

**REPORT OF THE SG1 MEETING HELD FROM 8th TO 11th JULY, 2008
IN BUENOS AIRES, ARGENTINA**

Attendees

Chair - Ginette Michaud

Vice-Chair - Benny Ons

Secretary - Alan Kent

North America

Mark Melkerson – FDA, USA

Nancy Shadeed - Health Canada

Brenda Murphy – MEDEC, Canada

Marlene Valenti – AdvaMed, USA

Europe

Elke Lehmann – European Regulatory Authority

Peter Linders – COCIR/EMIG

Asia/Australasia

Mike Flood – TGA, Australia

Hiroshi Yaginuma – MHLW, Japan

Atsuchi Tamura – PMDA, Japan

Naoki Morooka – JFMDA, Japan

Tomomichi Nakazaki - JFMDA, Japan

Apologies

Cliff Spong - MIAA, Australia

Alfred Kwek – AHWP, Health Sciences Authority, Singapore

Daphne Yeh – AHWP, Industry representative, Chinese Taipei

John Brennan – European Commission

Carl Wallroth – EUROM VI/EMIG

Observers from the South America and the Caribbean Countries

Tim Missios - Boston Scientific (missiost@bsci.com)

Mercedes Boveri - Boston Scientific, Argentina (boverim@bsci.com)

Lilian Orofino - Boston Scientific, Brazil (orofinol@bsci.com)

Adriana Belza – Johnson & Johnson, MD & D (abelza@medur.jnj.com)

Sandra Dalberto – Johnson & Johnson, Brazil (sdalbert@medbr.jnj.com)

Monica Duarte – ANVISA, Brazil (monica.figueiredo@anvisa.gov.br)

Francielli Melo - ANVISA, Brazil (francielli.melo@anvisa.gov.br)

Marcio Varani – ANVISA, Brazil (marcio.varani@anvisa.gov.br)

Rogelio Lopez – ANMAT, Argentina (lopezr@anmat.gov.ar)

Emilce Vicentin – ANMAT, Argentina (evicenti@anmat.gov.ar)

Leandro Cian – ANMAT, Argentina (lcian@anmat.gov.ar)

Marta Ines Kaufman - ANMAT, Argentina (mkaufman@anmat.gov.ar)

Augustin Iglesias Diez – ANMAT, Argentina (aiglesiasdiez@gmail.com)

Humberto Olarte Cupas – MINSA, Panama (holarte@minsa.gob.pa)

Alejandro Martinez – MINSA, Panama (amartinez@minsa.gob.pa)

Mirtha Quiel - Ministerio de Salud, Panamá (mquiell@minsa.gob.pa)

Dulce Maria Martinez – CCEEM, Cuba (dulce@cceem.sld.cu)

1 **Welcome to the meeting and introduction of delegates**

Ginette Michaud, Chair of SG1, welcomed SG1 members and observers from the Latin American and Caribbean countries to the SG1 meeting. The Chair thanked Tim Missios of Boston Scientific for inviting SG1 to Buenos Aires and sponsoring the meeting. She also thanked his assistant Mercedes Boveri for her contribution to the arrangements.

The meeting included simultaneous translation services from Spanish/English and Portuguese /English.

The Chair provided apologies from five absent members of SG1 and described arrangements for the meeting.

John Brennan is leaving the EU Commission later this year and will no longer represent them on SG1. The Chair wished to record her thanks to John for his valuable and thoughtful contributions to SG1's work since he joined SG1.

2 **Adoption of Agenda and discussion of procedures for this meeting.**

The Agenda was agreed.

3 **Review of the report of the SG1 meeting held on 6th to 8th February in Bonn (Document GHTF. SG1. N067) and the report of the joint Study Group meeting held on 5th February 2008 in Bonn (Document GHTF. SG1. N068).**

The two meeting reports were accepted.

It was noted that an action from the SG1 meeting remained outstanding. The action read:

A note was to be added to the GHTF website to explain the discrepancy between guidance given in the STED and in *Principles of Conformity Assessment for Medical Devices* and how it will be addressed.

