Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1927-2017 FICCI @90

# 22nd Asian Harmonization Working Party Annual Meeting

MAKE IN INDIA

MAKE IN INDIA

**4-8 December, 2017 I New Delhi**

EXPERIENCE
A New Healthcare
Solution

SAMSUNG

# Changing Global Regulatory Environment

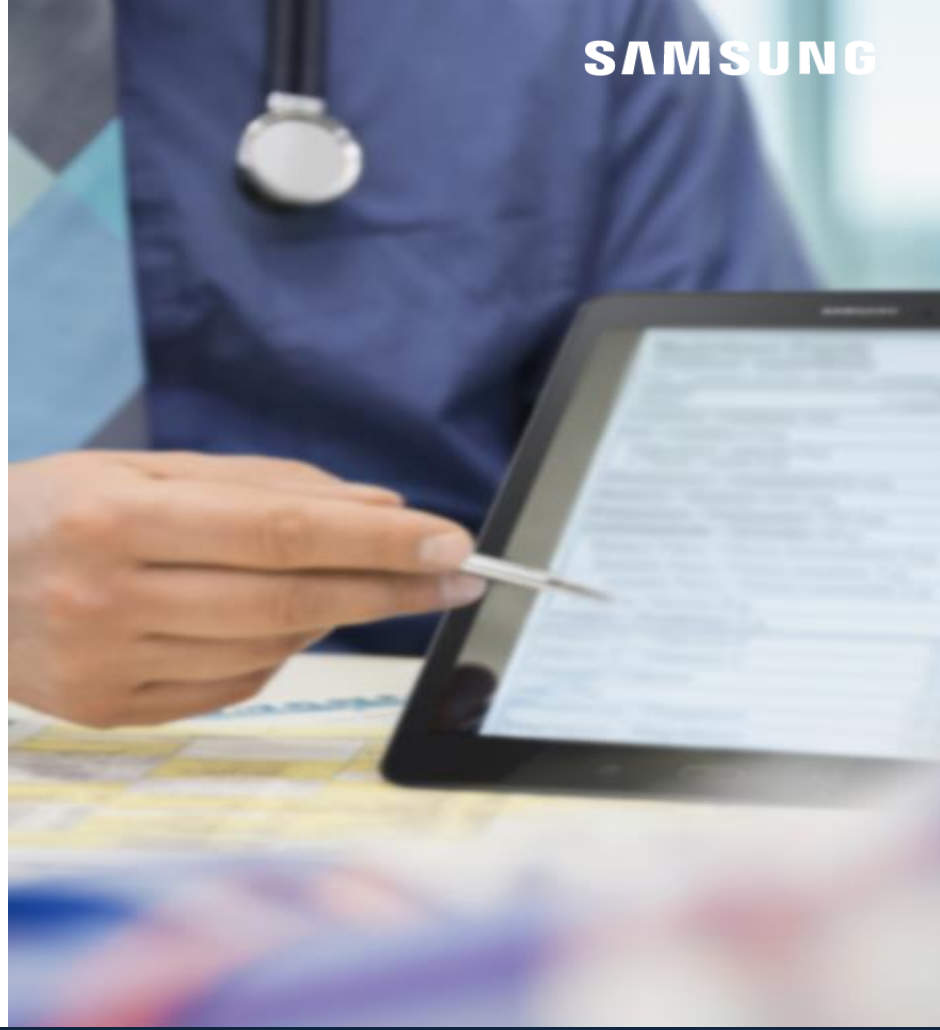
Opportunities & Threats in Industry – Focused on Premarket

