Summary of GHTF – Study Group 1 meeting held on 8th - 10th September at the premises of BSI – London

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The meeting was attended by 24 persons (members & observers) – 8 from each of Europe, North America and Japan/Australasia.

ITEMS DISCUSSED: -

1. Study Group 1 Work Programme
   The latest version – SG1/N034R15 was reviewed and suggestions for possible amendments were discussed.

2. Study Group 1 Documents
   Presented to the Steering Group asking for their publication on the GHTF Website. These are: -
   - SG1/N011R17 – "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices". This is presented for publication as a "Proposed Document".
     Comment – In its draft form as distributed for comment and use in a pilot study there has been considerable acceptance of this document, and SG1 would like this to be published as a "Proposed Document" for any other comments on the contents to be received so that a proposal for moving to a GHTF – "Final Document" stage can be soon achieved. *Note: - There are many trial users of the STED in its present form who have expressed the need for this to become finalised.*
   - SG1/N015/21 – "Principles of Medical Devices Classification" – offered for publication as a "Proposed Document".
     Note: - Comments on the status of this document have been addressed, by adding "Principles" to the title and by emphasising that the examples given of possible links between sample devices and individual rules, are for illustrative purposes only and emphasising that there may be other considerations which have to be considered. The table, however, was specifically identified as helpful when using this document.
   - SG1/N029R13 – Information Document Concerning the Definition of the Term "Medical Device" – Requested to be published as a Proposed Document – *Note: - Comments from Steering Committee members have been addressed.*

- SG1/N014R6 – "Essential Principles of Safety and Performance of Medical Devices (including In Vitro Diagnostic Devices)" – Request for this to be published as "Proposed Document" for comment. *Note: - Adds specific extra information for IVD's to the Final Document on "Essential Principles" already published.*
- SG1/N044R4 – "Role of Standards in the Assessment of Medical Devices (including In Vitro Diagnostic Devices)" – Requested to be published as an Proposed Document. *Note: - Addition of IVD – specific matters to existing "Final Document".*

3. A report was received from the SG1 sub-group on special IVD document features and documents under development. *Note: - includes an IVD draft document on "Principles of Classification for IVD's".*

4. Discussion on draft document "Labelling for Medical Devices (including IVD's) – SG1/N043R4
   Further changes were discussed to be incorporated in new version.

5. "Pre-market Conformity Assessment" – SG1/N040R8 – There was considerable discussion on this important document which is to be considered in conjunction with the "Principles of Classification for Medical Devices" document.
   Many changes were proposed to clarify the scope of this document and to remove reference to certain matters outside its scope and which are covered by other GHTF documents.
   An improved draft document is to be circulated.

6. Clinical Evidence – there was discussion on the need to establish a work item on "Harmonised Principles for the regulation of Clinical Investigations of Medical Devices" and another to "Establish a framework for the exchange of design evaluation reports amongst Regulator Authorities".
   These matters are referred to in the Steering Committee draft document on Common Data.
   The Steering Committees advice on this matter will be sought.

7. Consideration on the need for further information documents on a consolidated Compilation of Definitions was discussed – SG1 will ask if it should pursue the development of a document on "The Format and Content of Registration and Listing Information for Medical Devices" as proposed by members.

8. S.T.E.D discussion – Details of specific experiences of the pilot study using the Summary Technical Documentation and suggestions for exchanging such experiences were made.

9. Preparation for the forthcoming Steering Committee meeting in San Francisco – November 5th-7th - included agreement in the SG1 to propose to the Steering Committee a simple 3 category approach to the identification of GHTF documents -
   This is: –
   Category A – Information Documents (or status Documents)
   Category B – Guidance Documents (intended to encourage convergence)
   Category C – Documents for Adoption by GHTF members
   It was agreed that present SG1 documents only fall into categories A&B (mainly B).

10. SG1 Chair reported on progress with the Global Medical Device Nomenclature (GMDN) – *Note: - EU regulatory bodies have agreed to use this for data-exchange purposes in the Community*
   - *Japan has now translated GMDN into Japanese language*
   - *The FDA is mapping its nomenclature to GMDN*
   - *A new database is being developed to improve development and distribution of GMDN on a worldwide basis.*

11. An invitation was received to hold the next SG1 meeting in Australia in February 2004.

M.F FREEMAN – CHAIR SG1