

**REPORT OF THE SG1 MEETING HELD FROM 5th TO 8th OCTOBER, 2010
IN SANTA ROSA, USA**

Attendees

Chair - Nancy Shadeed
Vice-Chair - Benny Ons
Secretary - Alan Kent

North America

Mark Melkerson – FDA, USA
Brenda Murphy – MEDEC, Canada
Michael Morton – AdvaMed, USA

Europe

Peter Bischoff-Everding – European Commission
Peter Linders – COCIR/EMIG

Australia/Japan

Atsushi Tamura – PMDA, Japan
Naoki Morooka – JFMDA, Japan
Tomomichi Nakazaki – JFMDA, Japan
Kentarō Azuma – MHLW, Japan
Gary Burgess – TGA, Australia

AHWP

Meshal Al Amri – Saudi Food and Drug Authority, KSA
Lindsay Tao – J&J, China

Apologies

Daphne Yeh – AHWP, Industry representative, Chinese Taipei/AHWP
Cliff Spong – MIAA, Australia
Huifen Bai – AHWP, Health Sciences Authority, Singapore.

Observers

Monica Hernandez-Solo – Medtronic
Lucinda Fox – Medtronic
Diana Johnson – Medtronic
Shivanth Bhaskaran – Medtronic
HyeWon Roh - Korea Food and Drug Administration

1 Welcome to the meeting and introduction of delegates

Nancy Shadeed, Chair of SG1, welcomed SG1 members to the meeting in Santa Rosa and thanked Michael Morton and his staff for organising the meeting.

Michael Morton welcomed SG1 to Santa Rosa and described arrangements for the week.

Dr Kweli Thompson, Vice President of Global Marketing, Medtronic EndoVascular Innovations, welcomed SG1 to the meeting and described the work of the Santa Rosa facility. Later in the meeting, most SG1 members toured part of the Medtronic R&D facility.

Lennart Philipson from the Swedish Regulatory Authority has resigned from the Study Group since the last meeting. The Chair acknowledged his valuable contribution to the work of SG1. As yet, his replacement has not been nominated.

The Chair announced that Alan Green of EUROM VI will be replacing Carl Wallroth as a representative of European industry. He was unable to attend this meeting but should join SG1 for its London meeting.

Apologies of absence have been received from Cliff Spong, Daphne Yeh and Huifen Bai.

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

The Agenda was approved after adding a few topics for discussion under Any Other Business.

3 **Review of the report of the SG1 meeting held from 18th to 21st May, 2010 in Tokyo (Document GHTF. SG1. N80 of 19th July 2010) and review of action items**

The Tokyo Meeting Report was circulated prior to the meeting. It was approved after editorial changes to three of the names of attendees.

Meeting actions were reviewed. All actions have been completed with the exception of the following:

- Benny Ons to raise with the Steering Committee the suggestion that the GHTF website should have a facility that allows interested parties to register and be informed automatically when new documents are posted on the website.

Action: Benny Ons

- To draft a procedural document to clarify the future handling of SG1 documents that incorporate text for IVD medical devices.

Action: Chair

Both actions are carried over to the next meeting.

A third action, namely “to obtain a copy of a key Steering Committee document on training, dated 2008, and circulate to SG1” was investigated by Benny Ons who discovered the document in question was a draft for internal purposes only and not available for circulation outside the Steering Committee. Currently, the GHTF Secretariat is drafting a statement on GHTF training.

4 **Review of SG 1 accomplishments.**

The GHTF website has been updated regarding SG1 Meeting Reports, change of Chair, the most recent Work Plan and the publication of ***GHTF/SG1/N065:2010 Registration of Manufacturers and other Parties and Listing of Medical Devices*** as a Final Document.

Comments on SG1's proposed document **SG1(PD)/N70R5 Labels & Instructions for Use for Medical Devices** have been received and will be discussed later in the meeting.

The IVD sub-group has discussed **SG1(PD)/N068 Essential Principles of Safety and Performance of Medical Devices (revised)** and the resulting edited document will be discussed later in this meeting prior to forwarding it to the Steering Committee.

SG1/NO34 Status of GHTF Study Group 1 Work Programme and the **SG1 Work Plan** will be updated before the next meeting.

Action: Secretary

5 **Report from the In Vitro Diagnostic Medical Devices Subgroup (IVD MD Subgroup)**

A report on the activities of the sub-group was circulated prior to the meeting.

Nancy Shadeed reported that she would be standing down as Chair of the IVD Medical Devices sub-group after its next meeting and would be replaced by Shelley Tang of the TGA.

