



GLOBAL HARMONIZATION TASK FORCE

Working Towards Harmonization in Medical Device Regulation

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STATEMENT FROM THE CHAIRMAN

Today the GHTF releases a new strategic action plan. The plan aims to enhance the capacity of GHTF to deal effectively with emerging medical technology issues and broaden the impact of its regulatory harmonization activities around the world. The four-pronged plan comes as the GHTF celebrates the 15th anniversary of its founding.

Essentially, this plan is a call to action. Its core objectives are designed to energize the process by which the harmonization work results of GHTF are put into actual practice, make the GHTF more inclusive, and establish a forward-looking work agenda that responds to today's challenges and those on the horizon.

The *Action Plan for 2007-2010: Path Forward for the Global Harmonization Task Force* (available on this website) serves as a working "road map." The plan focuses on various GHTF operations: guidance implementation, organizational logistics, expansion, and new topics for GHTF attention. It also calls for a study of the organization's accomplishments as a way of beginning the identification of new operational directions that may be needed to enable GHTF to fully carry out its mission.

Larry G. Kessler, Sc.D.
GHTF Chairman

Action Plan for 2007-2010:



**Path Forward for the
Global Harmonization Task Force**



ACTION PLAN FOR 2007-2010:
Path Forward for the
Global Harmonization Task Force

No Implied Agreement With Any of These
Provisions By Any Party Should Be Inferred or Implied

Offered by

United States and Canadian Delegations to the GHTF

With Endorsement by GHTF Steering Committee

April 2007

Introduction

Since 1992, with clarity of purpose and a firm commitment to international cooperation, medical device government regulators and industry representatives from around the world have closely collaborated through the Global Harmonization Task Force (GHTF) in the pursuit of international consensus on product regulatory controls and practices. In partnership, the European Union, United States, Canada, Japan and Australia, as GHTF Founding Members, have in good faith put forth considerable time and energy toward the convergence of national, sovereign regulatory systems.

The work of the GHTF has been guided by two overarching goals:

- first and foremost, enhancing medical device safety -- thus improving public health -- through information-sharing, general agreement on principles of pre-market, post-market, inspectional/regulatory enforcement activities and national import-export systems;
- fostering medical technology innovation and facilitating global trade among major medical device-producing nations of the world by reducing or eliminating redundant or conflicting regulatory systems, without diminishing public health protections.

Since inception of the GHTF nearly 15 years ago, much has been accomplished. In that time, the GHTF has been able to produce 27 voluntary guidance documents, fulfilling its pledge to develop a global regulatory model for medical devices. While more work remains, GHTF has developed and made publicly available the foundational "building blocks" of a comprehensive, tiered approach to medical device regulation. Indeed, the "GHTF story" is one worth telling because it well illustrates the public health value of international dialogue and cooperation. It shows how parties with different interests and sometimes polar differences of view can come together to do what is truly in the interest of advancing global health.

As important as it is to acknowledge and celebrate cumulative achievement, however, it is just as important to continue to be forward-looking, to continually plan -- strategically -- for the future of this international enterprise. The United States and Canadian Delegations would offer that it is now time for GHTF to move from a consensus-building mode to an implementation mode: from focusing on organizational management to organizational transformation.

GHTF should re-focus its attention to both the form and direction of the organization. In that regard, this plan, which incorporates aspects of the "New Approach" working Paper [1], is designed to position the GHTF for the 21st century in terms of organizational growth and leadership potential.

[1] Time for a New Approach to the Work Processes of GHTF? - Proposal to GHTF Steering Committee", 9-10 November 2006, London; Michael Gropp.

Action Plan Elements

With the foregoing discussion as a backdrop, this section outlines four specific goals that will serve as guideposts for the Task Force's next three years of operation (i.e., 2007-2010), and perhaps beyond: Guidance Implementation, Organizational Logistics, Expansion and New Topics for GHTF Attention.

