Summary of SG2 Meeting

SG2 met in Stuttgart, Germany from 19-21 April 1999. Seventeen members from industry and regulatory agencies met under the leadership of Chair Larry Kessler. Dr. Kessler identified the following meeting goals:

- review work products to date
- develop SG2 workplan
- develop timelines and responsible persons
- finalize manufacturer's reporting guidance document
- determine in which documents to clarify various SG2-specific definitions
- hear updates from liaisons to other international efforts
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During the proceedings the manufacturer's reporting guidance document, known as SG2 N21R7, was discussed at length, with significant changes occurring in section 2.6 "Expected and Foreseeable Adverse Events". This section is now dedicated to "side effects". Other editorial changes were suggested, and it was decided that the annex should be deleted and the examples placed within the text of the guidance document within the sections where the rationale is explained.

It was also noted that each participating NCA anticipates the need to make changes to current regulations or laws in order to come into complete compliance with the recommendations of this document. The Chair also made note that many of the changes suggested throughout the meeting and made to the guidance document actually brought the harmonization document into closer alignment with current FDA requirements, though this was done by non-FDA participants.

Also presented were SG2 N20R6: Vigilance Report Criteria and Processes, SG2 N9R4: NCA to NCA Vigilance Report Form and Instructions. These documents assure that NCAs have a consistent process for exchange of vigilance reports and can more readily establish and maintain an effective alert system for the exchange of significant medical device adverse events.

Several new guidance documents were proposed. SG2 N30: List of Nationally Known and Well Characterized Medical Device-Related Adverse Events, SG2 N31 Reporting of Use Errors of Medical Devices, SG2 N32: Universal Manufacturer's Adverse Event Report Format, and SG2 N33: Medical Device Adverse Event Reporting Timeframes. Each of these new documents is intended to provide clarity to postmarket medical device adverse event reporting considerations and requirements.

It is hoped that GHTF will endorse several of the SG2 documents that have been ready for global distribution. These include SG2 N6R2: Comparison of Regulatory Requirements, SG2 N7R4: Manufacturer's Minimum Dataset for Reporting to the NCA, and SG2 N8R4: How to Handle Vigilance Nationally. These documents, together with final revisions to SG2 N9, SG2 N12, SG2 N20 and SG N21 represent a major and significant effort for SG2 and the harmonization process.

SG2 next meetings are scheduled for June, 1999, in the USA and again in the Fall tentatively also planned for the USA. More definitive planning will occur after the June GHTF meeting, when Canada assumes the Chair position, and sets dates for the next plenary meetings.