6 **Update on the Work of the Steering Committee**

Nancy Shadeed, Benny Ons and Kentaro Azuma updated SG1 on recent activities of the Steering Committee as follows:

- SG1's summary document on HL-7 was circulated to the Steering Committee but a decision on any future involvement of SG1 awaits its next meeting after a presentation by a senior representative of HL-7 who will be in attendance.
- A new procedural document to accompany documents submitted to the Steering Group has been agreed and circulated to SGs.
- UDI – a second document on the subject is being prepared for the Steering Committee's next meeting.
- Global Regulatory Model – a revised document will be discussed at the next Steering Committee meeting.
- PAHO – Mexico and Brazil appear to be willing to fund a representative each to attend Steering Committee meetings. Antonio Hernandez has retired from PAHO. The FDA are providing some funding to PAHO. A Brazilian regulator may attend SG1's next meeting as an observer.
- IVD STED – forwarded by SG1 for endorsement but discussion delayed until November 2010 while the EU formulates a position on some aspects of the guidance.
- Next meetings - Sydney 2/4 Nov 2010 / 11 March 2011 (telecom) / 11/13 May 2011 Brisbane. Any SG documents must be submitted 60 days earlier than these dates.

7 **HL-7 and Regulatory Product Submissions Update**

Michael Morton, with others in a sub-group, prepared a summary document to describe a potential collaboration between GHTF and HL-7, drawing attention to the challenges and benefits of such engagement. It was copied to SG1 and forwarded to the Steering Committee for consideration. SG1 await feedback from the Steering Committee which may occur after the Steering Committee's November meeting.

Peter Linders explained that ISO would adopt an HL-7 standard after circulating it for voting. After the meeting he provided the following information from Tim Buxton, one of his contacts:

The RPS project was initiated by US-FDA, and Release 2 is being worked upon. Experts from ISO TC215 are involved in this project as the intention for release 3 is to take it through the process for it to become an ISO standard once it is complete within HL7.

Structured Product Labeling is a separate HL7 specification, and was developed to allow the annual submission of labeling information required of US sponsors of human pharmaceuticals to be undertaken in a structured, electronic format. Release 5 is its current phase, and although the specification is formally universal in its application, it is only implemented in the US. The submission process is I believe currently separate (RPS is not implemented for human pharmaceuticals).

I understand that US-FDA is seeking to develop specifications within HL7 that can be applied across all its Centers.

8 **Report from the Asian Harmonization Working Party**

Lindsay Tao updated the meeting on the AHWP Technical Committee meeting during September. Some GHTF members present who also provided training. A major topic was the CSDT/STED comparison.

It was noted that the AHWP was establishing a legal entity in Hong Kong to act as the AHWP Secretariat It would also be responsible for collecting sponsorship from industry.

Singapore & China are joining the GMDN Board of Trustees. There are different opinions within AHWP as to whether to support GMDN throughout the region.

Lindsay Tao will send the Secretary her presentation for circulating to SG1.

Action: Secretary

9 **SG1(PD)/N068R4 Essential Principles of Safety and Performance**

SG1 reviewed the draft document to ensure the section for medical devices remained appropriate after the move of the IVD specific content into an IVD medical devices specific section in the document.

The numbering of the sections and clauses will be modified to improve the clarity of the document before the document is circulated.

Action: Secretary

Then the revised document will be submitted to SG1 for a brief review and subsequently to the Steering Committee as a Proposed Document for public comment.

Action: Chair / Secretary

Two of the comments from the TGA were discussed and action agreed. The third was bookmarked for consideration after the public comment stage.

Action: Secretary

10 **GHTF/SG1(PD)/N070 Label and Instructions for Use for Medical Devices (January 29, 2010)**

SG1 discussed the comments related to 'medical devices other than IVDs' that had been submitted during the public consultation stage. The document was modified where agreed. There was an extensive discussion regarding the location of information that appears on the label (the label affixed to the device or the device packaging or an accompanying leaflet). Eventually modified text was agreed.

UDI – there is a draft document being prepared for the November Steering Committee meeting. Once the contents of the guidance becomes clear, SG1 will consider whether it needs to modify its guidance to account for UDI.

Action: Chair / Secretary.

Those comments relating to 'IVD medical devices only' will be discussed by the IVD sub-group at its next meeting in early December.

Action: Chair

11 **Comparison of SG1 STED and AHWP CSDT**

Alan Kent reported on the work of a sub-group (consisting of Cliff Spong, Morooka-san, Peter Linders, Nancy Shadeed and Huifan Bai) that had compared the two documents. A copy of the comparison had been circulated to SG1 before the meeting.

