

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) | ≥ 1 year Depend on devices' risk classification |

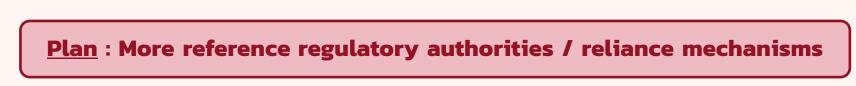


Product Registration Pathway

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



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





THANK YOU