



Global Harmonization Task Force

**GHTF Retrospective Assessment
Key Findings and Recommendations
January 11, 2008**

**Presented to the
GHTF Steering Committee
by the
GHTF Retrospective Assessment Study Team**

In Acknowledgement

For his dedicated leadership since the inception of the GHTF and for his diligence making possible this forward-looking evaluation of the GHTF, the Retrospective Assessment Study Team gratefully acknowledges Robert Eccleston.

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Executive Summary

The Global Harmonization Task Force (GHTF) was formed 15 years ago to promote worldwide harmonization of medical device regulatory practices. Membership in the voluntary partnership was initially limited to regulatory officials and industry representatives from the five Founding Member jurisdictions—Australia, Canada, the European Union/European Free Trade Association (EU/EFTA), Japan, and the United States (US). The GHTF has since expanded to include participating members from non-Founding Member jurisdictions—including countries developing regulatory systems—and representatives from other entities sharing similar goals.

Work to develop and promote a GHTF medical device regulatory model built on interlinking guidance documents is accomplished through five Study Groups and various Ad Hoc Working Groups under the oversight of the GHTF Steering Committee. GHTF efforts are focused in four priority areas: guidance to ensure the quality and safety of medical devices, international trade, technological innovation, and exchange of information. International conferences and training are among principal GHTF activities.

To assess the activities and accomplishments of the GHTF, Dr. Larry Kessler, 2007–2008 GHTF Chair, invited a Study Team composed of government and industry leaders formerly involved with the GHTF to conduct a qualitative *Retrospective Assessment* of the organization’s activities over the past 15 years. The Study Team worked during several months to develop a 14-question survey and interview representatives from government and industry familiar with the GHTF and/or having expertise in the medical device field. Survey questions were intended to gauge GHTF success in the four areas of priority focus and to inform Study Team recommendations to the GHTF Steering Committee on future direction of the organization. The Study Team analyzed responses from 59 interviewees to discern the 6 key findings presented in this report.

The first three key findings identified by the Study Team reflect interviewees’ consensus on the GHTF’s most successful achievements: developing guidance documents, providing a forum for information exchange and dialogue, and extending training, especially for jurisdictions developing regulatory systems.

The fourth and fifth key findings identified by the Study Team point to factors that limit the impact of the organization: perception that Founding Member jurisdictions are slow to adopt GHTF guidance and limited awareness of the GHTF beyond regulators and technical experts.

The final key finding emerging from the *Retrospective Assessment Survey* is evident desire for GHTF leadership on policy related to medical device regulation, especially on issues arising from emerging technologies.

Accompanying key findings, Study Team recommendations to the Steering Committee range from suggestions to continue, improve, and expand current work to actions to enlarge membership and lead on regulatory policy. In addition to recommendations

linked to the six key findings, the Study Team offers additional overarching recommendations to ensure consistent funding, improve operational efficiency, expand collaboration with key partners, and bolster internal and external communication. All recommendations to the Steering Committee are intended to further the mission of the GHTF and position the organization at the forefront of efforts to forge a single global model for regulation of medical devices.

The Study Team acknowledges the contributions of the 59 interviewees who generously shared their insights on the important work of the GHTF. The Study Team welcomes dialogue with the Steering Committee on how to best use this report to direct the GHTF moving forward.

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GHTF Background

In September 1992, senior regulatory officials and industry representatives from Canada, the European Union/European Free Trade Association, Japan, and the United States met to discuss forming a voluntary partnership to meet the growing need for global harmonization of medical device regulatory practices. The impetus for the proposed government-industry partnership was harmonization of regulatory controls and processes in major device-producing nations that had encumbered global action to avert or correct product safety problems or restricted international trade. The inaugural meeting of the Global Harmonization Task Force (GHTF) was subsequently held in January 1993. Australia joined the organization as an additional Founding Member in 1993.

The GHTF works through consensus to converge regulatory requirements and practices to achieve four overarching goals: promote the safety, effectiveness, performance, and quality of medical devices; encourage technological innovation; foster international trade; and serve as an information exchange forum.

In addition to the five Founding Members, GHTF members include Participating Members from non-Founding Member countries and Liaison Bodies. Liaison Bodies include public health organizations, international standard setting bodies, and other groups who can contribute or benefit from participation in GHTF. Chairmanship of the GHTF rotates between the national regulatory authorities of the three geographic areas: North America, Europe, and Asia-Pacific.

A first priority for the fledgling organization was to establish three Study Groups to examine discrete aspects of medical device regulation in Founding Member jurisdictions. As the GHTF evolved, two more Study Groups were created. Study Groups include a balance of members from government and industry and across geographical areas. Currently, the development of a GHTF regulatory model is accomplished through the work of five Study Groups.

- Study Group 1 compares operational medical device regulatory systems around the world, identifying elements/principles both compatible and antagonistic to harmonization. Study Group 1 is also responsible for developing a standardized format for pre-market submissions and harmonized product labeling requirements.
- Study Group 2 reviews the current adverse incident reporting and post-marketing surveillance requirements of developed regulatory systems with a view to harmonizing data collection and reporting systems.
- Study Group 3 examines existing quality system requirements in countries with developed regulatory systems to identify areas suitable for harmonization.
- Study Group 4 reviews quality system auditing practices and develops guidance documents establishing harmonized principles for the medical device auditing process.

- Study Group 5 works to promote convergence of regulatory requirements for evidence of the clinical safety and performance of medical devices.

Since its inception 15 years ago, the GHTF has produced 27 guidance documents. Many of the documents have been integrated into national medical device systems and everyday regulatory practice.

In 1998, the Chair's Advisory Group (CAG) was established to provide strategic direction to those involved in GHTF activities. The CAG also initiated work on a set of basic operational principles and an organizational structure for the GHTF. This work was continued by the Ad Hoc Procedures Group (AHPG), a group created to include industry members as well as regulators. At the 8th GHTF Conference in September 2000, the AHPG presented three procedural documents—*Guiding Principles, Roles and Responsibilities*, and *Operating Procedures*—which were accepted by all GHTF members. The GHTF Steering Committee was also established at the conference to replace the AHPG. The GHTF Steering Committee, composed of industry and government representatives from the Founding Member jurisdictions, provides policy and strategic direction, endorses guidance documents for publication on the GHTF website, and oversees the work of the GHTF.

The GHTF organizes a global conference approximately every 18 months to provide information on GHTF activities and initiatives and report progress toward goals. Training sessions and other sessions on topics of interest are also offered at the conferences. Additionally, the GHTF sponsors regional conferences to promote activities and offer training in specific geographic areas.

As a voluntary organization, the GHTF is not funded by a central levy or subscription. Member activity on behalf of the GHTF Secretariat, Steering Committee, and Study Groups is sponsored by the participants' employers—national medical device regulatory authorities and regulated industries.

Additional information on the GHTF is available on the GHTF website at www.ghtf.org.

GHTF Retrospective Assessment

In April 2007, the GHTF Steering Committee endorsed a plan (*Action Plan for 2007–2010: Path Forward for the GHTF*) proposed by the United States and Canadian delegations to the GHTF. The plan was intended as a roadmap to focus GHTF efforts in four areas: guidance implementation, organizational logistics, expansion, and new regulatory issues. The *Action Plan* also called for an objective assessment of GHTF activities and impacts over the past 15 years, including a forward-looking re-examination of the GHTF mission. Dr. Larry Kessler, U.S. Food and Drug Administration (FDA) and 2007–2008 GHTF Chair, and the Steering Committee invited a Study Team comprised of former GHTF leaders, and representatives from Founding Member countries, the Asian Harmonization Working Party (AHWP), and the Pan American Health Organization (PAHO) to conduct the retrospective assessment and propose recommendations for the future of the organization. Beth Pieterston served as Chair of the Study Team; other members included Robert Britain, Robert Eccleston, Horst Frankenberger, Alan Kent, Elizabeth Krell, Alfred Kwek, Shigetaka Miura, Nora Lucia Rodriguez, and Brian Vale.

The Study Team developed a 14-question survey (Appendix A) to interview representatives of government and industry concerning past achievements and future direction of the GHTF. Some interviewees were selected based on their experience with the GHTF. Other respondents, while having no direct experience participating in the GHTF, had past or current expertise in the medical device field. Prior to the interview, each interviewee received a letter outlining the purpose of the *Retrospective Assessment*, the GHTF *Guiding Principles* document, and the questionnaire. The Study Team conducted the interviews in-person and over the phone during the period August–October 2007.

The Study Team met in-person and via conference call over several months to develop this report based on responses to the survey from 59 respondents representing both government and industry and all geographical areas. In developing this report, the Study Team also considered other information such as the degree of implementation of GHTF guidance in Founding Member as well as non-Founding Member jurisdictions.

The Study Team did not attempt to quantify or measure any outcomes based on the information collected. Reported findings should not be considered a quantitative evaluation of GHTF activities. The survey findings did, however, assist the Study Team to qualitatively assess the past 15 years of GHTF activity, identify six key findings, and develop recommendations to the Steering Committee to enhance ongoing and future work of the GHTF.

The names of persons interviewed by the Study Team are listed in Appendix D; however, specific responses, comments, or recommendations are not attributed to any individual. Only Study Team members have been privy to all responses to questions and any other information provided during interviews; this information will be kept confidential.

Key Findings from the Retrospective Assessment Survey

The following key findings emerged from responses to the *Retrospective Assessment Survey*. (Detailed findings for each of the 14 questions follow this section.)

