- Mr. Pavan Kumar Malwade from Biocon Research Ltd India

Good Bye to:

- Musliha Abdullah from CIBA VISION Malaysia

Total: 31 WG1 Members

WG1 – Members Update

No.	Work Item	Sub-group Leader	Sub-group Members
1	Guidance on regulatory practices for Combination Products	Arthur Brandwood	8 Members
2	Guidance for Minor Change Reporting	Sung-In Baek Young-soo Seol	6 Members
3	White Paper for custom devices manufactured by 3D printer	Sung-In Baek Young-soo Seol	3 Members
4	Good Review Practice Guidelines	Sung-In Baek Young-soo Seol	1 Member
5	Grouping for pre-market submission	Need for a New leader – <u>Project postponed</u>	6 Members

WG1 – Original Work Plan

No.	Guideline Title	Target Completion Date
1	Guidance on regulatory practices for Combination Products	Nov 2016
2	Guidance for Minor Change Reporting	Nov 2016
3	White Paper for custom devices manufactured by the 3D printer	Nov 2016
4	Good Review Practice Guidelines	Nov 2016
5	Grouping for pre-market submission	Postponed to 2017-2018

WG1 – Work Plan Updates

No.	Guideline Title	Status	Target Completion Date
1	GUIDANCE ON REGULATORY PRACTICES FOR COMBINATION PRODUCTS	Finalized: the 'Proposed Final Document' has been submitted to AHWP Secretary on Nov. 11 for endorsement at Annual Meeting.	Nov 2016
2	GUIDANCE FOR MINOR CHANGE REPORTING	Finalized: the 'Proposed Final Document' has been submitted to AHWP Secretary on Nov. 11 for endorsement at Annual Meeting.	Nov 2016
3	E-LABELING AS AN ALTERNATE METHOD FOR COMPLIANCE TO LABELING REQUIREMENT	Proposed as a new topic and agreed among WG1 members to pursue.	2017

[Note] Originally planned, but are on hold.

- White Paper for custom devices manufactured by the 3D printer
- Good Review Practice Guidelines
- Grouping for pre-market submission