The text of the notice will be:-

**“DISCREPANCY BETWEEN
GHTF/SG1/N040:2006 *Principles of Conformity
Assessment for Medical Devices* and
GHTF/SG1/N011:2008 *Summary Technical
Documentation for Demonstrating Conformity to
the Essential Principles of Safety and Performance
of Medical Devices (STED)***

In SG1's guidance document *Summary Technical
Documentation for Demonstrating Conformity to the*

Essential Principles of Safety and Performance of Medical Devices (STED) it is stated that a STED for either a Class A or a Class B device should be prepared and submitted only at the request of a RA/CAB. This statement reflects the outcome of a long discussion on the matter.

However, in SG1's guidance document *SG1/N40:2006 Principles of Conformity Assessment for Medical Devices* that predates that on the STED, different guidance is given in that it recommends that a STED for either a Class A or a Class B device should be prepared and held by the manufacturer until such time as the RA/CAB requires it.

This discrepancy will be resolved when the guidance document on conformity assessment is next revised and in the meantime, the recommendation in the guidance document on the STED applies.

Please address any questions on this subject to the Chair of SG1 whose contact details may be found on the GHTF website.

Contact GHTF Secretariat to add the note to the website.

Action: Chair

4 **Report from the In Vitro Diagnostic Medical Devices Subgroup**

The main topic for discussion was an issue raised by the European Commission regarding the Final Document: GHTF/SG1/N46:2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices. In June 2008, the EU Commission indicated that the guideline contained insufficient guidance on the distinctions between the conformity assessment requirements for Classes C and D IVD medical devices. The EC's concern was described in a summary SG1 document that was circulated by the Secretary prior to the SG1 meeting.

In order to address this issue, the SG1 IVD Medical Devices Subgroup had proposed a change to GHTF/SG1/N46:2008 through the insertion into the text of "The main difference for a Class D STED would be in the level of details in the clinical/performance data and details of the manufacturer's QC release program" in Section 5.0 at the top of Page 8 and in the Notes under the tables for Class C and D on pages 13 and 14.

The purpose of this agenda topic in Buenos Aires was for SG1 to express an opinion on the suggested modification to the Final Document GHTF/SG1/N46:2008. During SG1's discussion, the following views were expressed:

- The additional information requested will be included within the IVD STED (currently being drafted) and does not belong in guidance document GHTF/SG1/N46:2008.

- Why not bookmark this change for incorporation when the document is reviewed in 3 years time? (The Chair confirmed that there is no obligation on SG1 to approve the additional text).

The following motion was put to the membership:

Motion: That SG1 approves the proposed revision to Section 5.0 at the top of Page 8 and in the Notes under the tables for Class C and D on pages 13 and 14 of “*SG1-N46:2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices*” through the addition of the text: -

‘The main difference for a Class D STED would be in the level of details in the clinical/performance data and details of the manufacturer’s QC release program’.

Action: SG1

Select members of SG1 asked to consult with their IVD specialists prior to voting. In order to allow for this consultation, and in order to capture in writing the vote of individual members, it was agreed that voting on the motion would be by email ballot. SG1 members were given one week to respond, with a YES or NO, to the Chair. (The voting period was subsequently extended to July 31, 2008 to accommodate members who would be away from the office during the originally proposed voting period).

The SG1 Chairperson stated that the result of the vote would be communicated to the GHTF Steering Committee through the GHTF Secretariat and that any further action on GHTF/SG1/N46:2008 would be determined by the Steering Committee.

Action: Chair and SG1 membership

Note: The GHTF/SG1/N46:2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices document was withdrawn from the GHTF website during the meeting of Study Group 1 in Buenos Aires by decision of the GHTF Chairperson.

It was reported that the EU Commission is preparing a paper on related topics (i.e. batch release verification and the so-called Common Technical Specifications) for discussion at a future Study Group 1 meeting.

Action: EU Commission

5 **Report from the Asian Harmonization Working Party –**

AHWP delegates were unable to attend the meeting in Buenos Aires. Consequently, a written report will be circulated to the Study Group 1 membership following the meeting.

Action: SG1 Secretary

6 Review of SG 1 accomplishments.

Prior to the meeting, the Secretary had circulated the most recent version of the *Status of Active GHTF Study Group Work Programme* (SG1/N034R30) dated 28th June 2008 together with SG1's Work Plan of June 2008.