- I. GHTF guidance documents are widely regarded as invaluable sources of information on medical device design, manufacture, use, and regulatory practice.
- II. The GHTF's success as a practical forum for information exchange and dialogue on many issues pertaining to medical devices—both between regulators and between regulators and the regulated industry—is overwhelmingly viewed as a major achievement that should continue.
- III. GHTF sponsored training, which is regarded as especially beneficial for jurisdictions developing regulatory systems, is ranked among the GHTF's most successful achievements.
- IV. The impact of the GHTF is offset by the perception that Founding Member jurisdictions are slow to adopt GHTF guidance into their own existing regulations.
- V. Awareness of the GHTF is limited primarily to regulators and technical experts within the regulated industry due, in part, to the failure of the organization to promote its purpose and achievements more widely.
- VI. Regulators and the regulated industry look to GHTF for leadership on policy surrounding medical device regulation, particularly on issues pertaining to emerging technologies.

Study Team Recommendations to the GHTF Steering Committee

To enhance the work of the GHTF and ensure its continuing relevance, the Study Team has analyzed the key findings from the *Retrospective Assessment Survey* and formulated the recommendations that follow.

Finding I: *GHTF guidance documents are widely regarded as invaluable sources of information on medical device design, manufacture, use, and regulatory practice.*

In response to questions throughout the survey, interviewees repeatedly underscored the value of guidance documents. Guidance documents were most frequently cited as an example of how the GHTF has satisfied its first objective—*promote the safety, effectiveness, performance, and quality of medical devices*. Additionally, interviewees ranked development of guidance documents among the GHTF's top three achievements and as a way the GHTF has made a significant impact.

Looking to the future, interviewees called for continued development and implementation of guidance documents among the top three things they would most like to see the GHTF

accomplish in the next 15 years. Survey respondents identified gaps in guidance document development related to nanotechnology, biotechnology, and combination products.

The Study Team recommends the Steering Committee:

- Maintain development and dissemination of guidance documents on basic medical device regulatory practices as a major organizational objective.
- Continue to review and revise existing guidance documents to aid understanding and to address any editorial or technical shortcomings.
- Ensure all Steering Committee members are fully briefed by their representative on the relevant Study Group before a submitted guidance document is discussed. Avoid ‘wordsmithing’ documents presented for endorsement.
- Develop a mechanism to receive feedback from jurisdictions on rationale for local modification of GHTF guidance documents and use the information to inform Study Groups revising guidance documents.
- Compare guidance documents to ensure consistency. As part of this process, instruct Study Groups to poll regulators in non-Founding Member jurisdictions to identify problems encountered when using GHTF guidance documents.
- Commission new work items to address emerging technologies (e.g., medical devices incorporating nanotechnology) and difficult regulatory issues (e.g., reuse of single-use devices and reprocessing).

Finding II: *The GHTF’s success as a practical forum for information exchange and dialogue on many issues pertaining to medical devices—both between regulators and between regulators and the regulated industry—is overwhelmingly viewed as a major achievement that should continue.*

Interviewees affirmed the success of the GHTF as a forum for discussion and exchange of information and included this success among the organization’s top three achievements.

Respondents overwhelmingly judged the GHTF successful in providing regulators and industry with a forum for dialogue and exchange of information. Over four-fifths of interviewees judged GHTF contributions toward enhanced dialogue between industry and regulators as *satisfactory* or *significant*. Three-quarters indicated that the GHTF had satisfied its fourth objective—to *serve as an information exchange forum through which countries with medical device regulatory systems under development can benefit from the experience of those with established systems—to a satisfactory or significant degree.*

In addition to providing a forum for regulators and industry representatives, respondents lauded GHTF for fostering discussion between regulators and with representatives from partner organizations. GHTF dialogue with AHWP was frequently mentioned.

Among top priorities for the organization moving forward, interviewees recommended

broadening participation in GHTF to accelerate global harmonization of medical device regulatory practices. The Study Team notes that when the GHTF was founded 15 years ago, expertise on medical device regulation was limited to the Founding Member jurisdictions. This is changing. In recognition of this greater diversity of expertise, the GHTF Steering Committee now includes representatives from outside Founding Member jurisdictions (e.g., AHWP, the World Health Organization [WHO]) as non-voting participants rather than solely as observers. Last year AHWP representatives were invited to join Study Group 1 on equal status with representatives from Founding Member jurisdictions.

The Study Team recommends the Steering Committee:

- Expand membership on the Steering Committee, Study Groups, and Ad Hoc Working Groups to non-Founding Member jurisdictions with careful attention to maintaining balanced representation between regulators and the regulated industry.
- Broaden representation while maintaining groups to a manageable size and while searching for a continuity of participation to facilitate working efficiency.
- Modify the three GHTF procedural documents to account for expanded membership and any other changes to the organization and its practices.
- Encourage non-Founding Member Regulatory Authorities to form regional “working parties” along the same lines as the AHWP, with equal participation from industry representatives.

Finding III: *GHTF sponsored training, which is regarded as especially beneficial to jurisdictions developing regulatory systems, is judged to be among the GHTF’s most successful achievements.*

Interviewees ranked conferences and training among the GHTF’s top achievements. Nearly three-quarters indicated that GHTF international conferences do provide a global forum to address regulatory issues; a tenth recommended that training be the primary focus of conferences.

Interviewees cited international conferences as an example of a specific GHTF activity contributing to success in achieving the organization’s fourth objective—to *serve as an information exchange forum through which countries with medical device regulatory systems under development can benefit from the experience of those with established systems*. Over half of the respondents judged that countries/jurisdictions with developing or planned systems benefit most from the conferences. GHTF trainings offered in collaboration with AHWP, Asia-Pacific Economic Cooperation (APEC), FDA, PAHO, and Australian Therapeutic Goods Administration (TGA) were included among examples of efforts to further partnership between countries with established regulatory systems and those with developing systems.

To better communicate GHTF objectives and accomplishments, interviewees recommended that GHTF sponsored training be provided more frequently and more broadly. They included training, especially for countries developing regulatory systems,

among things they would like the GHTF to accomplish in the next 15 years.

The Study Team submits that although the GHTF has been at the forefront in providing training resources (e.g., expert instructors), the organization has never truly coordinated GHTF sponsored trainings. GHTF has also not received recognition for trainings commensurate with the organization's contributions.

The Study Team recommends the Steering Committee:

- Make the provision of training a major objective of the organization and implement training through a structured education program that describes the purpose of the guidance documents and the way in which they interlink to provide a global regulatory model for medical devices. Continue to offer training as an integral part of GHTF meetings and conferences.
- Coordinate and provide Steering Committee leadership for GHTF sponsored trainings and related activities.
- Make Departments of Commerce in member jurisdictions aware of the GHTF and urge them to promote GHTF trainings as part of their own activities. Explore other mechanisms to promote and provide formalized training.
- Commission the development of a “professional” training package. The training package should be structured to assure consistency across individual trainers and be available via computerized means to assist trainees with limited understanding of English.
- Explore opportunities to establish a financial mechanism to sustain training. Consider annual member contributions, in-kind assistance, and industry support.

The Study Team recognizes that continuity of funding is necessary to sustain training. Posting video recorded trainings on the GHTF website is a cost effective way to disseminate trainings. As participation in the GHTF expands, the challenge of delivering training in multiple languages will also have to be addressed.

Finding IV: *The impact of the GHTF is offset by the perception that Founding Member jurisdictions are slow to adopt GHTF guidance into their own existing regulations.*

Although over half of interviewees reported that some guidance documents had been adopted in their country or jurisdiction, nearly one-fourth reported that GHTF guidance had not been adopted by their country. (The remaining interviewees were uncertain about implementation status of guidance documents or did not respond to the question.)

In response to the first question of the survey, interviewees indicated that failure to implement guidance documents negatively impacted success in achieving GHTF objectives 1, 2, and 3—*promote safety, effectiveness, performance, and quality of medical devices; encourage technological innovation; and foster international trade.*

Respondents cited intractability of existing regulatory systems and lack of formal mechanism for adoption as major barriers to implementation.

Nearly half of the interviewees recommended that implementation of guidance documents be the primary focus of GHTF conferences. Interviewees also pointed to action to implement guidance documents as a top GHTF priority in the next 15 years. Many recommendations to enhance GHTF operations were intended to facilitate development, dissemination, and implementation of guidance documents.

The Study Team notes that the term “adoption” may not properly represent the extent of implementation of GHTF guidance. As demonstrated in the GHTF Steering Committee document, *Implementation Status of GHTF Guidance Documents May 2007* (Appendix C), implementation may encompass adoption as regulation or as guidance, whole or partial adoption, pending adoption, or adoption under consideration. Comments from several interviewees also suggest a need for a broader measure of implementation; several noted that guidance documents are often “adapted” rather than adopted exactly as written by the GHTF.

The Study Team recommends the Steering Committee:

- Reconsider use of the term adoption to gauge implementation of GHTF guidance. Modify language in GHTF procedural documents regarding adoption of guidance documents to include implementation beyond strict statutory adoption.
- Encourage all Founding Members to make a public statement in their own jurisdictions committing to implement GHTF guidance within their national medical device regulatory system and associated practices when the opportunity arises.
- Proactively promote implementation of GHTF guidance documents when jurisdictions periodically review and revise their own regulations.
- Report on progress with implementation of GHTF guidance at each Steering Committee meeting and present results on the GHTF website.

Finding V: *Awareness of the GHTF is limited primarily to regulators and technical experts within the regulated industry due, in part, to the failure of the organization to promote its purpose and achievements more widely.*

Interviewees attributed lackluster support for participation in GHTF to limited knowledge of the organization coupled with lack of conviction regarding benefits of involvement.