AHWP

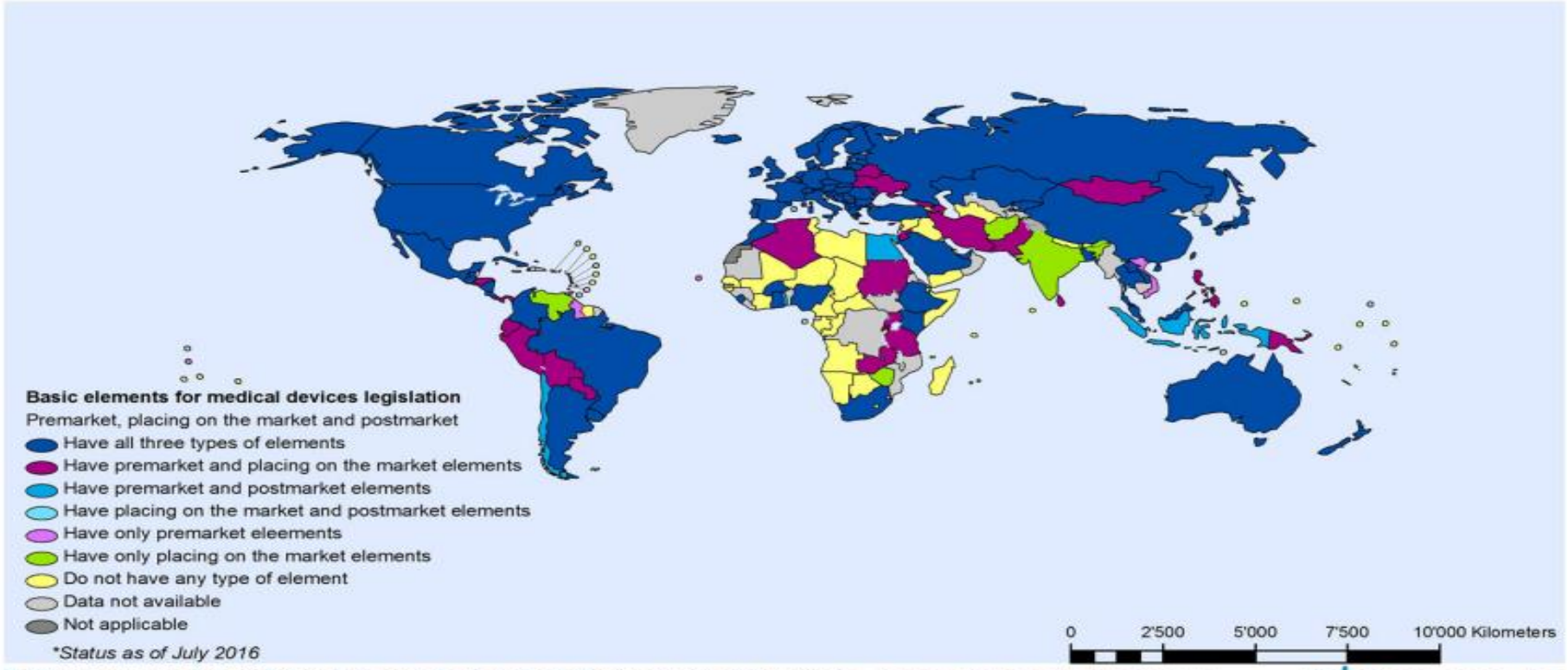
2017.December.06
Jeongpyo Hong
Health & Medical Equipment Business

# Contents





# Worldwide Medical Device Legislation




* Reference: WHO website, http://www.who.int/medical_devices/safety/all_basic_levels_types_mod.jpg?ua=1, extracted at Aug.28, 2017

Presenter: Jeongpyo Hong

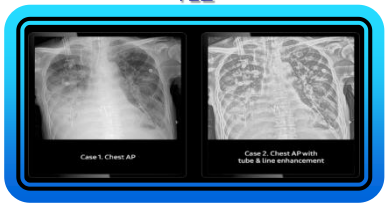
# At Glance - Premarket approval/clearance landscape

SAMSUNG

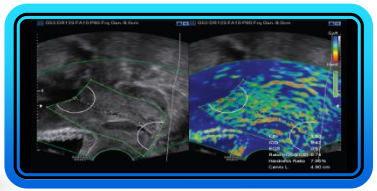
**# Modalities: Digital X-ray, Ultrasound, Mobile CT, IVD, Specialty MRI***