GOAL I. GUIDANCE IMPLEMENTATION

Perhaps the single most important of the four goals is the need to implement consensus documents in order to further demonstrate the will of Founding Members to carry out the GHTF mandate and move the output of the organization forward. Understandably, this step may pose the greatest challenge Task Force Members have had to face given the varying laws, regulatory controls and policies, and operational resources and conditions that exist within individual Member nations or nation clusters. This challenge is made even greater by the fact that the GHTF is a voluntary organization whose work outputs carry no mandatory force.

Yet, ultimately, the real success of the Task Force will be evidenced by the actions of Founding Members and others to adopt and utilize, as national laws allow, consensus guidance produced by the Task Force as part of their device regulatory systems. A related measure of success can be seen when non-Founding Member countries incorporate substantial elements of GHTF guidance into their own regulatory programs.

Only when this happens will the true benefit of the work of the GHTF be achieved and the GHTF, as an organization, will be able to tangibly demonstrate a return on investment by Founding Members over the past 15 years. To do this requires shared commitment on the part of all Founding Members. As a first step, it is recommended that Members join together to declare their intent (or commitment) to promulgate -- to the extent allowed by their laws -- relevant existing and future GHTF guidance and to document their implementation experience so other GHTF Members can benefit from these efforts. Initially, this full-scale implementation "experiment" (or exercise) should focus on:

- single audits used in multiple jurisdictions, in order to economize GHTF partner operations and resources by minimizing duplicative inspections and sharing inspectional findings by developing pilot projects;
- and,
- improvement in the operation of the National Competent Authority Report system, in order to facilitate the exchange of vigilance reports, including confidential information (consistent with existing national laws and regulations) to enable GHTF partners to take preventive or regulatory actions to avert device safety problems.

Should these pilot efforts succeed, the Task Force should endeavor to address more challenging guidances, such as mutual convergence and, possibly at some future point, acceptance of others' decisions to allow or withhold market clearance.

GOAL II. ORGANIZATIONAL LOGISTICS

Since its founding, the GHTF has continually strived to enhance the efficiency, process order and continuity of its operations. To a large extent, this has been facilitated by today's communications technology. Yet given the pace of technological change and the ever-increasing world-wide interest in deliberations of the Task Force, we should not be content with the status quo.

This ongoing search for improvements in organizational management is particularly crucial in light of potential resource impacts on traditional means of conducting GHTF business. It is therefore suggested that the GHTF concentrate on the following administrative actions in an effort to streamline and otherwise improve current management oversight practices.

A. Administrative enhancements.

Every enterprise, regardless of its longevity or success, can be improved. Greater process efficiency, orderliness, transparency and self-renewal are essential to an organization's long-term growth and impact. With this in mind, the following reforms are suggested for further discussion.

- narrowly focused and unambiguous objectives for work products (i.e., single guidance documents or position papers addressing narrowly-defined topics or issues, as assigned by the Steering Committee and where possible, in collaboration with the Study Groups)
- work products based on existing GHTF guidance (i.e., elaboration of specific points or issues)
- work performed by small, ad hoc working groups with designated experts drawn from government and industry rather than exclusively from large Study Groups
- limited timeframes for production of proposed guidance documents
- adherence to established GHTF Operating Procedures for all guidance documents
- avoidance of duplicative work by GHTF and related ongoing activities of international standards bodies and the strengthening of ties between GHTF and standards bodies to better leverage the ongoing efforts in those organizations
- introduction of a process for nomination and approval [1] of work topics and project accountability.

Ibid. [1]

B. GHTF website utility and visibility.

Since coming on-line in the late 1990's, the GHTF website has undergone a series of design changes aimed at giving it more "screen appeal" and making it more user friendly and navigable. While periodic improvements are advised to attract and maintain user interest, a concerted effort is needed to enhance the utility of the site and make it an authoritative resource for governments, industry, academia, accrediting organizations and the public. The website should provide definitive information on trends in major medical device regulatory systems throughout the world in addition to a global regulatory model on which developing systems in the future can be based.