SG1 is invited to add comments to the document and send them to the Secretary.

Action: Members of SG1

12 **Revision of SG1/N029:2005 Information Document Concerning the Definition of the Term 'Medical Device'**

The previously revised version of the document was circulated to SG1, the IVD subgroup and other GHTF SGs after the Tokyo meeting. The only comments received were from the FDA. These were discussed and the text modified as agreed.

The document will be forwarded to the Steering Committee for endorsement as a Proposed Document for public comment.

Action: Chair / Secretary

13 **SG1(WD)/N077R01 Principles of Medical Devices Classification (revised)**

SG1 continued to discuss the public comments received on the document and revised the document where agreed.

Before the next meeting, revised text for Section 5.0 will be drafted to reflect the ‘philosophical debate’ that occurred during this meeting

Action: Chair/Vice-Chair/Secretary

Industry will prepare an 'evidence-based' justification for the ‘down-classification’ of some or all diagnostic X-ray devices, before the next meeting.

Action: Peter Linders / Naoki Morooka

14 **Document Priorities and Timetable**

Work in progress is as follows:

DOCUMENT TITLE	REFERENCE	STATUS	PRIORITY	TARGET FOR COMPLETION
SG1 IVD Medical Devices Subgroup – New Documents				
Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices [SG1/N063(PD)	Document has undergone minor revisions by SG1; final check of document by IVD Subgroup underway, after which document will be submitted to SC for advancement as a Final Document.	1	Final Document 2010/Q4 (Subject to discussion by the Steering Committee during its November Meeting)
Revision of SG1 Final Documents by SG1 and IVD MD Subgroup				

Label and Instructions for Use for Medical Devices	SG1/N070(PD)	Document posted as Proposed Document on GHTF website on April 26, 2010.	1	Final Document 2011/Q2
Essential Principles of Safety and Performance of Medical Devices	SG1/N068 Working draft	Document undergoing revision by IVD Medical Devices Subgroup.	1	Proposed Document 2011/Q1
Information Document Concerning the Definition of the Term “Medical Device” (revised)	SG1/N071	Document undergoing revision by GHTF Study Group 1.	2	Proposed Document 2011/Q1
Pending Revisions of SG1 Final Documents				
Principles of Medical Devices Classification	SG1/N015	Revision underway.	3	Proposed Document 2011/Q3
Principles of Conformity Assessment for Medical Devices	SG1/N040	Revision pending.	4	Proposed Document 2011/Q4
Possible New Work Items				
HL-7 and e-STED		SG1 Liaison group working with HL-7	?	Awaits Steering Committee Feedback

15 Any Other Business

a) Update on the ‘recast’ of the three European Directives for medical devices.

It is likely that:

- The directives on medical devices and on active implantable medical devices and their amending directives will be merged.
- The IVD directive will be kept separate but revised.
- Scrutiny of Notified Bodies by Member States will be strengthened.

- A process is considered aiming to ensure uniform assessment of high risk or new technology devices by NB's, in particular as regards the assessment of the manufacturer's clinical evaluation.
- The existing conformity assessment modules may be streamlined and the number of modules reduced.
- Consideration is being given to how post-market clinical experience can be accommodated in the directive.
- Improve the consistency of responses by Member States to vigilance reports.
- Regulation of 'reprocessed single-use' devices is considered.
- Consider a rules based approach to classification of IVDs adoption the GHTF classification rules.
- Further extension of EUDAMED (European Database on Medical Devices). Use of GMDN by Member States is encouraged but not mandatory. Use of EUDAMED will become mandatory (currently voluntary) for Member States by 2011 for specific activities.
- Consider the introduction of the concept of the STED and review other GHTF guidance documents to see whether they should be accounted for.
- Consider either extending the role of European Medicines Agency (EMA) or increasing the administrative resource at the Commission in order to improve the management of the system.

b) Update of USA regulations

Proposed changes to the 510(k) process and CDRH methods of working:

- The 510(k) program is being reviewed. It will continue to seek to strike a balance between medical device innovation and improving patient safety.
- One of the proposals is to split FDA's Class II devices into two parts, Class IIa and IIb.
- Clarify the interpretation of 'substantial equivalence'.
- Clarify the concepts of 'intended use' and 'indications for use'.
- Streamline the 'de novo' process to allow innovation.
- Improve scientific skills and knowledge of staff.
- Strengthen the CDRH external expert collaborations.
- Provide and improve transparency with searchable, online, public-accessible databases.

c) Update from Canada

- About to publish draft guidance on using the STED for Health Canada submissions.
- Establishing a joint-initiative with TGA on QMS Certificates.
- Analysis of the multi-purpose audit pilot between FDA and Health Canada will soon be completed

d) ISO 13485

An e-mail from SG3 and a paper from the Steering Committee on ISO 13485 were discussed. The outcome of the discussion was as follows:

- SG3 should take leadership in the review.
- SG1 will suggest to the SG3 Chair that ISO 13485 definitions should be aligned with those of GHTF. Also that consideration should be given to updating ISOTR16142.