The Secretary reported progress as follows:-

- a) SG/N044:2008 of February 21st, 2008: *Role of Standards in the Assessment of Medical Devices* has been endorsed as a Final Document by the Steering Committee.
- b) SG/N011:2008 of February 21st, 2008: *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)* has been endorsed as a Final Document by the Steering Committee.
- c) SG/N045:2008 of February 19th, 2008: *Principles of Classification of In Vitro Diagnostic Medical Devices* has been endorsed as a Final Document by the Steering Committee.
- d) SG/N046:2008 of February 26th, 2008: *Principles of Conformity Assessment of In Vitro Diagnostic (IVD) Medical Devices* has been endorsed as a Final Document by the Steering Committee but discussion continues as reported above.
- e) SG1/N055R6 of 26th February, 2008 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer* has been endorsed by the Steering Committee as a Proposed Document and is on the GHTF website for public comment. Comments will be accepted until early December.
- f) SG1/N065R05 of 26th February, 2008: *Registration of Manufacturers and other Parties and Listing of Medical Devices* will be discussed later in this meeting. Comments on the document have been received, consolidated and circulated to SG1. These will be discussed later in this meeting.
- g) Comments received for consideration when SG1 revises its guidance entitled *Essential Principles of Safety and Performance of Medical Devices* later in this meeting. A list of consolidated comments has been circulated. These will be discussed later in this meeting.
- h) Comments received for consideration when SG1 revises its guidance entitled *Information Document Concerning the Definition of the Term "Medical Device"*, at a future meeting, have been circulated.
- i) Comments received for consideration when SG1 revises its guidance entitled *Labelling for Medical Devices*, at a future meeting, have been circulated.

During discussion it was proposed that the Chair consider applying to the Steering Committee for undertaking a New Work Item on the subject of Change Control. This proposal will be discussed in Ottawa.

Action: Chair

The Chair agreed that in Ottawa, SG1 would discuss with the other SGs whether there is a need to prepare a justification for a new Work Item to prepare guidance on what should be understood by “technical documentation” (i.e. the entirety of technical documentation and not only its summary as described in the STED).

Action: Chair

7 **SG1(WD)/N065R3 Registration of Manufacturers and Listing of Medical Devices.**

During the meeting, attendees were asked to provide opinions on the purpose of establishment registration and medical device listing. It was noticed that significantly different replies were given by different jurisdictions.

Opinions on the purpose of Registration

- In the event of an adverse event investigation or withdrawal/recall of a device already on the market, the list of registered organisations will help the RA to trace both manufacturers and distributors with medical devices on the market.
- Helps control a manufacturer/distributor withdrawing from the market and possibly leaving devices already in use without support.
- Could be used to identify those organisations in the supply chain that operate a QMS.
- Used to generate income (registration fee) in some jurisdictions to offset or completely recover costs; while in others, registration is free of charge. Full cost recovery in Australia; substantial recovery in Canada; minor in the EU and USA.
- Could be used to identify organisations (manufacturers and importers) that have been audited prior to registration. In some jurisdictions, the audit confirms the organisation operates to GMP requirements which are aligned but not identical to ISO 13485 (including of overseas companies).
- Manufacturers can be removed from the register as part of a regulatory action.

Opinions on the purpose of Listing

- Helps the RA to trace devices on the market in the event of an adverse event investigation. However, Japan believes this will not help unless listing requirements incorporates details of specific devices (model code rather than generic code).
- Where listing information is available for scrutiny by others, it allows the users and purchasers of medical devices (including the public) to assess what devices are available on the market and comply with the existing regulations (for low risk devices this is likely to be through a manufacturer’s declaration).
- Where listing information is available for scrutiny by others, it allows public/purchasers to assess which devices have undergone “regulatory review” (not relying on the manufacturer’s declaration of compliance alone).
- Where listing information is available for scrutiny by others, it allows users to know which organisation(s) is responsible for a particular medical device.
- In some jurisdictions, income generation through listing fees may offset (or completely recover) the regulators operating costs; in others, listing is free of charge. Full cost recovery in Australia; substantial recovery in Canada; minor in the EU and USA.
- Applying ISO 14971 (the risk management standard) is mandatory prior to listing in some jurisdictions.

- Devices can be “delisted” as part of a regulatory action.

In Latin America, Registration and Listing is the key regulatory process that incorporates some procedures that, within the GHTF regulatory model, are described in a range of different guidance documents (e.g. conformity assessment, quality system audits, STED review etc.).

