

The role of regulators, industry, and distributors in global medical device regulatory harmonization and the integrity of the medical device supply chain

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Common stage of Medical Device regulation

Figure 2. Persons who directly manage the different phases of medical devices



WHO: MEDICAL DEVICE REGULATIONS: *Global overview and guiding principles*

Supply/Distribution Chain Control

► Overview of regulatory controls

- ◆ To ensure quality of medical device is maintained throughout distribution chain
- ◆ To ensure systems are in place for
 - Proper packaging and storage
 - Documentation of supply and distribution
 - FSCA reporting system
 - Adverse event assessment and reporting
 - Advertisement and promotion
 - Prohibition on false or misleading advertisement

Asia Pacific Industry Challenges

- ▶ Distributors business models
- ▶ Quality of distributors??
- ▶ Awareness of local industry
- ▶ Unavailability of global standard/GHTF guidance documentation for supply/distribution control
- ▶ Individual development of Good practice in the region
 - ◆ Korea GIP
 - ◆ Singapore GDPMDS
 - ◆ Thailand GIP development
 - ◆ Malaysia QS for importer/distributors development
 - ◆ More coming

Thank you