

## Strategy -All actions linked to the AHWP Regulatory Model – ARM (IVD/MD) –

What elements of a comprehensive regulatory system are not addressed in the ARM

### A. Gap Analysis

- Building blocks not made yet – i.e. quality management system for distributors
- Building blocks that do for the purpose in the regional context
- New work items proposals for IMDRF

### B. Consider a focus on three kinds of work

1. New AHWP documents –
  - GHTF/IMDRF adoption, or create a document unique to AHWP
2. Interpretive documents on existing documents –
  - AHWP competency and clarification - Learning (Capacity Building)
3. Collaborative decisions on borderline issues –
  - AHWP decision, position on standards

### Processes

- Need more governance process and oversight to verify work items fit in the approved AHWP regulatory model.
- Address recruitment, qualified, balanced, consistent participation on work groups.
- Industrial participation is not limited to MNC especially if topic is directly related to local environment
- Implementation/adoption what does this mean or look like for AHWP

### Structure and International Alignment

- Consider a more flexible working structure not like GHTF. More horizontal linkages for example a mirror group on standardization
- Role of advisors
- Liaison activities

### TC Thoughts

- Regulatory Model - License, Establishment, etc...
- Technical – Standards, Guidance, Justify why accept standards
- What is the role of the representatives in ISO, IMDRF, etc....
- How can the advisors help
- Can we consolidate work and maybe work closer across groups
- Documentation – What do we really accept and implement
-