It was noted that in Latin America,

- the term “registration” applies to product listing and not the registration of organisations such as the importer, distributor, manufacturer etc.
- the procedure to add organisations to a database is known as ‘establishment registration’.
- Most, but not all, of the RAs use the ECRI nomenclature system rather than GMDN.

Views on the registration of distributors

During discussion, it became clear that there were different views as to the value of registering/regulating distributors. In the US, only distributors of overseas manufactured devices (i.e. the importer) are registered. Brazil audits distributors; its database incorporates 15,000 companies and 40,000 products. In Latin American countries, there is a particular problem with manufacturers ‘dumping’ devices onto their market through local distributors who do not provide proper storage, installation and maintenance services.

Views on the period between updating the registration and listing database

There were different opinions over whether SG1 guidance should recommend ‘annual’ updating of information provided to the RA or whether the guidance should say ‘periodically’.

Link to conformity assessment

The Chair used SG1 guidance on Conformity Assessment (*GHTF/SG1/N040:2006*) to explain that within the global regulatory model, registration and listing is only one element of conformity assessment, and is common to all device risk classes. The relevant text of Section 5.3.1 says:

Registration of manufacturers and their medical devices by the Regulatory Authority
Registration of manufacturers and their medical devices by the RA is considered to be the most basic level of regulatory control of devices in the market. This registration system will identify the device/s and the party responsible for the device/s within the particular jurisdiction, thereby facilitating any regulatory activity.

Prior to placing a medical device on the market, the manufacturer, its local distributor or its Authorized Representative should provide the Regulatory Authority with the required information.

Discussion of comments received

The comments received on the proposed document (SG1(WD)/N065R3) were discussed in turn and the guidance document modified as agreed. The revised document, an updated comments table and a blank comments table will be circulated to SG1, other Study Groups and the observers attending this meeting.

Action: Secretary

Comments are invited on the revised text and should be submitted by end August 2008.

Action: all attendees at this meeting

8 **Recast of the European Directive**

Peter Linders presented to the meeting the reaction of European Industry to the recent initiative from the EU Commission to 'recast' the 3 European medical device directives. The presentation will be circulated to meeting attendees but is for his/her own use and not for further circulation.

Action: Secretary

9 **Future of the STED**

Peter Linders provided the meeting with his thoughts on the use of the STED now it has been finalised. The presentation will be circulated to meeting attendees but is for his/her own use and not for further circulation.

Action: Secretary

10 **Revision of GHTF/SG1/N41:2005 Essential Principles of Safety & Performance of Medical Devices.**

The consolidated comments regarding the final document GHTF/SG1/N41:2005 were discussed in turn and the guidance document modified as agreed. Due to the lack of time, this exercise was not completed and will continue in Ottawa.

Comments received from NB-Med did not arrive in time to be incorporated into the list of consolidated comments circulated prior to the meeting but will be before the Ottawa meeting.

Action: Secretary

The revised document and an updated comments table will be circulated to SG1 and the observers attending this meeting.

Action: Secretary

11 **Report from Latin American and Caribbean Regulators and Industry**

PowerPoint presentations were made by:

- Marta Kaufman on Argentina
- Dulce Maria Martinez on Cuba
- Monica Duarte on Brazil
- Mirtha Quiel on Panama
- Adriana Belza on the joint industry perspective within the region

Points of note are as follows.

Argentina

- Cultural change required to move from original regulations to the current ones.
- In recent years – requirement for QMS – modelled on 21 Part 820 – adopted by MERCOSUR countries.
- Step-wise approach:
 - Establishment registration and device listing (self-declaration) (2004).
 - Enforcement of full compliance to QMS of all manufacturers and importers (from 2005 to 2007).
 - Post-market surveillance program.
 - Pre-market approval procedure for devices marketed for the first time in Argentina.
 - If device is manufactured in GHTF founding member or MERCOSUR (including evidence that it is legally marketed in these jurisdictions, e.g., free sales certificate) – STED is received but no QS audit; if device is from Argentina or other countries – QMS audit is required.
- Essential requirements similar to EU MDD.
- Risk Class similar to GHTF class system.
- Main activities currently under discussion: considering implementation of ISO 13485; development of guidelines for product listing; the development of guidelines of combination products; development of guidelines to know when a device has been modified and when a listing needs to be modified; new IT infrastructure.
- Working Group created in Argentina on combination products – joint committee involving all the offices of the Agency – modelled after the FDA office (workload of 3-4 products per year).

