



# **11<sup>th</sup> GHTF Conference**

**Washington, D.C., USA**

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## **IVD Subgroup Study Group 1: Status Report**

**Nancy Shadeed  
Chair IVD Subgroup**

# overview of report

our role ...

membership...

what we've done so far...

what we plan to do in the near future...

## our role ...

“IVD Subgroup SG1 is responsible for comparing operational medical devices systems for In-Vitro Diagnostic Devices from around the world and from that comparison isolating elements/principles that are suitable from harmonization.” The group is responsible for working on a harmonized format for pre-market submissions.

[www.ghtf.org/sg1/sg1.htm](http://www.ghtf.org/sg1/sg1.htm)

# membership...

## Australia

Ms Shelley Tang

TGA

Ms Sandi Russell

MIAA

Ms Jilliane Keller

MIAA/Panbio

## Canada

Ms Nancy Shadeed

HC/MDB (Chair of IVD  
Subgroup)

Ms Maria Carballo

HC/MDB

# membership...

## European Union

Mr John Brennan	EU Commission
Ms Marie-Lise Migueres	AFSSAPS
Mr Benny Onns	EDMA/BD Bioscience
Dr Michael Thein	EDMA/Roche
Dr. Petra Kaars-Wiele	EDMA/Abbott

## Asian Harmonization Working Party

Ms Quan Tran	AHWP/J & J, Singapore
Ms. Seow Phing Lee	AHWP/Ministry of Health Malaysia

# membership...

## Japan

Dr Masaki Sugiura

PMDA

Mr Eiichi Chikami

JACRI/Daiichi

Mr Hirofumi Koide

JACRI

## United States of America

Dr Sousan Altaie

FDA

Ms Andrea Casper AdvaMed/Ortho-Clinical

# membership...

Regulatory reps.	8
Industry reps.	7
Observers	2 –3 (upon request)

# what we've done so far...

Since 2002, the study group has contributed to the revision of two published guidance documents to include elements for In-Vitro Diagnostic Devices.

## Final Documents

SG1/N41R9/2005      Essential Principles of Safety and Performance of Medical Devices

SG1/N43/2005      Labelling for Medical Devices

## Proposed Documents

SG1(PD)/N045R12      Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

SG1(PD)/N46R3      Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices

# what we've done so far...

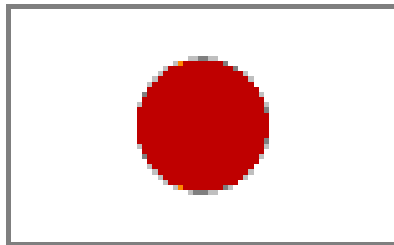
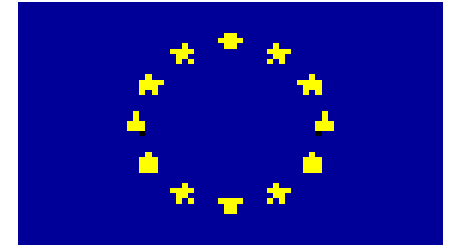
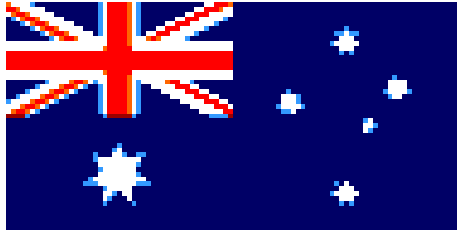
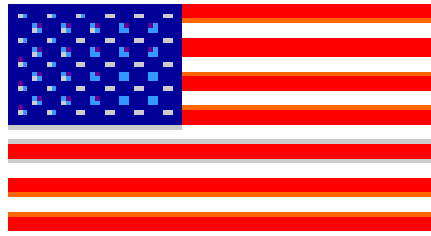
Presently developing a new guidance document called SG1(WD)N063/R2 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance for In Vitro Diagnostic (IVD) Medical Devices*

Intent of SG1(WD)N063/R2 to provide harmonized guidance on a format describing the type and detail of information a manufacturer would need to have as objective evidence to support their conformity with the Essential Principles.

# what we plan to do in the near future...

Currently working with Study Group 5 to address Clinical Evaluation for In-Vitro Diagnostic medical devices. The IVD subgroup will prepare a working draft for consideration by Study Group 5.

Review the comments received (September 2007) for the proposed documents Principles of Classification for In Vitro Diagnostic (IVD) Medical Devices and Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices.



Thank You ...