



## Global Harmonization Task Force

November 24, 2008

### STATEMENT FROM THE CHAIR

In 2007, under the Chairmanship of Dr. Larry Kessler of the U.S. Food and Drug Administration, the Global Harmonization Task Force (GHTF) Steering Committee commissioned a report concerning the work of the GHTF over its first 15 years, and the challenges it faces in the future. A Study Team composed of government and industry leaders formerly involved with the GHTF was created and led by Beth Pieteron of Health Canada and former Chair of the GHTF Steering Committee. The team was responsible for conducting the qualitative assessment and drafting the GHTF Retrospective Assessment. Their effort consisted of a review of GHTF documents and accomplishments, accompanied by interviews with medical device industry representatives and regulators from around the world.

In the report, the Study Team made recommendations in six areas, with overarching recommendations in the areas of funding, operational efficiency, collaboration and evaluation. The GHTF Steering Committee has reviewed and accepted the report and its recommendations, but notes that certain activities and process improvements that have been implemented since the Retrospective Assessment was commissioned have, in part, addressed some of the recommendations.

The six areas noted in particular are as follows, with a general response from the GHTF to each finding. Further details on each finding can be found in the Retrospective Assessment.

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

The GHTF Steering Committee agrees with the finding and continues to focus the majority of its attention on the development of new guidance documents and the revision

of existing guidance documents. The Steering Committee implemented the creation of Ad Hoc Working Groups to supplement the work of the Study Groups in order to address specific emerging issues of concern to regulatory authorities and industry. Obtaining feedback from a wide variety of stakeholders has been a hallmark of the GHTF; additional outreach that has occurred in the past few years should continue to maximize the reach of these guidance documents and the ability of the GHTF to solicit varied feedback.

**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.*

The GHTF is actively working to strengthen its relationships with other organizations involved in the medical devices sector, including the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and the World Health Organization (WHO) through the establishment of Liaison Body memberships. In addition, the Steering Committee and Study Groups have welcomed representation from the Asian Harmonization Working Party (AHWP) as active participants. In addition, participation in the National Competent Authority Reporting (NCAR) system continues to grow to include regulatory authorities outside the GHTF.

**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.*

The GHTF Steering Committee has created an Ad Hoc Working Group to explore partnerships with other organizations in order to develop and deliver high quality training on the GHTF model and guidance documents. Discussions with several leading regulatory training organizations, including the development of course curricula, are currently underway and it is expected that delivery of world-wide training will be available in the near future. In the interim, the GHTF continues to provide training in conjunction with various GHTF meetings held around the world and at its annual conference.

**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 the regulatory authorities do support and follow the principles on which the GHTF model is based, it is not a simple process to make changes to an existing regulatory framework. Individual changes often have major impacts and pose significant challenges on other aspects of the regulations and so can not be implemented as quickly

as might be assumed. However, GHTF regulatory authorities are dedicated to implementing GHTF guidance wherever and whenever possible. The implementation of GHTF guidance and frameworks has differed between Founding Member jurisdictions, with all jurisdictions adopting significant elements of the GHTF framework. Some jurisdictions have adopted the entire GHTF model into legislation as the basis of their regulatory framework.

It should also be reiterated that the guidance documents in development reflect the ideal model for regulating medical devices and not what is only possible due to existing regulatory frameworks around the world. Therefore, countries that are looking to develop a regulatory framework should be able to adopt the GHTF model with few or no revisions

**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.*

Over the past 16 years, the efforts of the GHTF have been focused on the development of the regulatory model and guidance documents, rather than promoting itself or the model. As we now have a robust and workable model, the GHTF has been more proactive over the past two years in promoting the model through workshops sponsored by the Asia-Pacific Economic Cooperation (APEC) in Asia and Latin America. The work to promote the model will further be enhanced through the training partnerships that are in development. In addition, the work being done by the AHWP, as supported by the GHTF, is another example of the promotion of the valuable work that has been done by the GHTF.

**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.*

As indicated under Finding I, the GHTF has recently implemented the creation of Ad Hoc Working Groups whose purpose is to provide guidance on a specific issue of concern to regulatory authorities and industry. Among the topics which are currently being addressed by individual Ad Hoc groups are: global medical device nomenclature; combination products; unique device identifiers; and medical device software. The creation of other Ad Hoc Working Groups will be considered by the Steering Committee to provide guidance on issues such as nanotechnology and other emerging issues.

With respect to the comments on evaluation contained in the Retrospective Assessment, this report was the first systemic attempt to evaluate the work of the GHTF. Further efforts will be considered following the release of this report.

The GHTF Steering Committee welcomes the report of the GHTF Retrospective Assessment Study Team. It appreciates the time, effort and considered thought that the Study Team put into the Retrospective Assessment. It is the intent of the Steering Committee to implement as many of the recommendations of the Study Team as is feasible.

A handwritten signature in black ink, appearing to read 'R. Rotter', with a stylized flourish at the end.

Dr. Roland Rotter  
Chair, GHTF Steering Committee