Cuba

- Presentation looks back at 15 years of work.
- Regulator is located within National Health System – mission is registration and premarket assessment and postmarket use within the health system.
- Main work strategies:
 - Development of national industry.
 - Ongoing analysis of regulatory trends.
 - Mission to guarantee safety and effectiveness of medical devices.
 - Step-wise process – high risk radiation equipment was an initial focus.
- Centralized model; level of regulation correlated to the risk of the device; all devices are subject to premarket controls; mandatory premarket registration; assessment of safety and effectiveness has balance between premarket review / QMS / postmarket controls.
- First decade: QMS based on ISO 900 and 13485; system of adverse event reporting; premarket evaluation; control of radiation emitting devices; development of statutes, standards, regulations and guidelines; Cuban standards are an adoption of international standards – we understand their use to be mandatory.
- 374 domestic manufacturers.

- Nuevo Reglamento 2007 – extended regulatory framework.
- Recently – Cuba has increased ability to import medical devices (because of improved economic situation); regulatory authority has progressed to address this increase in imports.
- Registration presently of 1000 entities.
- SOPs/guidelines developed for assessment of medical devices.
- Surveillance – adverse event reporting by manufacturers and importers; creation of safety committees; Cuba has been accepted into the NCAR program.
- Quality – manufacturers present their certificate of QMS obtained in foreign country; auditing against ISO 9000 and ISO 13485.
- Challenges: risk management.
- Medical radiological activities – are regulated; current efforts to regulate and follow-up radio-diagnostic medical devices.
- Science and technical activities are science-based.

Brazil

- Government agency; employees are public servants; contract with Ministry of Health; created in 1999, 2830 employees; 250M annual budget; 25% of the country's GDP is regulated by ANVISA.
- Areas of activities include devices, blood, drugs, food, etc.
- 29 employees for medical devices.
- 32000 products registered.
- Regulation of devices and IVDs.
- Risk criteria define Classes 1, II, III, IV under 18 rules.
- Some devices are bench tested in premarket.
- GMP regulation.
- IVD classes I, II, III, IIIA (self tests)– equivalent to GHTF risk classes A through D
- These medical device controls including IVDs (submission requirements and GMPs) are harmonised with MERCOSUR.
- If product is only manufactured for export, it is exempt from regulatory controls.
- Registration focus is on risk management.
- Brazil consumes US\$ 6billion in medical devices.
- Investment of US\$ 2billion in local development of medical devices.
- Brazil is presently revising its classification of medical devices; public consultation on GMDN utilization for premarket program; ANVISA receives adverse events in ECRi nomenclature in its medical device surveillance program.
- How to obtain the device register:
 - obtain establishment authorization;
 - GMP and type examination;
 - published in Gazette.
- Database for registration and listing – contains information on all distributors associated with manufacturer and its devices; all trade names are also included; the database also contains alerts e.g., regarding the withdrawal of license.

Panama

- Ministry of Health – Health Code of 1947 – not amended since – covers the promotion, protection, prevention, and recovery activities.
- Law 1 of Jan 10 2001 for drugs and medical devices includes radiology devices but does not cover all medical devices – the law is primarily drug law.

- In 2006, resolution from Social Security Office created Depart of Evaluation and Management of Health Technologies.
- 2007 Executive Directive established the medical device surveillance program.
- Program subject to interest and support of Minister.
- Program includes vigilance activities and technology evaluation (for government acquisitions).
- Regulation of medical devices according to GHTF – definition of medical device, concept of “device families”, classification according to GHTF.
- Technical certificate required every 5 years.
- General requirements and special requirements; more information required of higher risk classes; conformity letter of conformity assessment from the manufacturer and sworn declaration of conformity assessment; suspension of the technical certificate for cause.
- Panama receives FDA alerts; use of ECRI nomenclature (cost free); involved in PAHO’s Med-Devices group
- Current Minister has seen the value of sharing information with local public health offices.
- Surveillance activities in each public and private hospital.
- Ministry planning to establish the registry for medical devices; also planning to strengthen the technical cooperation with other countries.
- Great support by government authorities for regulation of medical devices.
- Cooperation with Brazil, Argentina, PAHO – exploring possibility of working with FDA (Larry Kessler) - Panama has targeted countries that already have adopted GHTF guidelines
- Panama has not identified any other Central American country that has adopted GHTF.