Although over half of interviewees judged the impact of GHTF dialogue on getting quality products to the market or on policy direction as *satisfactory* or *significant*, nearly one-third felt the impact was *minor*. (The remainder indicated that the GHTF had *no impact at all* or did not respond to the question.) Interviewees attributed the GHTF’s limited impact to lack of visibility and insufficient contact with regulators in countries developing regulatory systems, political and industry leaders, and small and medium sized manufacturers.

Interviewees pointed to internal and external communications as an important aspect of GHTF operations to improve in the future. The call to improve communications was echoed in recommendations to improve the work of the Study Groups.

Survey findings indicating limited GHTF impact due to lack of awareness, coupled with findings confirming the value of guidance documents, GHTF sponsored trainings, and the organization as a forum for dialogue, compel the Study Team to urge priority action to increase knowledge of the GHTF.

The Study Team recommends the Steering Committee:

- Develop a communication plan to market the GHTF using available tools such as conferences, trainings, and the website.
- Commission a new work item to develop a professionally written informational package for people outside the regulatory world describing the GHTF, its objectives and achievements, and how the organization contributes to safeguard public health.
- Distribute the informational package widely within government—both to representatives with a special interest in healthcare matters and to senior government officials developing healthcare policy—and to leaders of medical device companies, industry associations, and to groups representing patients.
- Improve and maintain the GHTF website to add value, enhance impact, and ensure transparency.
- Through the website, develop a data base of registered interested parties. Use the database to announce the publication of new draft or final GHTF documents (e.g., GHTF policy statements, invitations to comment on draft guidance documents).

Finding VI: *Regulators and the regulated industry look to GHTF for leadership on policy surrounding medical device regulation, particularly on issues pertaining to emerging technologies.*

Well over half of the interviewees agreed that to a *satisfactory* or *significant* degree the GHTF has successfully achieved the organization's first objective—to *promote the safety, effectiveness, performance, and quality of medical devices*. Three-quarters indicated that to a *satisfactory* or *significant* degree the information forum provided by the GHTF has successfully *helped countries developing regulatory systems to benefit from established systems* (objective four).

Respondents included GHTF efforts to promote harmonization—successful work to converge existing systems, to prevent the development of unnecessary regulations, and to assist states with nascent regulatory systems—among the organization's top achievements. They stressed repeatedly the importance of GHTF efforts to strengthen global cooperation on vigilance, notably through the National Competent Authority Report (NCAR) exchange program.

According to respondents, organizations representing both government and industry heartily endorse participation in the GHTF. To enhance and to influence the medical device industry were among reasons given for support.

Although a quarter of interviewees judged that the GHTF has *not at all* encouraged technological innovation, almost a third indicated that *emerging technology and proactive attention associated with regulatory challenges* should be a primary focus of GHTF conferences.

To better communicate GHTF objectives and accomplishments, survey respondents called for the GHTF to step up efforts to reach leaders in government able to influence policy on medical device regulation. Increasing efforts to promote global harmonization was among things respondents would like to see the GHTF address or accomplish in the next 15 years.

Findings from the *Retrospective Assessment Survey* indicate to the Study Team that despite many challenges—barriers preventing implementation of GHTF guidance, limited awareness of the GHTF, call to expand participation—the GHTF has influenced global medical device regulatory practices. With support from members and partner organizations, the Study Team believes the time is opportune for the GHTF to proactively influence decision making and further global harmonization by taking a more prominent stance on issues of critical importance to medical device regulation.

The Study Team recommends the Steering Committee:

- Issue GHTF policy statements on major issues concerning medical device regulatory practices, such as:
 - Use/evaluation of third parties where individual governments have approval/disapproval authority
 - Mutual acceptance of the results of pre-market reviews, product testing, and/or Quality Management System audits
 - Medical device related issues surrounding emerging technologies
 - Regulation of medical devices incorporating human tissue
- Publish a quarterly bulletin to promulgate GHTF policy statements and other newsworthy items (e.g., guidance documents, training opportunities).

Additional Overarching Recommendations to the Steering Committee

To augment the recommendations presented above, the Study Team offers the following additional recommendations addressing the overarching challenges of funding, operational efficiency, collaboration, and evaluation. Addressing these challenges will help the Steering Committee continue to improve and expand the important work of the GHTF.

Funding

The Study Team believes that lack of consistent, dedicated funding to support the work of the GHTF may have contributed to some of the shortcomings reported by interviewees including the following examples:

- limited recognition of the GHTF beyond regulators and the regulated industry
- inadequate communication
- less than comprehensive approach to training

These deficiencies could be addressed if funds were available for a permanent Secretariat to prepare an informational package for distribution to government and industry leaders, to maintain the website, and to develop professional training programs.

The Study Team recommends the Steering Committee:

- Examine potential sources of funding to support a permanent Secretariat.

Operational Efficiency

The Study Team submits that basic Study Group-related operational improvements will result in a more transparent, more efficient organization.

The Study Team recommends the Steering Committee:

- Stress upon industry Study Group members that they represent their industry as a whole, not solely their company. Reiterate that it is important for Study Group members to communicate with their industry partners before and after meetings to ensure industry input is representative of opinions for a wide range of companies.
- Post comments received during the public consultation phase for proposed documents and the outcome of Study Group discussions of comments on the GHTF website.
- Ensure Study Groups post all meeting reports on the GHTF website in a timely fashion.

Collaboration

Progress toward the ultimate goal of a single global medical device regulatory system is only possible in collaboration with a broad array of partners. Throughout the *Retrospective Assessment Survey*, interviewees cited important work the GHTF has accomplished in partnership with organizations as varied as AHWP, APEC, and the International Organization for Standardization (ISO). Looking forward, the Study Team envisages that the GHTF will need to increasingly work with both familiar and new partners to tackle challenges, including challenges associated with emerging technologies.

The Study Team recommends the Steering Committee:

- Develop a strategic plan for working with present and future potential partners to increase collaboration. The plan could include the activities of mutual interest of

present partners, meeting dates and venues, and important goals. The plan could also include a list of potential partners with assignments for contact.

- Expand collaborative work with partners to increase international certifications of third party Quality System assessors, especially in countries developing regulatory systems.

Evaluation

Nearly four-fifths of interviewees indicated that the GHTF should develop a more formal evaluation process. The Study Team concurs with this survey finding, proposing that formal evaluation and subsequent planning will not only inform GHTF efforts going forward but will ensure continuity of mission as the chairmanship of the organization rotates.

The Study Team recommends the Steering Committee:

- Develop a formal evaluation process to monitor GHTF progress over the short and long term.
- Conceive a midterm strategy for the GHTF based on evaluation results and consideration of the *Action Plan for 2007-2010: Path Forward for the Global Harmonization Task Force* offered by the Canadian and United States delegations to the GHTF.
- Develop and make public an annual plan for the Steering Committee including concrete deliverables.

Survey Results: Questions 1–14

Following is a summary of responses to the 14-question survey. Questions 1–7 focused on GHTF accomplishments to date; questions 8–14 focused on recommendations for the future.

Assessing Accomplishments

Question 1: In your opinion, to what degree has the GHTF achieved the objectives laid out in the GHTF *Guiding Principles* document?

For each of the four objectives, survey respondents were asked to assess if the objective was achieved to a *significant degree*, to a *satisfactory degree*, to *some degree*, or *not at all* and to provide concrete examples.

Objective 1: Promote the safety, effectiveness, performance, and quality of medical devices

- 34% of respondents qualified success in achieving objective one *to some degree*; 34% *to satisfactory degree*; and 31% *to significant degree*. None of the respondents replied *not at all* in response to this question.
- Guidance documents were the most commonly offered example of GHTF efforts to achieve objective one. Specific guidance documents mentioned included *Essential Principles of Safety and Performance of Medical Devices*, *Principles of Medical Devices Classification*, *Summary Technical Documentation (STED)*, and *Quality Management Systems - Process Validation Guidance*. One respondent noted that documents “provided a solid background for education and training programs for both regulators and industry; helped the technical staff of regulatory authorities in developing countries to get attention from political decision-makers.”
- Respondents cited GHTF influence on medical device regulations as evidence of success in achieving this first objective. However, one respondent qualified this assessment, stating, “The impact is difficult to assess without clear measurement criteria being established. There are many other factors which impact the promotion of these ideals and isolating one to GHTF initiatives alone is difficult.”
- Respondents offered NCAR as an exemplar of success in achieving the first objective.
- The following are additional examples provided to demonstrate achievement toward GHTF’s first objective: number of participating countries and Association of South East Asian Nations (ASEAN) interest; cooperation between regulators, Conformity Assessment Bodies (CABs), and industry; the Quality Management System standard, audits, vigilance reports, and device recalls.
- Respondents credited less than complete success achieving objective one to a failure to implement guidance documents. “These documents,” commented a respondent, “have not been directly implemented to any significant degree by the regulatory jurisdictions represented amongst GHTF members. Full implementation is imperative.”

- Questioning the validity of the first objective, one respondent commented, “In my mind, promotion of safety, quality, performance, and effectiveness of medical devices is not achievable by an organization that does not have any actual authority in any territory. It seems a more realistic goal is the promotion of harmonized regulatory approaches that result in a consistent approach by health authorities in insuring devices are safe and effective, meet their performance criteria, and are manufactured in a controlled way.”

