Asian Harmonisation

- **Covers devices AND diagnostics**
- **AHWP**
  - *broader membership*
  - *mainly training/consensus group*
- **ASEAN**
  - *smaller group*
  - *specific proposals for ASEAN MDD by 2015*

Asian Harmonisation Working Party

- Membership includes all China, all South and SE Asian jurisdictions plus Mid East and South Africa
- Forum for training
- Facilitates GHTF based regulatory reform amongst members

AHWP

- Coordinates activities
- Training
- Shared Experience

GHTF

AHWP

- *Abu Dhabi*
- *Brunei*
- *Cambodia*
- *Chile*
- *China*
- *Hong Kong*
- *India*
- *Indonesia*
- *Korea*
- *Laos*
- *Malaysia*
- *Myanmar*
- *Philippines*
- *Singapore*
- *Saudi Arabia*
- *South Africa*
- *Taiwan*
- *Thailand*
- *Vietnam*

Brunei Darussalam

Cambodia

Indonesia

Lao PDR

Malaysia

Myanmar

Philippines

Singapore

Thailand

Vietnam

The ASEAN Medical Device Directive (AMDD)

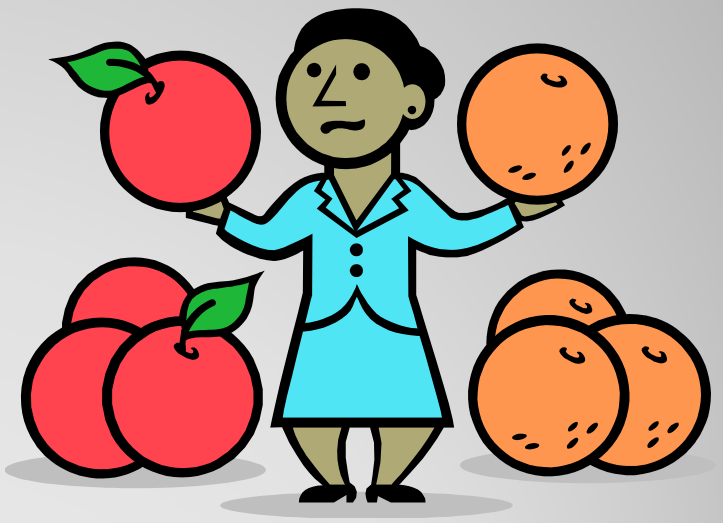
- **Closely Based on GHTF model**
  - ***Technical File***
  - ***Classification***
  - ***Conformity Assessment and Postmarket system***
- **Draft – to be finalised by August 2013**
- **Required to be implemented into national regulation in ASEAN members (same as for European Directives)**
- **Deadline for implementation is 2015**

Common Ground

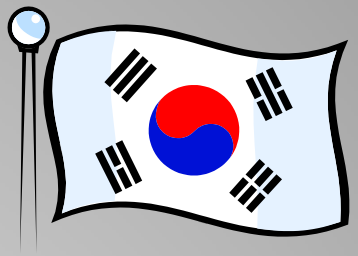
- ISO 13485
- In country representation
- Postmarket surveillance requirements
- Asia Pacific Laboratory Accreditation Programme

Differences

- **Legal Basis and Regulatory Model**
  - *Device, Drug, Exempt*
- **Classification**
  - *GHTF, US, local*
- **Review times**
  - *3 months – 2 years*
- **Fees**
  - *Nil to >$70,000*
- **Test Data**
  - *GHTF STED, or local requirements.* ***Local Type Testing*** *(CH,KR,TW)*



Korean Prohibitions on Specified Genetic Tests



Prohibited	Permitted for use only in defined clinical circumstances
• Hyperlipidemia related gene: LPL • Hypertension related gene: Angiotensinogen • Osteoporosis related genes: VDR, ER • Diabetes mellitus related genes: IRS-2. Mt16189 • Obesity related genes: UCP-1, Leptin, PPAR-gamma, ADRB3(B3AR) • Alcoholism related gene: ALDH2 • Depression related gene: 5-HTT • Longevity related gene: Mt5178A • Intelligence related genes: IGF2R, CALL • Asthma related genes: IL-4, beta2-AR • Endurance related gene: ACE • Lung cancer related gene: CYP1A1 • Violence related gene: SLC6A4 • Curiosity related gene: DRD2. DRD4	• Ankylosing spondylitis related gene: HLA-B27 • Leukaemia related genes: BCR/ABL • Short stature related gene: SHOX • Cancer related gene: P53 • Breast cancer genes: BRCA1, BRCA2 • Alzheimer related gene: Apolipoprotein E

Taiwan Acceptance of International Manufacturer GMP

US manufacturers	European Manufacturers
• the most recent FDA Establishment Inspection Report (EIR)	• Most recent audit report of the manufacturing facility
• Certificate of Foreign Government/ Free Sale Certificate	• Free Sale Certificate
• ISO 13485 certificate	• ISO 13485 certificate, and
• Completed Application Form	• Completed Application Form

Special Case: Companion Diagnostics

- Specific Link between Rx and Dx – e.g. Herceptin
- Diagnostic regulation may be REQUIRED to be linked to drug approval
- May need IVD approval even for in–lab test if it is a Companion Dx
- Need to factor in Dx approval process
- What does this mean for Drug approval and launch planning?

What does this mean for an IVD developer/exporter?

- **Most Technical Requirements are still common**
- **Good Clinical Data and Good statistics**
  - *These have currency everywhere*
- **Consider the USE risks**
  - *Specific purpose*
  - *Place of use – Clinic? Home?*

What does this mean for an IVD developer/exporter?

- **Talk to the Regulators in your chosen markets**
  - *Understand their needs and get their buy in before you submit*
- **Understand the sum of requirements and then <u>stage</u> applications**
  - *Early revenues in easier markets*

Thank You

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