UPDATE ON MEDICAL DEVICE REGULATION IN THAILAND

27th GHWP Annual Meeting

30th November 2023

✓ Legislations are aligned with ASEAN Medical Device Directive (AMDD)

- Risk classification

  Class 1-4 in Thailand = Class A-D in AMDD

- Common Submission Dossier Template (CSDT)

  Fully implement 15th Feb 2024

NEW REGULATIONS

Regulations	Status	**Effective date** (from the date of publishing in the Government Gazette
1. Ministerial regulation on the Manufacturing Quality System of Medical Devices (GMP)	Waiting for publishing in the Government Gazette (by Jan 2024)	180 days
2. Ministerial regulation on the Distribution and Sale Quality System of Medical Device (GDP)	Waiting for publishing in the Government Gazette (by Jan 2024)	1 year
3. (Draft) Ministerial regulation on the Rules, Procedures, and Conditions on the Use of Medical Devices in Clinical Trials (GCP)	In process of an approval from the ministry (expect to publish in Government Gazette by 2024)	$\geq$ 1 year Depend on devices' risk classification

Product Registration Pathway

- Full Evaluation Pathway
- Concise Pathway: CLASS 2-4 Medical Devices registered and marketed for more than 1 year

Therapeutic Goods Administration: **TGA**

Health Canada: **HC**

European Union Notified Bodies: **EU NB**

Japan Ministry of Health Labour and Welfare: **MHLW**

US Food and Drug Administration: **US FDA**

OR **WHO Prequalification of in Vitro Diagnostics (IVD)**

- Thai FDA-HSA Reliance pathway: CLASS 2-4 Medical Devices that approved from HSA 

Plan : More reference regulatory authorities / reliance mechanisms

THANK YOU