Objective 2: Encourage technological innovation

- 51% of respondents judged that the GHTF encouraged technological innovation *to some degree* and 19% *to satisfactory degree*. Only 2% of the respondents felt that GHTF had encouraged technological innovation *to significant degree*, in contrast, 24% of the respondents judged that the GHTF had fostered innovation *not at all*.
- Respondent comments reflected a variety of opinions as to how the GHTF fosters technological innovation: as a coalition of industry and regulators sympathetic to the different nature of devices, by promoting standards such as the *Essential Principles of Safety and Performance of Medical Devices*, by providing a forum for discussion of combination products and emerging technologies, and by reducing barriers through exchange of information.
- Several respondents commented that although the GHTF is not the main driver of technological innovation, the organization has had an impact by creating a favorable regulatory environment for innovation (and international trade). A respondent pointed out that “manufacturers have deemed GHTF inspired regulations more predictable and have felt more confident to take risks with research and development.”
- Two respondents offered comments explaining why the GHTF does not play a role in fostering technological innovation: because this is an objective well beyond the purview of an organization with no regulatory authority and because regulatory authorities have failed to fully implement guidance documents, which would spur innovation by reducing barriers.

Objective 3: Foster international trade

- 46% of respondents judged that the GHTF fostered international trade *to some degree* and 41% *to satisfactory degree*. Only 8% felt that GHTF had fostered international trade *to significant degree*, while 5% of the respondents indicated that the GHTF had fostered international trade *not at all*.
- Through guidance documents was most commonly cited as the way GHTF fosters international trade. *Essential Principles of Safety and Performance of Medical Devices* was the guidance document noted most often. Respondents also credited acceptance and adoption of principles, elements, etc. with a role in promoting international trade.
- GHTF efforts to build trust among regulatory bodies and to influence countries developing regulatory systems are additional examples provided on how the organization has positively impacted international trade. Respondents noted integrating industry input into harmonized requirements and Mutual Recognition Agreements (MRAs) as an indication of success in support of this objective. One

respondent credited the GHTF with increasing awareness that the medical device industry is indeed regulated and with influencing foreign governments' greater involvement in medical device-related international trade issues.

- A comment by one respondent reflects concern for lack of implementation, "Given the relatively low take-up of GHTF-inspired regulatory programs by many countries, it is difficult to measure or gauge any increase in international trade due solely to GHTF programs. However, the GHTF has at least raised the awareness of the need to foster international trade."

Objective 4: Serve as an information exchange forum through which countries with medical device regulatory systems under development can benefit from the experience of those with established systems

- 24% of respondents judged that the GHTF had achieved the organization's fourth objective to *some degree*; 29% to *satisfactory degree*; and 47% to *significant degree*. None of the respondents judged that the GHTF had benefited countries with medical device regulatory systems under development *not at all*.
- Collaboration with AHWP was offered most frequently as an example of GHTF efforts to support countries with emerging regulatory systems through information exchange. "The advances represented by the addition of AHWP to the GHTF 'mix' and the interest expressed by other jurisdictions developing regulatory systems is very encouraging," commented one respondent.
- Respondents also cited activities with APEC, ASEAN countries, Pacific Asia Conference on Mechanical Engineering (PACME), PAHO, and WHO.
- Examples offered of specific activities of benefit included GHTF conferences, revised Pharmaceutical Affairs Law (PAL), countries adopting common data, work among regulatory authorities concerning adverse events, vigilance guidelines, and NCAR.
- Respondents cited GHTF influence on the following countries: Australia, Canada, China, and Taiwan.
- Although one respondent noted that success meeting the fourth objective was GHTF's most significant achievement, he added, "Disappointing these countries not more directly included in GHTF processes which could result in better exchange of information, knowledge and experiences." Similarly, another respondent commented, "Opportunity not being fully developed. Developing countries should be encouraged to attend Steering Committee meetings and Study Group sessions to learn from dialogue/exchange of information so their developing systems benefit from the experience of others with mature systems. There appears to be some reluctance to embrace those with developing systems to attend and engage in the dialogue. Such involvement would require 'open and closed' sessions at the Steering Committee meetings and could raise potential financial issues for less fortunate countries. Information is not 'pushed' to these countries, but rather a passive approach is taken leaving the developing countries to seek out the GHTF information."

Question 2: As a follow-up to my question concerning Objective 4, I would also like to ask about the international conferences GHTF sponsors every year or so.

Respondents were asked to respond to four related questions, a, b, c, and d.

Question 2a: Have the conferences helped to effectively further the aims of the GHTF to provide a global forum to address regulatory challenges?

- The majority of respondents, 73%, affirmed that, *Yes*, the conferences were effective in furthering GHTF aims; 24% were *not sure*; 3% had *no opinion*. None of the respondents judged that, *No*, the conferences were not effective in furthering GHTF aims.

Question 2b: In terms of who benefits more from these conferences, would you say Founding Members or countries or jurisdictions with developing medical device regulatory systems?

- 53% of the interviewees felt that the *countries/jurisdictions with developing or planned systems* benefited more from the conferences; 20% judged the conferences most beneficial to *Founding Members*; 19% responded *not sure*; and 8% had *no comment*.

Question 2c: In your view, do the benefits outweigh the costs of these conferences and should they be continued?

- The majority of respondents, 64%, affirmed that, *Yes*, the benefits of the conferences outweigh the costs and the conferences should continue; 25% were *not sure*; 7% had *no opinion*; only 3% responded *No*.

Question 2d: Assuming the GHTF continues its sponsorship of annual conferences, should their primary focus be on: implementation of guidance documents it produces, emerging technologies and proactive attention to associated regulatory challenges, training, other.

- Many interviewees offered more than one response to this question: 44% thought *implementation of guidance documents produced* should be the primary focus of annual conferences; 31% indicated *emerging technology and proactive attention associated with regulatory challenges*; and 10% selected *training* as priority focus for GHTF conferences. (14% of the respondents did not reply to this question.)

Question 3: In your opinion, what are the top three achievements of the GHTF to date, and by this I mean activities, outputs, or outcomes?

- Survey respondents clearly view development of guidance documents among GHTF's top achievements. *Essential Principles of Safety and Performance of Medical Devices*, *Principles of Medical Devices Classification*, and *STED* were documents most often mentioned. Some respondents also noted implementation of guidance in Founding Member countries and use by countries developing regulatory systems. Said one respondent, "GHTF is a global living network for regulators, CABs, and industry. GHTF guidance documents indicate a harmonized state of the art in regulatory affairs."
- Providing a forum for dialogue and exchange of information is equally regarded as a top GHTF achievement. Respondents noted that due to GHTF, Founding Member countries, countries developing regulatory systems, and industry benefit from greater

mutual understanding and trust, and closer cooperation. One respondent described this achievement as “promoting and creating a harmonized, collegial environment that includes industry input and recognizes their interests and needs.”

- Many considered developing and promoting a global regulatory model a top GHTF achievement. Respondents noted that the GHTF has worked successfully to converge existing systems, to prevent the development of unnecessary regulations, and to assist countries developing regulatory system. Specific examples of harmonization included quality management systems, auditing, and vigilance.
- Respondents also cited annual conferences and training, especially for countries developing regulatory systems, as noteworthy GHTF achievements.
- GHTF work with collaborative partners (e.g., AHWP, the International Electrotechnical Commission [IEC], ISO, PAHO) was also offered as an important GHTF achievement.

Question 4: The guidance documents produced by the Study Groups are significant outputs of the GHTF. Are you aware if the regulatory authority in your country or jurisdiction has actually adopted any GHTF guidance documents as opposed to committing to do so?

- Over half of respondents (58%) responded that, *Yes*, guidance documents were adopted; 22% said, *No*, they were not adopted; and 12% reported *don't know* if adopted or not. (8% of respondents did not reply to this question.)

Question four was followed by three follow-up questions.

Question 4a: If so, which ones?

- *Essential Principles of Safety and Performance of Medical Devices* was the guidance document cited most often, followed by *Principles of Medical Device Classification* and *Principles of Conformity Assessment for Medical Devices*.
- Several respondents noted that guidance documents are often not adopted exactly as written but that elements from the documents are incorporated or guide development of country/jurisdiction specific regulations. A comment from one respondent: “There is no formal ‘adoption’ of GHTF guidance documents. Only mandatory regulations can be legally adopted according to our law. However, GHTF documents have been taken into account when drafting our current regulations and their concepts and principles have been incorporated in our regulations, whenever suitable. Some documents are not meant to be enacted as a mandatory regulation, but are routinely used in our staff training programs, and are used as the cardinal reference for regulations interpretation and application.”
- One respondent pointed out that the footer on GHTF documents states that countries have no obligation to implement guidance. The respondent commented, “This dilutes the objectives of GHTF and the urgency of regulators to make changes.”
- Another respondent reported, “Many of the GHTF documents already align closely with existing legislation (e.g., *Essential Principles of Safety and Performance of Medical Devices*, *Principles of Medical Device Classification*, *Role of Standards in the Assessment of Medical Devices*).”

- The comment—“GHTF should give priority to assessing implementation.”—may be representative of 12% of respondents who are unaware if guidance documents have been adopted or not adopted in their jurisdiction.

Question 4b: If not, do you know why they have not been adopted, or why a particular guidance has not been adopted?

