The Role of International Standards in Supporting an Efficient Regulatory Framework

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• DITTA is a global organization representing Industry Associations of Manufacturers around the world
• DITTA was officially incorporated in 2012 as a non-profit trade association in the United States after more than 12 years of existence
Do We Need Standards?
Roughly 80% of global trade is impacted by standards and by regulations that embody standards

Source:
National Institute of Standards and Technology
Testimony before the U.S. House of Representatives – Committee on Science, Subcommittee on Technology
September 13, 2000
International standards are everywhere: key in global trade and interoperability of products and services.

The WTO advocates for its members to base their technical regulation as much as possible on international standards.
International standards provide for a common set of technical requirements that are kept up to date.

In healthcare, international standards assure high levels of safety and performance of medical devices, in addition to facilitating trade.

Access to innovative and safe technology is ensured by adoption of these standards at national level.
Q: Why do we have standards?

• Make sure technology “fits”
  • Example: plugs and sockets

• Common methods = Common language

• Proven methods, clear decision criteria

• Test results can be compared and trusted

• A practical way to demonstrate “the rules” are met
Q: From where do standards come?

- International Standards Development Organizations
  - IEC, ISO
- Domestic Standards Development Organizations
  - ANSI, CEN, CENELEC, SAC
- Membership Associations (industry, professional)
  - AAMI, NEMA/MITA, WFUMB, ASTM
- Regulators
  - CFDA/CDMSA, MFDS, MFDA, ANVISA...
Q: What is the relation between regulations and standards?

- **Regulations** describe “what” is required.
- **Standards** describe “how to meet” the requirements in practice.
  - Useful for *all* stakeholders: industry, users, conformity assessment, test labs, ...
- Therefore, regulations and standards are complementary and should continue to be developed in a collaborative effort.
Standards Developers and Conformity Assessment Bodies

Commercial Interests

Consumers, Educational Institutions, and General Interests

Government Interests (Federal, State and Local)

Standardization is a global activity encompassing a myriad of interests
PREMISE

ONE STANDARD : ONE CONFORMITY ASSESSMENT: MANY MARKETS
GHTF & AHWP

In a global marketplace, the objective of the standardization process must be a single, technically valid and globally relevant standard with a single test of conformance to that standard. This will allow products to be distributed for worldwide commerce without change or modification.
GUIDING PRINCIPLES

International standards should meet societal and market needs and should not be developed to act as barriers to trade.

ISO and IEC follow globally accepted principles of standards development:

1. Transparency
2. Openness
3. Impartiality
4. Effectiveness and relevance
5. Consensus
6. Performance-based

- Coherence
- Due process
- Technical Assistance
KEY MESSAGES TO IMDRF

1. IMDRF, a critical partner in standards, should jointly
   • Establish a follow-up mechanism to review work done to date and
   • Identify next step collaborations.

2. Refrain from regulatory adoption of standards that result in technical barriers to trade.

3. International standards are an excellent tool for ensuring safety & performance.

4. It is important to develop the standards according to strategic policy (updating frequency and timing).

5. International standards are tools for all stakeholders: joint development of standards.
KEY MESSAGES TO STAKEHOLDERS

1. DITTA is a global organization with a deep understanding of standards and provides the perspective of Industry Associations of Manufacturers from around the world.

2. DITTA is open to and supports collaboration on standards “recognition” by IMDRF members.

3. DITTA welcomes the opportunity to co-host and support a workshop on standards at the Sept IMDRF meeting.
THANK YOU !