



**WSC high-level workshop on  
"International Standards for Medical technologies",  
Geneva, 26-27 February 2004  
Results and directions for future action**

## **The Workshop**

**Hosts:** World Standards Cooperation, on behalf of its members (ISO, IEC and ITU-T), under the patronage of the World Health Organization, WHO.

**Partner organizations:**

Global Harmonization Task Force, GHTF [<http://www.ghtf.org/>], European Medical Technology Industry Association, Eucomed [<http://www.eucomed.be/>], Association for the Advancement of Medical Instrumentation, AAMI [<http://www.aami.org/>], Japan Federation of Medical Devices Associations, JFMDA [[www.jfmda.gr.jp/](http://www.jfmda.gr.jp/)].

**Participants:** 130 experts representing the major players in this sector – industry, regulators, patient care community, professional societies, standards development organizations.

**Focus:** Providing a forum where high level representatives of the major players involved in this field could interact to review the present situation, highlighting the main trends for the future and providing input on how to address present and future challenges.

## **Results and Directions for future actions**

**Results:**

Presentations and discussion panels provided an overview of the state-of-the-art in a variety of medical technology fields, highlighting the links with standardization activities and the importance of the international standardization system for this sector. All speakers' presentations and rapporteurs' summaries of the various sessions have been posted on the workshop's web-site [<http://www.iso.org/wsc-medtech/>] and are available for consultation.

In general terms, the workshop confirmed that key players in the field of medical technologies are willing to contribute and collaborate in the development of standards for this sector.

Participants cited numerous success stories of how International Standards helped to contribute to the efficiency and dissemination of medical technologies and there was consensus on the need for globally relevant solutions for this innovative and rapidly changing sector.

Participants analysed achievements, opportunities and challenges concerning standardization in the medical technologies sector and offered rich and qualified input on a variety of issues.

An attempt to summarize the input received from stakeholders has been made, highlighting the following list of key recommendations:

- enhance collaboration in setting standardization priorities in relation to essential health and safety principles, devices and technologies, between the Global Harmonization Task Force for Medical Devices, the World Health Organization and the WSC members.
- increase the visibility of the WSC members' standardization programmes and of the important achievements already gained in the medical technology sector, as well as enable the optimal and effective use of the international standardization system by the worldwide community of stakeholders.
- strengthen partnerships between IEC, ISO, ITU-T and global standards developing organizations (SDOs), in order to improve coordination, avoid duplication of work, and promote the use of already existing standards to optimize the production of International Standards in the medical technology sector.
- increase efforts to optimize the flexibility and timeliness of standardization processes.
- enhance and promote new approaches to address emerging and fast changing technologies – noting that in these cases it is particularly important to focus on fundamental safety, performance and other risk management aspects, and that standards should be performance-based (rather than design-oriented) so as not to inhibit innovation.
- highlight and promote the complementarities between regulations and standards, as well as encourage the participation of all stakeholders having relevant interests in the medical technologies sector.
- work to secure the participation of developing countries in the standards-setting process, along with the promotion of the adoption of International Standards and assistance in their implementation.

### **Directions for future actions:**

Addressing the stakeholders' recommendations underlined above will be a collective effort, requiring the commitment and cooperation, at different levels, of all the players involved in the sector.

The WSC members and the partner organizations that have promoted the workshop have already identified a set of concrete action items as a way to implement the workshop's recommendations.

#### 1. Strengthen the dialogue between ISO/IEC/ITU-T, the WHO and the GHTF.

The three entities need to share strategic information aiming at:

- defining a clear and harmonized presentation of the respective standardization programmes;
- mapping the existing standardization programmes and priorities in the medical technology field;
- when relevant, promoting the adoption of the GHTF essential principles as a guiding reference for the development of standards that can be used by regulators.

#### 2. Foster cooperation among the globally relevant SDOs:

- exchange information on deliverables and projects (from various players) covering priority items;
- encourage ISO, IEC and ITU-T technical committees to define appropriate mechanisms to favour and optimize cooperation among relevant SDOs, WSC members and WHO;
- promote benchmarking and use of best practices across the various organizations.

#### 3. Promote the visibility of achievements and existing programmes, enable optimal and effective use of the international standardization system:

- develop presentation materials and guides;
- favour communication and dissemination of results;
- highlight successful models of cooperation between developers of voluntary standards and regulators.

#### 4. Incorporate effectively the risk management approach in the standardization process:

- promote its application, especially in emerging technology fields;
- prepare case studies/success stories;
- undertake broader educational efforts.

#### 5. Join forces and achieve better synergies to support developing countries:

- improve coordination between WSC members and WHO on technical assistance and education.