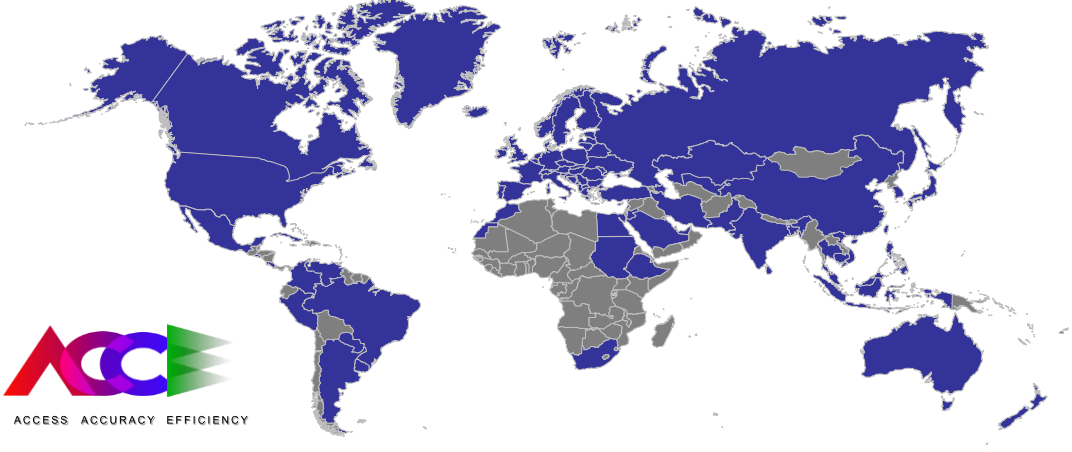
**# Selling 79 Countries**

**# Hold Premarket approval/clearance from 51 countries**







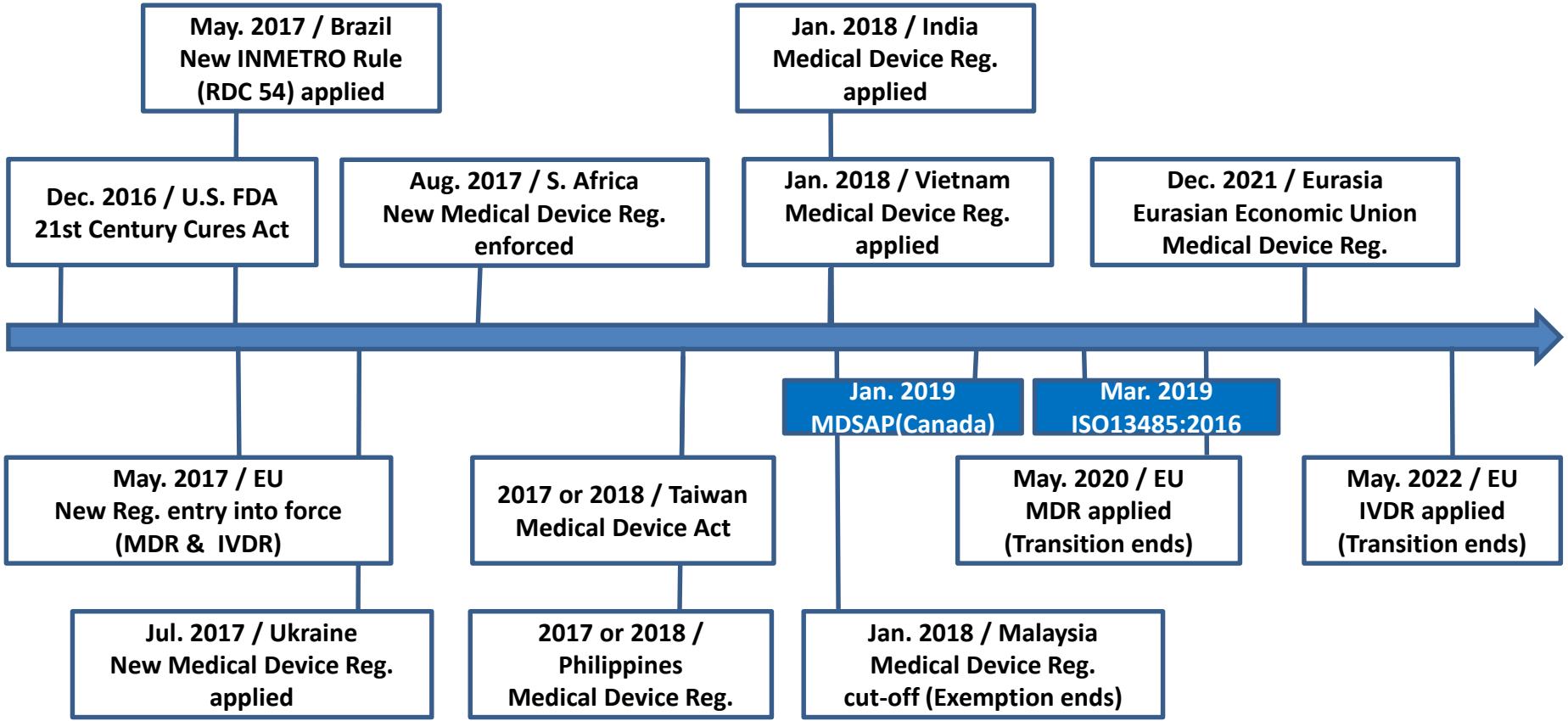
ACCESS ACCURACY EFFICIENCY

Presenter: Jeongpyo Hong

* Specialty MRI is under development * Some of the products and features are not cleared for use and not available for purchase in some countries

# Changing Global Medical Device Regulatory Environment

SAMSUNG




Presenter: Jeongpyo Hong

## Transforming Regulatory Framework

- Introduce medical device regulation / technical review
  . India, Malaysia start to regulate medical device.
  . Vietnam, South Africa start to require technical documentation.
  . Philippines expand regulated product coverage 10% to 100%.
  . Taiwan separates Medical device Act from Pharmaceutical Act.