Also, since more and more countries are following GHTF activities, it seems appropriate for GHTF to foster and facilitate in-country translation of its work products by those nations with an interest in learning from or using GHTF work products. Furthermore, GHTF should explore the use of current-day electronic translation technology to help ensure that translated GHTF documents stay current with Task Force deliberations.

Additionally, more hyperlinking with sites from which interested parties can obtain supplemental or "hot topic" information may also be beneficial. Also, it would be helpful to post recognized GHTF training materials on the website, including for example, the global regulatory model.

GOAL III. EXPANSION

Medical device manufacturing is surging in a number of the world's countries that are not participants in the GHTF. These and other countries are developing new medical device regulatory programs. Given the rising wave of interest in international collaboration and harmonization of certain aspects of its processes among nations with advancing regulatory programs and those with programs in early stages of development, the GHTF should reach out to non-member countries in a manner consistent with the procedures set forth in GHTF/SC/N2R9:2005 – GHTF Roles and Responsibilities. The Task Force will commit itself to increasingly welcome nations and regions wishing to be more active participants in the ongoing work of the organization.

However, in making inclusiveness a future hallmark of the GHTF, organizational expansion must be gradual in order to avoid unwieldiness and overtaxing current GHTF management capacities. Participation and membership criteria, thoughtfully defined and transparently applied, should allow for incremental and beneficial growth of GHTF, especially in cases when nations or regions are able to demonstrate a level of experience in managing medical device market controls and surveillance programs.

As presently envisaged, this move to expand GHTF's membership would involve the following steps.

A. Involve other organizations in a manner similar to the Asia Harmonization Working Party (AHWP).

The AHWP has made great strides in bringing together government and industry from Asian countries to participate in the GHTF and has recently been granted Liaison Member status. The GHTF should similarly engage other nations, world regions and organizations that show an interest in medical device regulatory harmonization and the ongoing work of our organization, such as Central and South America and the World Health Organization, and encourage their active participation. As a precursor to this action, the GHTF should develop and adopt clear procedures that:

- elucidate the criteria by which the Steering Committee will evaluate requests for membership from applicant nations and organizations; and
- set forth the specific rights and privileges, differentiated from those accorded the general public, that are conferred upon applicants whose membership requests have been accepted.

B. Increased public availability of procedures and documents.

As stated previously, interest in GHTF harmonization activities throughout the world is burgeoning and thus a concomitant demand for information and materials exists. Whether by electronic means only or hard copy of such material is deemed to be the most efficient and cost-effective method for sharing information, the Task Force has a unique opportunity to establish an international clearinghouse. At least for now, the GHTF website should be used as the primary conduit for relaying regulatory system guidance.

C. Development and implementation of a GHTF training plan.

Of the three expansion goals, this action may provide the greatest opportunity for the GHTF to provide world leadership and, over the long haul, position the organization as the preeminent resource on medical device regulation. The development of a training plan that encompasses, for example, the global regulatory model and accompanying "handbook", would be a useful first step to more broadly connect the GHTF with the world community.

With this as a springboard, and over the longer term, GHTF could explore the possibility of establishing an international "training institute" (perhaps in partnership with other organizations) that provides general and specialized training for nations interested in establishing medical device regulatory systems or upgrading existing regulatory controls. Such an entity could serve as a "quality assurance" point for training materials and trainers. It could also, for example, produce a GHTF training manual containing a compilation of GHTF guidance documents with accompanying explanations of how they are interrelated and can be implemented to form a comprehensive or partial regulatory system.

Such an institute could conceivably serve as a revenue generator, making GHTF less dependent in the future on financial support from Founding Members. Exactly what if any institutional framework reforms might be required to pursue such activity deserves

further consideration. Were this commercial activity possible, training proceeds could be reinvested into GHTF operational activities, thereby enabling the organization to broaden its consensus-building activities, patient safety and product hazard communications, audit and inspectional information sharing, etc. In turn, in the true spirit of global harmonization, this could prevent (or at least curtail) the spread of disparate regulatory systems and avoid the problem of nations having to revamp their regulatory practices after the fact in order to conform to harmonized practices elsewhere in the world.