- In responding to this question, interviewees overwhelmingly referred to the constraint of current regulatory systems. A typical response: “This is a real problem for the GHTF. Unless the government authorities can go back to the legislators in their countries and get their laws changed, many of the GHTF documents will not be adopted.” Another respondent noted, “Particular guidance documents are difficult for regulators and industry to apply or adopt, especially in developing countries.”
- Guidance on medical device classification, quality systems, and definition of a medical device manufacturer were offered as specific examples of documents conflicting with existing laws.
- Several respondents commented on the lack of “a defined mechanism for formal adoption” of guidance documents. One respondent noted, “The internal GHTF network is well designed (closed shop), the link to an external network to governments seems to be missing in Europe.”
- Respondents also reported that although documents may not be adopted fully, principles are considered best practice and incorporated into statutes. Commented one respondent, “It would be good to find other ways to recognize guidance documents as a good way to do business and not worry about adopting them as regulations.”
- Respondents also cited need for more communication and effort to implement documents.

Question 5: One of the objectives of the GHTF, as stated in Question 1, is to foster cooperation between countries with established regulatory systems and those with developing regulatory systems. Do you have any concrete examples of such cooperation (e.g., training by Canada or US FDA, APEC training programs)?

- Collaborations with APEC and AHWP on training for Asian and Latin American countries were the most commonly provided examples of cooperation.
- Other examples included PAHO seminars for Latin American countries, TGA training for ASEAN regulators, the pilot inspection program underway between Canada and the United States, in-region training provided by FDA, an experiment with clinical trials between Japan and the United States, and NCAR training planned for Latin American and Asia.
- One respondent commented, “No, and this is a challenge. India is an example of where GHTF could, and should, have been able to extend into a gap, and was less than successful.”

Question 6a: What was your organization’s response or reaction to your participation in GHTF and why?

- Respondents overwhelmingly reported a positive response to participation in GHTF: “very supportive, major supporter, very positive, no obstacle for participation, full

support, supported positively, no problem, excellent, very enthusiastic, positive reaction, no difficulties with support, very interested, generally positive, willing to fund, and once understood is approved.”

- The many reasons given for organizations’ support of participation included: to have input and influence process; to gain and exchange information and develop contacts; to enhance medical device industry (e.g., development, marketing, and inspection); to save duplicate work; to further develop post-market surveillance; and to have global perspective.
- Several respondents whose organizations had mixed reaction to participation in GHTF noted financial burden of membership, limited knowledge of GHTF, and questionable benefit of participation.
- Despite initial reservations, two respondents noted increasing support for GHTF. One commented, “Discussion of new technologies such as combination products and medical device software will stimulate the industry.”

Question 6b: Do you have any suggestions how the GHTF could better communicate its objectives and accomplishments?

Respondents offered numerous recommendations broadly encompassing the following areas.

- Improve and update the GHTF website to improve currency and transparency. Make the website interactive to improve communication. Link the GHTF website to related sites.
- Through conferences and training—more frequent, with broader participation, and conducted regionally in countries with emerging regulatory systems. Have a presence (e.g., a booth) at major regulatory/standards conferences.
- Enhance communication with governments. Consider using a roving ambassador and make contact with government officials beyond technical staff. Communicate benefits (e.g., via official government publication).
- Engage and communicate with industry—business leaders not just technical experts. Communicate with industry media/trade press, perhaps through quarterly e-newsletter. Send thank-you letters to industry supporters of GHTF.
- Employ the “multiplier effect” of working with other organizations to disseminate information. Create new working parties and more liaison bodies. Appoint a contact person to attend all AHWP meetings.
- Communicate information in plain language understandable to non-regulators (e.g., politicians, CEOs). Translate guidance documents into languages of target regions/countries.
- Develop a midterm strategy/plan with identifiable deliverables that includes conferences and training, work with other continents, and communications.
- Direct efforts to educate lawmakers on the benefits of harmonization and develop guidance documents on consensus to implement. “The GHTF will not be taken seriously until the participating governments can actually adopt the principles being developed in its documents,” commented one respondent.

Question 7a: How would you rate the forum created by the GHTF in terms of its contribution toward enhanced dialogue between industry and regulators?

- 49% of survey respondents qualified GHTF contributions toward enhanced dialogue between industry and regulators as *significant*; 37% as *satisfactory*; and 12% as *minor*. None indicated that GHTF contributed *not at all*.

Question 7b: In your opinion, what impact if any would you say such a dialogue has had on achieving the goal of getting quality products to the market, or on policy direction, in your country?

- 24% of survey respondents judged the GHTF's impact as *significant*; 36% as *satisfactory*; and 31% as *minor*. 5% judged GHTF's impact as *not at all*.

Question 7c: If you believe GHTF has had a significant impact, in what ways has it had an effect?

- Several respondents commented on the positive role the GHTF has played in the development of regulatory systems, especially by establishing consensus standards through guidance documents. In the words of one respondent, "GHTF guidance documents have helped to some extent to provide "legitimacy" to local medical device regulations and made it significantly easier for us to enact stricter regulations and enforce them."
- Respondents noted GHTF's support and influence on non-member countries developing regulatory systems. One comment concluded, "...introducing products in our countries where requirements are based on documents of GHTF makes everybody's work easier."
- Respondents credited the GHTF for deepening mutual understanding and partnership between industry and regulators. Comments echoed the sentiments of this respondent: "[GHTF] allows the two parties, in a non-controversial and non-political forum, to raise issues, problems, and concerns which are often occurring in multiple jurisdictions."
- Two respondents attributed GHTF impact to global cooperation on vigilance.

Question 7d: If you believe GHTF has had little if any impact, can you offer any reasons as to why?

- Respondents indicated that GHTF impact is stymied by existing regulations that may be already similar to GHTF guidance documents or dominate and are difficult to change or are accorded priority commitment from Founding Member states.
- One respondent characterized the GHTF as "talking amongst the converted." Another urged the GHTF to "include AHWP or ACCSO representatives when composing guidelines and providing training." Others noted the GHTF's lack of confidence and limited visibility, and the need for greater promotion of harmonization and for increased contact with regulators in non-Founding Member countries, political and business leaders, and small and medium sized manufacturers.
- Respondents noted that both implementation of guidance documents is slow and that GHTF achievements are not measurable.

Question 7e: Have there been other effects of this government-industry partnership? Please explain.

- The majority of responses to this question echoed responses to question 7d, emphasizing the greater, clearer, and improved understanding between government and industry made possible by the GHTF. The following is representative of many comments: “The opportunity to discuss both regulator and industry requirements in an open forum would not necessarily occur otherwise at this same level.”
- Respondent comments indicated that GHTF has also influenced intra-industry relationships, local government/industry relationships, and collaboration with other organizations (e.g., WHO, ISO, Comité Européen de Normalisation [CEN], International Conference on Harmonisation [ICH]).

Question 7f: Do you believe the work of GHTF has affected or influenced the deliberations and outputs of other organizations involved in medical device standards and controls, such as ISO, IEC, WHO? Any examples?

- ISO was foremost among GHTF collaborative partners mentioned. GHTF Study Group/ISO Technical Committee outputs cited included ISO 13485, ISO 14155, ISO 14969, ISO 14971, ISO TR16142, and ISO 176. However, regarding ISO, one respondent commented, “There is an overlap of people involved with GHTF and ISO Technical Committee 210. The work plans are not yet sufficiently coordinated. This is where the next action has to be. The next level is to finish the process and turn to products.”
- Five respondents addressed GHTF collaboration with IEC. Three of the respondents noted a beneficial influence; however, two respondents credited GHTF with little influence on IEC.
- Comments regarding GHTF influence on WHO were mixed: no influence, possibility for influence, and demonstrable influence through information sharing and WHO guidance based on GHTF documents.
- Respondents also noted GHTF influence on AHWP, ICH, and PAHO.

Looking to the Future

Question 8: In your opinion are the goals and objectives for the GHTF as outlined in its May 2005 Guidance Document still valid?

- 83% of respondents responded, *yes*, goals and objectives are still valid; 14% indicated *no*. 2% *don't know*.
- Several respondents responded to this question with a qualified yes, pointing to the need for a “more *execution* style approach to implement (e.g., lobbying to governments, strong participation through ISO, IEC to move Guidelines towards Standards).” Other deficiencies noted included no GHTF roadmap; lack of strategies for participation of non-Founding Members and for marketing GHTF conferences, training seminars, and guidance documents; and no goals or objectives devoted to the ambition of technological innovation.

Question 8, If No: How would you change either the goals or the objectives to make them more relevant?

- Several respondents tied relevance of goals and objectives to implementation. They recommended clarifying the dissonance between regulatory systems and guidance documents, and developing guidance documents based on consensus to implement in Founding Member countries.
- Respondents recommended adopting more tangible, measurable goals and tackling more practical, urgent issues such as, “early access to new technologies, global acceptance of one pre-market application documents, multiple acceptances of audit results, and multiple acceptances of clinical trial data.”

Question 9a: What three things would you like to see the GHTF address or accomplish in the next 15 years?

- Based on responses, developing, updating, and finalizing (e.g., clinical evidence, combination products, in vitro diagnostic [IVD], software) guidance documents is a priority for respondents. In addition, respondents indicated a wish to see documents implemented in Founding Member countries and developing economies. Several urged GHTF to promote adoption of guidance documents without change or “deharmonization.” One respondent recommended the GHTF “establish and publish a world map indicating which GHTF documents have been adopted and where.” Another asked that the GHTF develop a “detailed guidance for regulators on how to implement the GHTF guidance.”
- Respondents urged the GHTF to increase efforts to realize true harmonization, including lobbying governments. A respondent comment: “Somehow the governments that participate must commit to changing their regulations where their laws allow or asking their legislators for changes in their laws to allow them to change their regulations.” Another respondent proposed an alternative path to convergence: “Some systems can/will never be harmonized—perhaps alignment is the best that can be achieved between the European Union, Japan, and the US. Identify those aspects that are both core to submissions and can be aligned; obtain commitment from the key regulators that, if alignment can be achieved, that the resultant harmonized process will be used in lieu of country-specific processes.”
- Respondents would like to see GHTF membership expand beyond Founding Members to include countries developing regulatory systems. A respondent noted, “Open Steering Committee and Study Groups to new members from outside the GHTF. This is essential to accelerate harmonization. The retention of a *closed club* is neither warranted nor helpful in moving harmonization forward.”
- Combination products and innovation/emerging technologies are also areas respondents would like the GHTF to address going forward.
- Respondents also recommended offering more regional training, especially for countries developing regulatory systems, and improving GHTF operations.