- European legislation change from Directive to Regulation
  . MDD, AIMDD → MDR / IVDD → IVDR
  . Premarket scrutiny review, New IVD classification, Reinforced clinical evidence, etc.

## Transforming Regulatory Framework (Continued)

- The 21st Century Cures Act in US FDA
  . Streamline premarket review process and bring treatments to market faster
  . More PMN exemption, Accept real world evidence, Breakthrough Device Program, HDE expansion, CLIA waiver improvements, Least burdensome device review, etc.
  **Digital Health Software Precertification (Pre-Cert) Program***

## Harmonization

- Increasing harmonized regulation/standards across countries
  . ASEAN Medical Device Directive, MDSAP, Eurasian Economic Union, etc.

# Global Regulatory Trends

SAMSUNG

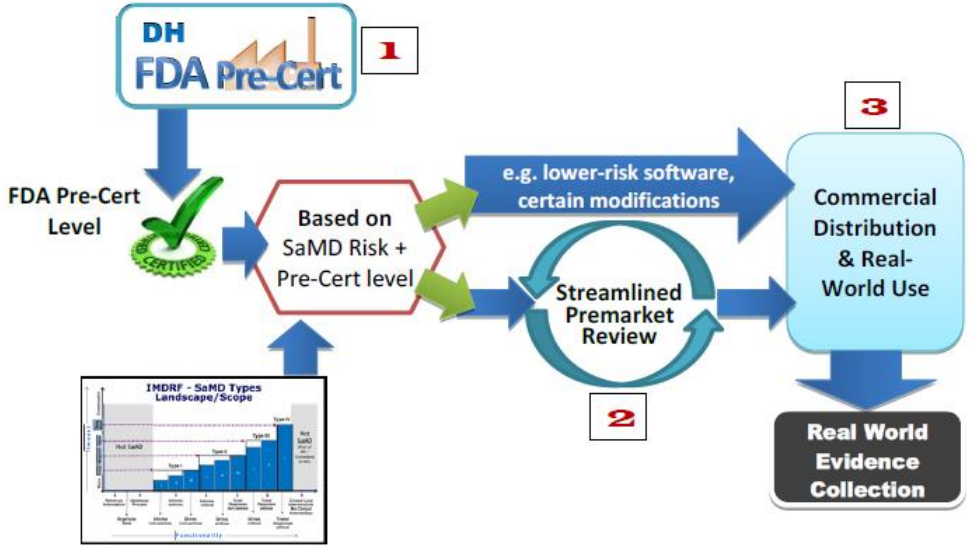
## * Digital Health Software Precertification (Pre-Cert) Program

. A company based streamlined approach for SaMD that demonstrated a robust CQOE

# SaMD: Software as a Medical Device, # CQOE: Culture of Quality and Organizational Excellence

. Strive for excellence rather than compliance, Promote high quality and innovation,

Increase user confidence beyond regulatory oversight, FDA to focus higher risk product




### . Program Flow

1. Pre-Cert → 2. Streamlined pre-market review → 3. FDA access to post-market data collection

### . Pilot program participants

Samsung, Apple, Fitbit, Johnson & Johnson, Pear Therapeutics, Phosphorus, Roche, Tidepool, Verily

Presenter: Jeongpyo Hong

# Global Regulatory Trends

SAMSUNG

## On-site inspection

- MDSAP

  . Less inspection from participated countries, More requirements

- Increasing on-site factory inspection

  . Ukraine new medical device regulation requires on-site GMP audit

  . Brazil INMETRO requires on-site inspection for each new device certification

## Clinical trial

- Increasing number of clinical trial

  . EU MDR restricts to use literature review method using other manufacturer’s device

# Opportunities & Threats in Medical Device Industry

SAMSUNG

## Opportunities

- Market access with same/similar technical documentation

  . Harmonized regulation – ASEAN, Eurasian Economic Union

- Strengthen product development and management process

  . Rigorous requirements → Procedural approach - Safer design, Stricter evaluation

## Threats

- Increasing time and cost to market

  . Scrutinizing premarket review, More clinical investigations needed

  . Harmonized standards have more requirements. Eg. MDSAP

- Increasing technical / regulatory barriers

- Need more experts on Regulatory and Clinical research

Presenter: Jeongpyo Hong

Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1927-2017 FICCI @90

# Thank you