Industry Presentation

- Challenges faced in Latin America:
 - Latin American regulators do not clearly define term “origin”.
 - Increased customs scrutiny over products – country of origin in import license and invoice must be identical to origin approved for regulatory practices.
 - Custom officials have poor knowledge of sanitary regulations.
 - Different terminology: different sources countries have different wordings: “assembled in Dominican Republic but made in US”; assembled in UK but made of US parts” - all this is confusing.
 - Many products assembled in Mexico (“maquilas”), then they go to US or EU for sterilization, etc., to become finished product.
 - Risk-based approach not widely accepted – regulators do not trust company’s self-declaration because of past history of poor quality products entering market – regulatory burden not very different between classes; product history not taken into account.
 - Suggested edits to SG1/N043 – Labelling guideline:
 - “Country of origin” is requirement by US customs and trade commission.
 - Add a note to clarify that any misalignment is not necessary false or erroneous.
 - Registration and Listing per GHTF is not an endorsement.
 - Drug industry still influencing the handling of medical devices.
 - Issues related to definition of ‘medical device’ and ‘drug’.
 - Some jurisdictions give more value to a “Certificate of analysis” versus a QMS certificate.
 - ‘Legal manufacturer’ concept not widespread in Latin America.

- Legal documents needed for registration must indicate the country of the REAL manufacturer (manufacturing site).
- Subcontractors and OEMs are not regulated by Notified Bodies or Competent Authority.
- Definition of a Manufacturer SG1(PD)/N055: the license is issued under the name of the “real” or “physical” manufacturer – furthermore some jurisdictions want industry to add additional labelling saying “manufactured for *** by ***”.

Milestones for the future:

- Need for industry participation in the Latin America working party.
- Seek both industry and regulator participation in all GHTF SGs.
- Seek ways to make AHWP WG6 work (training group) available to Latin America.
- Reinforce PAHO Resolution on Medical Devices to develop regulations, promote Latin American & Caribbean participation in GHTF & promote use of GHTF guidance.
- Speed up the translation process of the GHTF documents.
- Improve document control e.g. version control between published documents versions and the translated documents.

A comment will be added to the compilation of consolidated comments on the labelling document review (GHTF/SG1/N43:2005) regarding the problem raised by Adriana Belza during her presentation on ‘Country of Origin’ issues and the like.

Action: Secretary

The presentations will be e-mailed to SG1.

Action: Secretary

The Chair will contact Antonio Hernandez of PAHO and provide feedback from the meeting.

Action: Chair

12 Study Group 1 Communications Database

The Secretary reported on the status of the Communications Database. The Latin American attendees will be added to it.

Action: Secretary

13 Document Priorities and Timetable

Work in progress is as follows:

DOCUMENT TITLE	REFERENCE	STATUS	PRIORITY	TARGET FOR COMPLETION
Study Group 1 – New Documents				
Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer.	SG1/N055	Proposed document available for public comment.	1	Final Document 2009/Q3
Registration of Manufacturers and other Parties and Listing of Medical Devices	SG1/N065	Comments on Working Draft discussed in Buenos Aires and revised document circulated.	1	Proposed Document 2008/Q4
SG1 IVD Medical Devices Subgroup – New Documents				
Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices.	SG1/N063	Working Draft in preparation.	1	Proposed Document 2008/Q4
Revision of SG1 Final Documents				
Essential Principles of Safety and Performance of Medical Devices (revised)	SG1/N069	Comments received on GHTF/SG1/N0 41:2005 discussed in Buenos Aires and revised document circulated.	2	Proposed Document 2009/Q2
Information Document Concerning the Definition of the Term “Medical Device” (revised)	SG1/N071	Comments received on GHTF/SG1/N0 29:2005 to be considered in Ottawa.	3	Proposed Document 2009/Q4
Labelling for Medical Devices (revised)	SG1/N070	Comments received on GHTF/SG1/N0 43:2005 to be considered in Ottawa.	3	Proposed Document 2009/Q4

14 **Any Other Business**

a) Updating the GHTF website

The website includes a description of the purpose of each Study Group. That for SG1 is out of date. The existing text reads:

“SG1 has been charged with comparing operational medical device regulatory systems around the world and from that comparison, isolating the elements / principles that are suitable for harmonization and those that may present obstacles to uniform regulations. In addition, the group is also responsible for developing a standardized format for pre-market submissions and harmonized product labelling requirements.”