Question 9b: What do you see as the principle barriers to achieving these accomplishments?

- Nearly half of the survey respondents indicated that social and political constraints impede GHTF efforts to achieve desired goals. Constraints cited included national and industry interests, legal and political restrictions, language and cultural barriers, lack of influence and political will, “red tape,” and entrenched, parochial views.
- Many respondents noted resource constraints including inadequate human resources, financial support, and time. Respondents linked lack of resources to insufficient political commitment, reduced budgets for regulatory authorities (especially in developing countries), and lack of data demonstrating the benefits of harmonization. Time constraints included time required to participate in GHTF activities on top of day-to-day jobs, protracted process to finalize guidance documents, and the simple fact that “change is a time consuming process.”
- Additional barriers cited included differences in country-by-country regulatory systems, the gap between regulatory and market environments, and lack of sufficient, focused efforts.

Question 10: In your opinion, what are the three most important aspects of GHTF operations should improve on in the future?

- Respondents indicated that membership/participation should be expanded to non-Founding Member jurisdictions, “multiplier effect” organizations such as WHO, and industry representatives who work in Societies of Manufacturing Engineers (SMEs). Responses to this question included the terms *atmosphere of trust*, *inclusiveness*, and *transparency*. One respondent urged the GHTF to “provide more accessibility so that it appears less like a club.”
- Specific recommendations to improve GHTF operations included the following: establish a permanent Secretariat; set clear objectives, identify priorities, develop plans, and measure outcomes; and improve procedures for routine operations (e.g., for interaction between Steering Committee and Study Groups, feedback from stakeholders, conferences and training, document management). Several respondents offered suggestions to enhance functioning of the Study Groups: rotate membership, meet more via teleconference, define goals for each meeting, avoid scheduling meetings that conflict with Steering Committee meetings, and form new groups to address emerging issues.
- Respondents focused on finances—both the need to do business in more economical ways and the need to secure a reliable funding mechanism.
- Survey respondents recommended improved communications both within the GHTF and externally. Recommendations included greater use of the website, wider (and faster) diffusion of guidance documents, and routine reporting on progress toward harmonization. One respondent suggested a quarterly newsletter from the Steering Committee to communicate information within the GHTF.
- “Redirect strategies,” one respondent stressed, “because guidance documents are established, it’s about time to conduct intensive training so that the guidance documents can be implemented.”

Question 11a: Can you identify any gaps in guidance document development (i.e., areas the Study Groups should tackle in the future)?

- Nanotechnology, combination products, and software were the most common responses. A respondent recommended, “These items should be treated in guidance documents in the first step as supplements or annexes to main documents. In the second step: integration into the main document.”
- Development of common data set for clinical evaluation was offered as a gap to fill.
- Other suggestions for guidance documents included: distribution and traceability of devices; necessary qualification of users; competence requirements for regulatory assessors/auditors; medical device identification, coding, and registration; recalls; CAB activities; and Premarket Approval/Investigational Device Exemption (PMA/IDE).

Question 11b: Do you have any other suggestions related to the operation or work of the Study Groups?

- Several respondents offered suggestions to enhance the composition of Study Groups: continually refresh the groups; include Working Party members and representatives from non-Founding Member countries (e.g., Asian and Latin America); ensure members have expertise necessary to produce specialized guidance documents; involve CABs; and importantly, achieve this broader representation while keeping groups a manageable size. Respondents also indicated the need for clear, concrete directions from the Steering Committee and mechanism to report back. One respondent recommended, “Improved standard operating procedures should be developed for all Study Groups (e.g., ensure that agenda and documents are available in due time, that minutes are posted on website in good time). The Steering Committee should come to a clearer decision on whether Study Groups continue their work or enter *maintenance mode* (and what this maintenance mode means).” Another recommendation was for joint meetings and continued and better communication between Study Groups.
- To facilitate communication and make it possible to meet more frequently, respondents recommended greater use of teleconferences, Internet forums, blogs, etc.
- “Improve the communication to industry associations, CABs, and regulators,” commented one respondent, “to ensure that decisions are based on a broader basis—the global acceptance will be improved.”
- Survey respondents recommended needs-based training, including training on GHTF operational details.
- Comments included the following recommendations to enhance GHTF operations: adopt the project oriented approach used by Study Group 1 sub-groups; systematize communications on documents in discussion; define GHTF working area clearly and develop guidance documents systematically as does ICH; have more discussions (and agreement) on principles, less writing type exercises or training in MS Word; require more homework assignments for details and discussions on group outcomes; and consult existing standards or standards project to assure that GHTF does not duplicate work.

Question 12: Are you aware of other organizations or groups that might be interested in, or wish to collaborate with, the GHTF?

The many organizations indicated by respondents are listed below.

- AHWP
- APEC
- ASFAN
- EUnetHTA
- IAF
- ICH
- IEC
- ISO
- KGHC
- NBO Group
- PAHO
- RAPS
- South Africa
- WHO
- Countries with developing regulatory systems
- Organizations supporting work on free trade
- Scientific societies
- Universities of medicine, science, and technologies

One respondent reposed the question—“Which organizations could be GHTF multipliers in the future?”—and responded, “Politicians, political groups, parties promoting GHTF guidelines and the global regulatory model initiatives, and groups representing the patient.”

Other respondents suggested that non-Founding Member countries be accepted as GHTF members, not guests, and that medical community users be allowed to participate in Study Groups as nonvoting observers.

Question 13: Do you think the GHTF should develop a more formal evaluation process so that in 15 years from now, the organization is better able to assess its achievements?

- 78% of survey respondents responded, *Yes*, GHTF should develop a more formal evaluation process; 10% of survey respondents replied *No*; and 8% answered *don't know*. 3% did not respond to this question.

Question 14: Do you have any other comments you'd like to share?

Respondents offered many laudatory comments in recognition of GHTF achievements over the past 15 years. They characterized the purpose of the GHTF—to develop harmonized guidance through exchange of opinions and information—as a commendable and worthy goal. Interviewees also indicated a need for GHTF to continue and expand “in hope,” to quote one respondent, “that real convergence will be achieved 15 years later.”

Final comments also reflected themes emerging from responses to the 13 previous questions: development and implementation of GHTF guidance documents as a priority to further harmonization; the imperative to expand GHTF membership, especially to countries developing regulatory systems; and the need for new approaches to improve GHTF operations.

- Among comments addressing the need to press implementation of GHTF guidance was recommendation to develop a matrix indicating countries and their level of acceptance of guidance documents. Also suggested was replacing “harmonization” with the less formidable term “convergence” or perhaps using “convergence” in a tag line with the GHTF appellation. Another respondent commented, “When one expects some non-Founding Member countries to implement GHTF guidance, it seems necessary to allow and foster an active participation of them in GHTF activities, in particular in Working Groups.”
- Recommendations to promote global harmonization included: support single audits across jurisdictions, increase efforts to develop common specifications and procedures, and develop procedures to “recognize” international standards.
- Recommendations to improve GHTF operations included the following: review the Secretariat option; assess activities and achievements each time the GHTF Chair changes; provide training for members on the relationship between Study Groups and the Steering Committee; operate disciplined Study Groups with tasks clearly defined by the Steering Committee; use smaller groups for special issues (e.g., IVD devices); have documents available in Spanish; and make greatest possible use of the website.

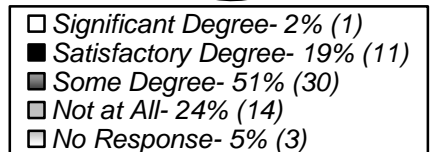
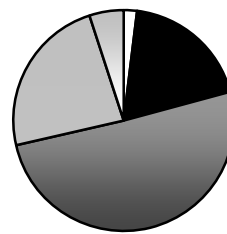
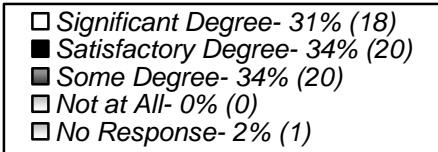
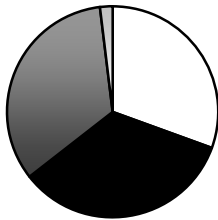
Responses to Multiple Choice Questions (Percentage/Number)

Responses to multiple choice questions are presented graphically below. Response choices may be abbreviated; the unabridged survey is included as Appendix A. Percentage totals may not equal 100% due to rounding.

Question 1: In your opinion, to what degree has the GHTF achieved the objectives laid out in the GHTF Guiding Principles document?

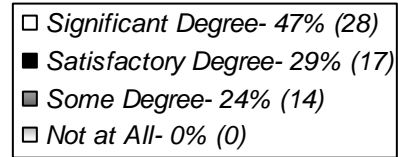
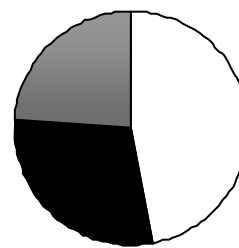
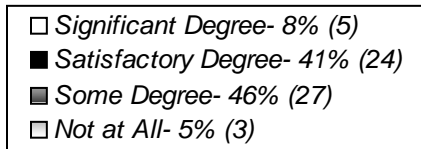
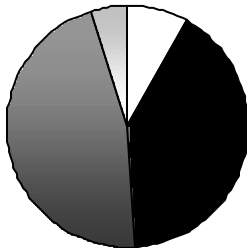
Objective 1: Promote the safety, performance, effectiveness, performance and quality of medical devices.