Action: Chair

- SG1 does not support the extension of the scope of the standard as implied in the draft document from an ad-hoc committee of the Steering Committee and felt that any suggestion for significant revision should be left to SG3 and TC210.

Action: Chair

e) COCIR Proposal re the Qualification of Software as a Medical Device

COCIR has prepared a draft 'decision tree' which was presented to SG1 by Peter Linders. This will be sent to the Steering Committee when it has been finalised.

Peter to send a copy of the slides to the Secretary for circulation to SG1.

Action: Secretary

Health Canada and MHRA have published guidance on the subject of medical devices and software.

16 Date and location of next meetings

- In London from Feb 7th to 10th 2011 at ABHI offices. Further information will be provided.

Action : Secretary

- In Beijing, China for the week of Monday 6th to Friday 10th June 2011 in the Financial District. The meeting will include a one day public workshop on the 10th. The situation regarding the cost of the meeting room and the format of the Workshop will be clarified. J&J will translate any PowerPoint presentations required for the Workshop if they are provided prior to the meeting.

Action – Lindsay Tao / Secretary

SUMMARY OF ACTIONS

For the Chair

- Once the contents of the Steering Committee's guidance becomes clear, to consider whether SG1 needs to modify its guidance on Labelling.
- Revision of SG1/N029:2005 Information Document Concerning the Definition of the Term 'Medical Device' - forward the document to the Steering Committee for endorsement as a Proposed Document for public comment.
- ISO 13485 - to suggest to the SG3 Chair that ISO 13485 definitions should be aligned with those of GHTF. Also that consideration should be given to updating ISOTR16142.
- Steering Committee paper on ISO 13485 - to provide feedback that SG1 does not support the extension of the scope of the standard as implied in the draft document from an ad-hoc committee of the Steering Committee and felt that any suggestion for significant revision should be left to SG3 and TC210.

For the Secretary

- To send the GHTF Secretariat an updated SG1 Work Plan, Meeting Dates and Meeting Reports for posting on the GHTF website before the next meeting.
- To update *Status of GHTF Study Group 1 Work Programme* (SG1/NO34) and SG1 Work Plan before the next meeting and reissue to members.
- To update the *Communications Database* as necessary and reissue to SG1.
- To circulate the presentations made during the meeting to SG1.
- Renumber the sections of the document GHTF/SG1(PD)/N068R4 *Essential Principles of Safety and Performance* as discussed during the meeting and, after a brief review by SG1, send to the Steering Committee for endorsement as a Proposed Document for public comment.
- To forward GHTF/SG1(PD)/N070 *Label and Instructions for Use for Medical Devices* (January 29, 2010) and the outstanding comments to the Chair for discussion by the IVD sub-group.
- To forward the revised version of GHTF/SG1/N029:2005 *Information Document Concerning the Definition of the Term 'Medical Device'* to the Chair prior to forwarding to the Steering Committee.
- To circulate information on the London meeting

For Chair / Vice-Chair / Secretary

- To draft a revised text for Section 5.0 of GHTF/SG1(WD)/N077R01 *Principles of Medical Devices Classification (revised)* before the next meeting.

For Nancy Shadeed, IVD Medical Devices Subgroup Chair

- GHTF/SG1(PD)/N070 *Label and Instructions for Use for Medical Devices (January 29, 2010)* - to discuss the public comments relating to IVD medical devices and edit the document where agreed.
- To draft a procedural document to clarify the future handling of SG1 documents that incorporate text for IVD medical devices.

For Benny Ons

- To raise with the Steering Committee the suggestion that the GHTF website should have a facility that allows interested parties to register and be informed automatically when new documents are posted on the website.

For SG1 Members

- To review the document that compares the STED and CSDT and send any comments to the Secretary.
- Peter Linders / Naoki Morooka - to prepare an 'evidence-based' justification for the 'down-classification' of some or all diagnostic X-ray devices, before the next meeting.