

# **SWOT Analysis & New Streamlined TC structure**

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# SWOT Analysis

- Performed by Technical Committee Leaders over the course of the TC leadership (2012 – 2014)
- Aimed to set direction & assess progress of the AHWP TC work items
- Provide newly-elected office bearers of AHWP TC with background information for direction of future term



# SWOT Analysis

## Performed by Technical Committee Leaders

### Strengths

- Stable working relationship among core members
- Attained certain level of stature
- Generous sharing by established member economies, APEC LSIF & IMDRF
- Legal entity & permanent secretariat office
- Access to valuable expertise of TC Advisory

### Opportunities

- External support (e.g. APEC LSIF)
- Some member economies just beginning to regulate (clean white sheets with no baggage)
- Tried and tested GHTF fundamentals – flatten learning curve

### Weaknesses

- Lacks manufacturing expertise / background
- Lacks political commitment to implement
- Some member economies have historical controls - difficult to change

### Threats

- GHTF to IMDRF (maintenance of guidance document)
- Loss of core team members
- Time – expedite to remain relevant
- Implement – need to execute to demonstrate continual funding
- Different level of regulatory maturity

# New Streamlined TC Structure

## Reason for new TC structure:

- Rapid evolution of medical technology & new developments and trends in the regulation of medical devices (e.g. Software as a Medical Device)
- Critical for AHWP to respond effectively to regulatory needs, in line with goal to promote regulatory harmonization

# New Streamlined TC Structure

Working Group	Positions
<b>WG1: Pre-market - General MD</b>	Chair & co-chair (existing positions of WG1 Chair/co-chair)
<b>WG2: Pre-market - IVDD</b>	Chair & co-chair (existing positions of WG1A Chair/co-chair)
<b>WG3: Pre-market - Software as a Medical Device</b>	Chair & co-chair (NEW positions)
<b>WG4: Post-market</b> Scope includes post-market aspect of WG 1-3 device categories	Chair & co-chair (existing positions of WG2 Chair/co-chair)
<b>WG5: Clinical performance &amp; safety</b>	Chair & co-chair (existing positions of WG5 Chair/co-chair)
<b>WG6: Quality Management Systems: Audit &amp; assessment</b>	Chair & co-chair (existing positions of WG4 Chair/co-chair)
<b>WG7: Quality Management Systems: Operation &amp; implementation</b>	Chair & co-chair (existing positions of WG3 Chair/co-chair)
<b>WG8: Standards</b>	Chair & co-chair (existing positions of WG7 Chair/co-chair)
<b>WG9: Training</b>	Chair & co-chair (existing positions of WG6 Chair/co-chair)

The structure and management of ad-hoc group(s) will remain unchanged.

<b>Special Task Group on UDI &amp; Nomenclature</b>	Chair & co-chair (existing positions)
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# New Streamlined TC Structure

## Aim of new TC structure:

- Increase alignment of AHWP TC work to current global trends in device regulations, facilitating coordination with related international organizations (IMDRF, APEC, WHO)
- Position AHWP TC to effectively respond and adapt to trends in medical device technology and regulatory strategies
- Improve efficiency and clarity in proposal and assignment of work items



Thank You