Objective 2: Encourage technological innovation.



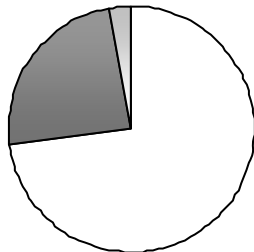
Objective 3: Foster international trade.

Objective 4: Serve as an information exchange forum.



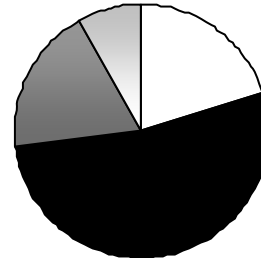
Question 2: As follow-on to my question concerning Objective 4, I would also like to ask about the international conferences GHTF sponsors every year or so.

Question 2a: Have the conferences helped to further the aims of GHTF?



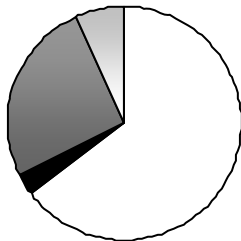
- Yes- 73% (43)
- No- 0% (0)
- Not Sure- 24% (14)
- No Opinion- 3% (2)

Question 2b: Who benefits most from the Conferences: Founding Members or Countries/Jurisdictions with developing or planned medical device regulatory systems?



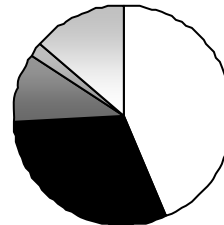
- Founding Members- 20% (12)
- Countries/Jurisdictions- 53% (31)
- Not Sure- 19% (11)
- No Comment- 8% (5)

Question 2c: Do the benefits outweigh the costs of these conferences and should they continue?



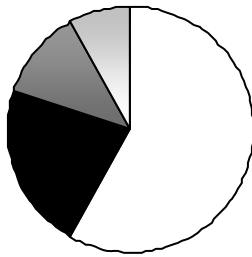
- Yes- 64% (38)
- No- 3% (2)
- Not Sure- 25% (15)
- No Opinion- 7% (4)

Question 2d: What should be the primary focus at future forums?



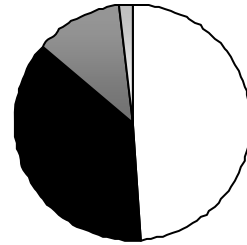
- Implement Guidance Docs- 44% (26)
- Emerging Technology- 31% (18)
- Training- 10% (6)
- Other- 2% (1)
- No Response- 14% (8)

Question 4: Has your country/jurisdiction adopted GHTF guidance documents?



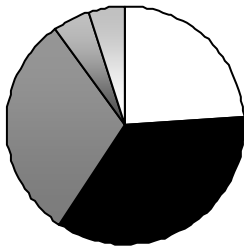
- Yes- 58% (34)
- No- 22% (13)
- ▒ Don't Know- 12% (7)
- No Response- 8% (5)

Question 7a: How would you rate the GHTF's impact as a forum for dialogue?



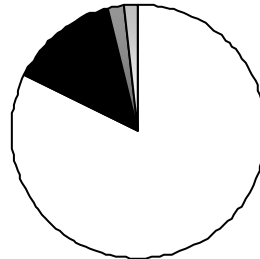
- Significant- 49% (29)
- Satisfactory- 37% (22)
- ▒ Minor- 12% (7)
- Not at All- 0% (0)
- No Response- 2% (1)

Question 7b: What impact has the GHTF had on getting products to the market or on policy?



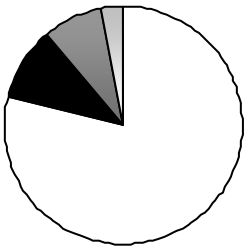
- Significant- 24% (14)
- Satisfactory- 36% (21)
- ▒ Minor- 31% (18)
- ▓ Not at All- 5% (3)
- No Response- 5% (3)

Question 8: Are the goals and objectives of the GHTF still valid?



- Yes- 83% (49)
- No- 14% (8)
- ▓ Don't Know- 2% (1)
- No Response- 2% (1)

Question 13: Should the GHTF develop a formal evaluation process?



- Yes- 78% (46)
- No- 10% (6)
- ▒ Don't Know- 8% (5)
- No Response- 3% (2)

Closing Remarks

The Study Team would like to acknowledge the 59 interviewees who contributed to the *GHTF Retrospective Assessment*. The assessment was only possible due to their willingness to share insights based on experience with the GHTF and/or in the field of medical devices. Each gave generously of their time and expertise to respond to the *Retrospective Assessment Survey*. The key findings and recommendations presented in this report reflect their collective wisdom, offered to benefit the GHTF as it looks to the future.

The Study Team would also like to thank the GHTF Steering Committee for the opportunity to undertake the *Retrospective Assessment*. As former members and supporters of the GHTF, the Study Team believes that responses to the *Retrospective Assessment Survey* provide the GHTF with invaluable information to help the organization increase in prominence as a global arbiter of medical device regulatory practices.

The Study Team invites the Steering Committee to include Study Team members in discussion as the Steering Committee considers the key findings and recommendations presented in this report.

Appendix A

Retrospective Assessment Survey

Retrospective Assessment Survey

Assessing Accomplishments

1. In your opinion, to what degree has the GHTF achieved the objectives laid out in the GHTF Guiding Principles document?

Objective 1: Promote the safety, effectiveness, performance and quality of medical devices.

- To a significant degree
- To a satisfactory degree
- To some degree*
- Not at all

Any concrete examples?

Objective 2: Encourage technological innovation.

- To a significant degree
- To a satisfactory degree
- To some degree
- Not at all*

Any concrete examples?

Objective 3: Foster international trade.

- To a significant degree
- To a satisfactory degree*
- To some degree
- Not at all

Any concrete examples?

Objective 4: Serve as an information exchange forum through which countries with medical device regulatory systems under development can benefit from the experience of those with established systems.

- To a significant degree*
- To a satisfactory degree
- To some degree
- Not at all

Any concrete examples?

2. As a follow-on to my question concerning *Objective 4*, I would also like to ask about the international conferences GHTF sponsors every year or so.

a) Have the conferences helped to effectively further the aims of the GHTF to provide a global forum to address regulatory challenges?

- Yes
- No
- Not sure
- No opinion

b) In terms of who benefits more from these conferences, would you say Founding Members or countries or jurisdictions with developing medical device regulatory systems?

- Founding Members
- Countries/jurisdictions with developing or planned systems
- Not sure

c) In your view, do the benefits outweigh the costs of these conferences and should they be continued?

- Yes
- No
- Not sure
- No opinion

d) Assuming the GHTF continues its sponsorship of annual conferences, should their primary focus be on:

- Implementation of guidance documents it produces
 - Emerging technology and proactive attention to associated regulatory challenges
 - Training
 - Other (specify):
-

3. In your opinion, what are the top three achievements of the GHTF to date, and by this I mean activities, outputs or outcomes?

4. The guidance documents produced by the Study Groups are significant outputs of the GHTF. Are you aware if the regulatory authority in your country or jurisdiction has actually adopted any GHTF guidance documents as opposed to committing to do so?

- a) If so, which ones?
 - b) If not, do you know why they have not been adopted, or why a particular guidance has not been adopted?
 - c) Don't know
-

5. One of the objectives of the GHTF, as stated in Question 1, is to foster cooperation between countries with established regulatory systems and those with developing regulatory systems. Do you have any concrete examples of such cooperation, e.g., training by Canada or US FDA, APEC training programs?

6.

- a) What was your organization's response or reaction to your participation in the GHTF and why?
 - b) Do you have any suggestions how the GHTF could better communicate its objectives and accomplishments?
-

7.

- a) How would you rate the forum created by the GHTF in terms of its contribution toward enhanced dialogue between industry and regulators?

- Significant
- Satisfactory
- Minor
- Not at all

- b) In your opinion, what impact if any would you say such a dialogue has had on achieving the goal of getting quality products to the market, or on policy direction, in your country?

- Significant
- Satisfactory
- Minor
- Not at all

- c) If you believe GHTF has had a significant impact, in what ways has it had an effect?

- d) If you feel GHTF has had little if any impact, can you offer any reasons as to why?

- e) Have there been other effects of this government-industry partnership?

Please explain:

- f) Do you believe the work of GHTF has affected or influenced the deliberations and outputs of other organizations involved in medical device standards and controls, such as ISO, IEC, WHO? Any examples?

Further point to be mentioned:

Looking to the Future

8. In your opinion, are the goals and objectives for the GHTF, as outlined in its May 2005 Guidance Document, still valid?

- _____ Yes
_____ If no, how would you change either the goals or the objectives to make them more relevant?
_____ Don't know
-

- 9.
- a) What three things you'd like to see the GHTF address or accomplish in the next 15 years?
- b) What do you see as the principal barriers to achieving these accomplishments?
-

10. In your opinion, what are the three most important aspects of GHTF operations should improve on in the future?
-

- 11.
- a) Can you identify any gaps in guidance document development, i.e., areas the Study Groups should tackle in the future?
- b) Do you have any other suggestions related to the operation or work of the Study Groups?
-

12. Are you aware of other organizations or groups that might be interested in, or wish to collaborate with, the GHTF?
-

13. Do you think the GHTF should develop a more formal evaluation process so that in 15 years from now, the organization is better able to assess its achievements?