It is recommended that the Steering Committee consider forming an ad hoc group to examine the merits, legal feasibility and other relevant aspects of this proposal.

GOAL IV. NEW TOPICS FOR GHTF ATTENTION

New regulatory issues will assuredly develop as technology advances and as public health threats emerge. To keep pace, the GHTF should vigorously embark upon new guidance development initiatives that address these leading-edge issues in a way that builds a global regulatory model based on future considerations, not just the regulatory status quo in Founding Member jurisdictions.

In keeping with the May 2002 GHTF *Strategic Direction: 2002-2007* document, GHTF must position itself as a forum for concerted efforts to identify and address these challenges in a more proactive fashion. In doing so, the Task Force should be operationally flexible, i.e.: as new issues arise and either overtake current issues or are outside the purview of standing Study or Ad Hoc Groups, such Groups should be reorganized or disbanded, or new issues addressed in some alternative fashion.

Listed below are examples of possible new issues, arrayed by priority, that should be discussed further by the GHTF to determine whether they involve real or potential problems in need of international collaboration and/or harmonization solutions.

High Priority

- defining the boundary between “medical devices” and medicinal substances or other regulated products and the way of handling combination products (drug-device, biologic-device)
- regulatory considerations for medical device software (now underway by the Ad Hoc Group on Medical Device Software)
- documenting “lessons learned” from pilot exercises relating to single manufacturer audits and the National Competent Authority Report system so others can benefit from this trial experience and feedback
- development of a global regulatory model “handbook” drawing together all existing GHTF guidance documents and explaining their interaction and possible implementation
- development of training programs on GHTF guidance

Medium Priority

- compilation of voluntary international standards recognized by GHTF Founding Members for conformity assessment purposes (as endorsed by the Steering Committee at the November 2005 meeting in London, UK)
- finalization of a list of harmonized standards
- device use in home and other non-clinical settings (e.g., regulatory purview)
- application of nanotechnology in medical devices and combination products involving medical devices
- registration of manufacturers/authorized representatives and listing of devices and unique device identification

Low Priority

- compatibility of implantable medical devices and high magnetic field intensity imaging devices
- regulatory treatment of telehealth systems (e.g., definition, classification, applicability of essential principles, conformity assessment, etc.)
- study of counterfeit (“grey market”) devices and potential cooperation among GHTF Members on prevention, detection, information-sharing

Taking Steps Now to Prepare for the Future

Articulating the above goals is but a first step in charting a new course for the future. This draft proposal recommends a systematic process for ensuring broad engagement, obtaining substantive input, and reaching agreement on which specific actions merit pursuit and how best to insure a positive result. To do this, while at the same time avoiding processes that are time-consuming and labor- and/or resource-intensive, it is proposed that a number of small working groups be formed, one for each of the above work initiatives, in addition to the retrospective assessment described below.

RETROSPECTIVE ASSESSMENT/PROSPECTIVE COMMUNICATIONS STRATEGY

In 2007, the GHTF will mark its 15th anniversary. On this occasion, it seems timely and appropriate to conduct a review of its work, which could be helpful in attracting more nations interested in medical device collaboration and harmonization as well as setting the stage for the next evolutionary phase of the GHTF.

To this end, GHTF Founding Members have agreed that in the coming year an independent project should be initiated that publicly communicates the vital work of the GHTF and thereby helps to ensure the organization’s future viability. This action alone seems advisable given the unpredictability of resources and priorities that could affect participation by Founding Members in the years ahead.

Current funding constraints and the purported lack of financial resources in the foreseeable future among Founding Members preclude contracting a professional strategic communications/public relations firm to conduct this assessment. Instead, it is planned to assemble a small panel of former GHTF leaders to lead this effort. This study will commence as soon as practicable.

Summary

This Action Plan is intended as a path forward for the GHTF, building on its success of the past, with the goal for the GHTF to be seen as a world leader and have its work serve as a model that nations with emerging medical device regulatory systems can emulate, thus furthering the real aims of global harmonization.

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