



Cooperating for the safety, quality and performance of medical devices

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Harmonisation Task Force
(GHTF)

Introduction to the Global Harmonisation Task Force

GHTF, or the Global Harmonisation Task Force for Medical Devices, is an informal platform for regulatory authorities and representatives of industry from Europe, the United States of America, Canada, Japan and Australia.

Each of these regions nominates representatives to the Steering Committee, which oversees work of GHTF, and in particular of the five Study Groups. GHTF started its activities in early 1993.

The goal of the Global Harmonization Task Force is to provide a forum for national regulatory authorities and industry representatives in the field of medical devices to promote international convergence in regulatory requirements and practices.

In particular, GHTF aims to promote the safety, effectiveness/performance and quality of medical devices; to encourage technological innovation; to foster international trade; and to serve as an information exchange forum through which countries developing medical device regulatory systems can benefit from the experience of those with established systems.

This is achieved through the development of guidance documents and recommended procedures in order to work towards convergence of the medical device regulatory systems of its members within the boundaries of their legal and institutional constraints. Since its inception GHTF has developed extensive guidelines that represent a regulatory model for medical devices. It is important to note that GHTF is not a standardization body.

All of these documents are accessible on the GHTF website: <http://www.ghtf.org/>.

The role of international standards in the GHTF regulatory model

GHTF has long recognized that international standards are a crucial building block for harmonized regulatory processes to assure the safety, quality and performance of medical devices.

In the document *Role of Standards in the Assessment of Medical Devices* (a revised version (SG 1 (PD) N 44) is currently open for comment on the GHTF website at: <http://www.ghtf.org/sg1/sg1-proposed.htm>, it is emphasized that Regulatory Authorities developing new medical device regulations should encourage the use of international standards.



Regulatory Authorities are also encouraged to introduce a mechanism for recognising standards that provide manufacturers with a method of demonstrating compliance with the GHTF harmonised Essential Principles.

An important feature of the regulatory model promoted by GHTF is that it does not in itself provide detailed technical requirements, but sets out Essential Principles of Safety and Performance. Standards provide a tool to demonstrate compliance with these Essential Principles.

In the GHTF model, the use of standards remains entirely voluntary. Manufacturers are free to select among

various solutions to demonstrate compliance with the Essential Principles, and compliance with the Essential Principles remains necessary even where standards do not exist.

Compliance with standards in itself does not mean that automatically the Essential Principles are being met. Manufacturers should comply with the Essential Principles, and remain responsible for the choice and use of standards in demonstrating compliance, verifying, for instance, whether use of the standard supports the intended purpose of a device.

Another important role for standards in the GHTF regulatory model is foreseen in relation to conformity assessment, in particular, in the field of quality management systems where ISO 13485:2003, *Medical devices – Quality management systems – Requirements for regulatory purposes*, was developed in cooperation with GHTF.

Cooperation between GHTF and ISO

Against this backdrop, cooperation between GHTF and ISO, as well as other international standardization bodies such as the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU), is important to ensure that the mutual needs are met, wherever possible, that there is no overlap of work and that all involved can benefit from existing expertise.

GHTF has therefore participated in the work of the Healthcare Technology Task Force (HTTF), which is a task force set up to work on the follow-up of the ISO-IEC-ITU High-Level Workshop on international standards for medical technologies in 2004.

This Task Force brought together the World Health Organization (WHO), GHTF, Association of Medical Microbiology and Infectious Disease Canada (AAMI Canada), Eucomed and the Japan Federation of Medical Devices Associations (JFMDA) and ISO, IEC and ITU representatives with the aim of addressing recommendations that

resulted from the ISO-IEC-ITU High-Level Workshop.

GHTF has also set up direct links with WHO and is in the process of setting up links with IEC; both WHO and IEC currently attend the GHTF Steering Committee Open Sessions.

Between GHTF and ISO cooperation takes place on different levels. ISO has become a liaison body to GHTF, and direct contacts between the GHTF Chair and the ISO Central Secretariat have been established in order to ensure a common strategy on the policy level. An ISO representative regularly takes part in the GHTF Steering Committee Open Sessions.

To coordinate work on specific issues Memoranda of Understanding are in place between specific GHTF Study Groups and ISO technical committees. In 1990, ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and GHTF prepared and agreed a Memorandum of Under-

About the author



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and medical device industry, the cosmetics industry, biotechnology and the food industries. Her previous post as a Director in the Commission was in Maritime Transport. From 2001 to 2004, she returned to Greece where she was CEO and President of Ktimatologio SA, the company which establishes the Land Register in Greece. Ms. Lalis studied law at the University of Athens and then completed a postgraduate degree in International and European Law at the University of Strasbourg in France. Ms. Lalis is the outgoing Chair of the GHTF, a revolving position which she held from 2004 to 2006 when it was with the European Commission. The GHTF Chair rotates every three years and from the beginning of 2007 it is held by North America.



standing and on this basis ISO/TC 210 has a very successful and active liaison with GHTF Study Group 3 in relation to quality management systems. Members of ISO/TC 210/WG 1 have taken part as experts in GHTF Study Group 3 meetings and vice versa.

A second Memorandum of Understanding was signed in 2005 between ISO/TC 194, *Biological evaluation of medical devices*, and GHTF. It defines the roles of each organization in relation to the work of Study Group 5, promoting convergence of regulatory requirements for evidence of the clinical safety and performance of medical devices.

These joint efforts have proven very successful in melding the expertise from both memberships and avoiding any duplication of work.

Outlook

To further enhance cooperation and to establish a well-defined communication process for liaison with ISO and IEC, the GHTF Steering Committee decided to nominate an ISO/IEC rapporteur at its meeting in November 2006. The rapporteur will identify and coordinate issues that require consideration by the GHTF Steering Committee.

Reflections are ongoing on how to link ISO standards and the GHTF Essential Principles. Such a link could take the form of an informative annex listing which elements of the Essential Principles are covered by the ISO standards. This listing could also indicate which parts in the ISO standards address the elements of the Essential Principles. Such an annex is already common practice in the European Union.

GHTF will continue to closely follow the work programme of ISO in order to ensure that the needs of the medical device industry are met. One concrete example of an area of future common interest is the work on software, where a GHTF *ad hoc* group is coordinating its work with ISO 8001:1984, *Cinematography – Underexposed motion picture film requiring forced development – Designation method*. ■