- Yes
 - No
 - Don't know
-

14. Do you have any other comments you'd like to share?

Appendix B
Glossary of Acronyms

Glossary of Acronyms

AHPG	Ad Hoc Procedures Group (pre-dated GHTF Steering Group)
AHWP	Asian Harmonization Working Party
APEC	Asia-Pacific Economic Cooperation
ASEAN	Association of South East Asian Nations
CABs	Conformity Assessment Bodies
CAG	Chair's Advisory Group (pre-dated GHTF Steering Group)
CASCO	ISO Committee on Conformity Assessment
CEN	Comité Européen de Normalisation
EFTA	European Free Trade Association
EU	European Union
FDA	US Food and Drug Administration
GHTF	Global Harmonization Task Force
IAF	International Accreditation Forum
ICH	International Conference on Harmonisation
IVD	In vitro diagnostic
IDE	Investigative device exemption (term used in US legislation)
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
ISO TC	ISO Technical Committee
KGHC	Korean Medical Devices Global Harmonization Committee
MRA	Mutual Recognition Agreement
NBOG	EU Notified Body Operations Group
NCAR	National Competent Authority Report
PACME	Pacific Asia Conference on Mechanical Engineering
PAHO	Pan American Health Organization
PAL	Pharmaceutical Affairs Law
PMA	Premarket Approval Application (term used in US legislation)
RAPS	Regulatory Affairs Professionals Society
SME	Society of Manufacturing Engineers
STED	Summary Technical Documentation (topic for Study Group 1 guidance)
TGA	Therapeutic Goods Administration (Australia)
US	United States
WHO	World Health Organization

Appendix C

Implementation Status of GHTF Guidance Documents May 2007

Australia, Canada, European Union, Japan, and the United States

Appendix C: Implementation Status of GHTF Guidance Documents May 2007

#	SG	Document (stage) <i>Title</i>	Adopted in Whole	Adopted in Part	Not Adopted Pending	Not Adopted	Under Development
1	1	SG1(PD)N44:2006 (archived) <i>Role of Standards</i>		Canada-G EU-G US-G	Japan-G		
2	1	SG1(PD)N11:2007 (proposed) <i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)</i>	US-G		Australia-G		
3	1	SG1/N41R9:2005 (final) <i>Essential Principles of Safety & Performance of Medical Devices</i>	Australia-G Canada-G EU-G Japan-G		US-G		
4	1	SG1/N29R16:2005 (final) <i>Information Document Concerning the Definition of the Term "Medical Device"</i>	Australia-S Canada-S Japan-S		EU- G US-G		
5	1	SG1/N43:2005 (final) <i>Labeling for Medical Devices</i>	Australia- S Canada-S, G Japan- S	EU- S	US- G		
6	1	SG1/N9R6 (archived) <i>Labeling for Medical Devices</i>	Canada- S Japan- S	EU- See #5	US- See #5		
7	1	SG1/N40:2006 (final) <i>Principles of Conformity Assessment for Medical Devices</i>	Australia- S Japan- S	Canada- S EU- S		US- UC	

Appendix C: Implementation Status of GHTF Guidance Documents May 2007

#	SG	Document (stage) <i>Title</i>	Adopted in Whole	Adopted in Part	Not Adopted Pending	Not Adopted	Under Development
8	1	SG1/N15:2006 (final) <i>Principles of Medical Devices Classification</i>	Australia- S Japan- S	Canada- S EU- S			US- LI
9	1	SG1/N12R10 (final) <i>Role of Standards in the Assessment of Medical Devices</i>	Australia- S Canada- G	US EU (See #5)	Japan- G		
10	2	SG2(PD)/N87R7:2006 (proposed) <i>An XML Schema for the electronic transfer of adverse event data between manufacturers, authorized representatives and National Competent Authorities (Based on GHTF SG2N32v5.2)</i>				Australia- UC	Canada EU Japan US
11	2	SG2/N21R8 (final) <i>Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative</i>	Australia- S,G Japan- G	EU- G	Canada- S US- S		
12	2	SG2/N38R15 (final) <i>Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program</i>	Australia- G Canada- G Japan- G UG- G	EU- G			
13	2	SG2/N16R5 (final) <i>Charge & Mission Statement</i>	Canada- G US- G				
14	2	SG2/N6R3 (final) <i>Comparison of the Device Adverse Reporting</i>	Japan- V				

Appendix C: Implementation Status of GHTF Guidance Documents May 2007

#	SG	Document (stage) Title	Adopted in Whole	Adopted in Part	Not Adopted Pending	Not Adopted	Under Development
		Systems in USA, Europe, Canada, Australia & Japan					
15	2	SG2/N9R11 (final) Global Medical Device Competent Authority Report	Australia- G Canada- G Japan- G US- G	EU- G			
16	2	SG2/N8R4 (final) Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices	Australia- G Canada- G Japan- G US- G	EU- G			
17	2	SG2-N36R7 (final) Manufacturer's Trend Reporting of Adverse Events	Australia- G Japan- G US- S	EU- G			Canada- See Attachment
18	2	SG2-N54R8:2006 (final) Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices	Australia- G Japan- G US- G	Canada- G EU- G	Canada- G		
19	2	SG2/N57R8:2006 (final) Medical Devices Post Market Surveillance: Content of Field Safety Notices	Australia- G Japan- G	EU- G	Canada- G US- G		
20	2	SG2-N20R10 (final) Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria	Australia- G Canada- G Japan- G US- G	EU- G			

Appendix C: Implementation Status of GHTF Guidance Documents May 2007

#	SG	Document (stage) Title	Adopted in Whole	Adopted in Part	Not Adopted Pending	Not Adopted	Under Development
21	2	SG2/N79R8:2006 (final) Medical Devices: Post Market Surveillance; National Competent Authority Report Exchange Criteria and Report Form	Australia- G Canada- G Japan- G US- G	EU- G			
22	2	SG2/N31R8 (final) Medical Device Postmarket Vigilance and Surveillance: Proposal for Reporting of Use Errors with Medical Devices by their Manufacturer or Authorized Representative	Australia- G Japan- G US- G				Canada- See Attachment
23	2	SG2-N33R11 (final) Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Event Reports	Australia- S Japan- S	EU- G		US- S	Canada- See Attachment
24	2	SG2/N32R5 (final) Medical Device Postmarket Vigilance and Surveillance: Universal Data Set for Manufacturer Adverse Event Reports	Australia- G Japan- G	EU- G US- G			Canada- See Attachment
25	2	SG2/N47R4:2005 (final) Review of Current Requirements on Postmarket Surveillance	Japan- V				
26	2	SG2/N68R3:2005 (final) Summary of Current Requirements for Where to Send Adverse Event Reports	Japan- V Australia- G Canada- G US- G	EU- G			

Appendix C: Implementation Status of GHTF Guidance Documents May 2007

#	SG	Document (stage) <i>Title</i>	Adopted in Whole	Adopted in Part	Not Adopted Pending	Not Adopted	Under Development
27	3	SG3/N15R8:2005 (final) <i>Implementation of Risk Management Principles and Activities Within a Quality Management System</i>	Australia- S Japan- S US- G		Canada- G		EU- Check email
28	3	SG3/N99-10 (Edition 2) (final) <i>Quality Management Systems – Process Validation Guidance</i>	Australia- G Japan- S		Canada- G US- G		EU- Check email
29	4	SG4(PD)N33R13:2006 (proposed) <i>Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports</i>	Australia- G Japan- G			EU- UC	Canada US
30	4	SG4(99) 14 (final) N28 revision <i>Audit Language Requirements (Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements – Supplement 1)</i>	Australia- G EU- G Japan- G		Canada- G US- G		

Appendix C: Implementation Status of GHTF Guidance Documents May 2007

#	SG	Document (stage) <i>Title</i>	Adopted in Whole	Adopted in Part	Not Adopted Pending	Not Adopted	Under Development
31	4	SG4(99)28 (final) N28 revision <i>Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 1: General Requirements</i>	Australia- G EU- G	Canada- G Japan- G	US- G		
32	4	SG4/N30R20:2006 (final) <i>Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy</i>	Australia- G	Japan- G	EU- G US- G		Canada- No Statement
33	4	SG4-N(99)24R3 (final) N28 revision <i>Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General Requirements – Supplement No. 4 – Compilation of Audit Documentation (Clause 5.7)</i>		EU- G Japan- G	US- G		Canada- No Statement

Appendix C: Implementation Status of GHTF Guidance Documents May 2007

#	SG	Document (stage) <i>Title</i>	Adopted in Whole	Adopted in Part	Not Adopted Pending	Not Adopted	Under Development
34	4	SG4-N26R1:2001 (final) N28 revision <i>Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General Requirements Supplement No. 6 Observed Audits of Conformity Assessment Bodies</i>		EU- G	Japan- G US- G		
35	4	SG4 (00) 3 (final) N28 revision <i>Training Requirements for Auditors (Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements – Supplement 2)</i>			EU- G Japan- G US- G		Canada- No Statement
36	5	SG5(PD)N2R7:2006 (proposed) <i>Clinical Evaluation</i>					Australia- G Canada- G EU- G Japan- S, G US- G
37	5	SG5(PD)N1R7:2006 (archived proposed) <i>Clinical Evidence – Key Definitions and Concepts</i>					Australia- G Canada- G EU- G Japan- S, G US- G