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Taiwan FDA excels at international regulatory harmonization of medical devices

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Taiwan is significantly participating in global medical device regulatory organizations to share knowledge and expertise with the global regulatory professionals

The Food and Drug Administration of Taiwan (TFDA) is diligently participating with many global organizations to facilitate the convergence of medical devices regulations and policies. One of the pivotal contributions to international regulatory harmonization of medical devices is as the Asian Harmonization Working Party/ Global Harmonization Working Party (AHWP/GHWP) WG2 Chair for years. TFDA has achieved outstanding performance on the regulatory harmonization and received positive recognition from the AHWP/GHWP Leaders.

AHWP/GHWP, a voluntary group of regulators and industry members with the goals of developing and recommending approaches for the convergence and harmonization of medical device regulations in Asia and other regions. Taiwan has been an official member since it was established in 1999. TFDA was elected as the Chair of In Vitro Diagnostic (IVD) workgroup (known as WG2) in 2012 and has continued in office for other terms until now.

Taiwan is an active workgroup in the AHWP/GHWP Technical Committee, WG2 has been focusing on the promotion of global harmonization in the premarket review processes and assisting AHWP/GHWP members economies in implementing a regulatory framework of IVD medical devices.

In the period of Taiwan chairing the WG2, it has already developed fourteen guidance or reference documents and endorsed by the AHWP/GHWP. Furthermore, Taiwan has been active in leading WG2 to collaborate with other AHWP/GHWP workgroups and international organizations.

As WG2 Chair, TFDA routinely joins the International Medical Device Regulators Forum (IMDRF) IVD working group meetings for reviewing and updating the Principles of IVD Medical Devices Classification document. In addition, WG2 has established a long-term cooperation relationship with WHO IVD pre-qualification team to contribute technical comments to WHO Technical Specification and Technical Guidance documents.

The continuous and significant participation of TFDA in global medical device regulatory organizations, sharing knowledge and expertise with the global regulatory professionals, have been greatly showing Taiwan’s medical device regulatory

leadership and significant role in Asia and beyond.