During discussion the text was modified to read:

Purpose of Study Group

SG1 has been charged with supporting convergence of medical device regulatory systems through the development of harmonized guidelines on elements of a global regulatory model. These elements include definitions of key terms such as ‘medical device’ and ‘manufacturer’; essential principles of safety, performance, and labelling; principles of classification and conformity assessment; and recommendations for summary technical documentation.

In developing these guidelines, SG1 collaborates with other GHTF Study Groups in creating a global regulatory framework. It has additionally welcomed the contribution to its work of regulators and industry in other parts of the World.

The modified text will be sent to the website co-ordinator and the other Study Group Chairs.

Action: Chair

b) Updating the SG1 membership list

SG1’s membership list as shown on the GHTF website will be updated to reflect the current status.

Action: Chair

15 **Date and place of next meeting**

- Ottawa from 14th to 17th October for a joint Study Group meeting.
- Australia (close to Sydney) from 20th to 23rd January, 2009, at the invitation of J&J – to be confirmed.

Action: Chair

- Toronto in mid-May 2009 for the next GHTF Conference (10th to 15th for the conference itself) and a joint Study Group meeting – meeting dates for the Study Groups to be confirmed.

Action: Chair

- Brussels in October, 2009 – to be confirmed

SUMMARY OF ACTIONS

For the Chair

- Contact GHTF website co-ordinator to make add a note to the website to explain the discrepancy between guidance given in the STED and in *Principles of Conformity Assessment for Medical Devices*.
- Discuss with the other SGs whether there is a need to prepare a justification for a new Work Item on what should be understood by “technical documentation” (i.e. the entirety of technical documentation and not only its summary as described in the STED).
- To consider applying to the Steering Committee for undertaking a New Work Item on the subject of Change Control and Technical Documentation and discuss in Ottawa if appropriate.
- Contact Antonio Hernandez of PAHO and provide feedback from the meeting.
- Circulate the modified text for the description of SG1’s purpose to the GHTF website co-ordinator and the other Study Group Chairs.
- Circulate an updated list of SG1 members to the GHTF website co-ordinator.
- Confirm details of future meetings in Australia and Toronto.

For the Secretary

- To update *Status of Active GHTF Study Group Work Programme* (SG1/NO34) and SG1 Work Plan before the next meeting and reissue to members.
- To incorporate agreed changes into SG1(WD)/N065 *Registration of Manufacturers and Listing of Medical Devices* and circulate the revised document, together with an updated comments table and a blank comments table to SG1, other Study Groups and the observers attending this meeting.
- To incorporate agreed changes into GHTF/SG1/N41:2005 *Essential Principles of Safety and performance of Medical Devices* and circulate the revised document, together with an updated comments table and a blank comments table to SG1 and the observers attending this meeting.
- Add a comment to the compilation of consolidated comments on the labelling document review (GHTF/SG1/N43:2005) regarding the problem raised by Adriana Belza during her presentation on ‘Country of Origin’ issues and the like.
- To circulate Peter Linders presentations on the “recast EU Directive” and the “future of the STED” to meeting attendees.
- To circulate Latin America presentations to meeting attendees.
- Add Latin America observers to the Communications Database and circulate.

- Circulate AHWP updates that are to be provided by AHWP delegates to Study Group 1

All Members of SG1

- To provide comments on guidance on Registration and Listing.
- To vote on the motion that recommends inserting additional text into *SG1-N46:2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices*.
- Send the Secretary by the end of August 2008 comments on the revised version of SG1(WD)/N065 *Registration of Manufacturers and Listing of Medical Device*.

EU Commission

- To prepare a paper on other topics concerning IVD Conformity Assessment (i.e. batch release verification and the so-called Common Technical Specifications) for discussion at a future SG1 meeting.