Standards WG

INTER-AMERICAN COALITION FOR
REGULATORY
CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

ANNIVERSARY

Standards WG (Standards Engagement - ISO, IEC, et al)

Enhancing Industry Meeting Participation

To emphasize the importance of increasing participation in industry meetings to address local and global challenges, highlighting the need to monitor relevant Standards Developing Organization (ISO, IEC, et al) Technical Committees and Working Groups and understand their requirements to avoid negative consequences and ensure proper understanding of standards by local regulators and industry.

Challenges in Translation and Participation

Challenges with translation accuracy for Spanish and Portuguese, and the need for industry participation in working groups, the companies could help promote meetings and support specialists in attending international discussions.

Importance of tracking working group sponsors, including industry representatives, associations, and consultants, to ensure transparency and proper management of meetings.

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SC 26:150 – QUALITY MANAGEMENT AND GENERAL ASPECTS RELATED TO MEDICAL DEVICES

CE-026:150.001 – Quality management and general aspects related to medical devices

Coordinator: Elaine Koda

Secretary: Carina Shindo

Frequency: Monthly

Participants: Associations and industry

Participation fee: Not applicable

RA participation: No

Access to documentation: After 3 consecutive meetings

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Context

Global and regional medtech regulatory convergence requires that all medtech interests participate in international standardization and via the local NSB TCs and WGs, voting to adopt international standards as national standards with a minimum of national deviations.

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- "Standard" is a term internationally defined together with "technical regulation," and "conformity assessment" by the World Trade Organization (WTO) in the Technical Barriers to Trade Agreement (TBT) Annex 1.
- *"Standard: Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory…"* (TBT Annex 1)
- It is a treaty obligation for the 166 members of the WTO (including all their regulatory authorities) to use international standards as a basis for national technical regulations (TBT Article 2.4).
- This is not a mandate from Geneva but rather a commitment of the WTO members made in their individual sovereignties in exchange for common trade benefits.

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- Standards Developing Organizations (SDOs) including ISO, IEC et al develop and maintain international standards and are open to all stakeholders.
- For ISO and IEC, participation in these SDOs is through National Standards Bodies (NSBs, e.g. ABNT, DGN, ANSI) where the administration is often delegated to authorized organizations (e.g. ABIMO, ANCE, AAMI et al.)
- For other SDOs, participation is per the organization (e.g. CLSI) or individual professional (e.g. IEEE).
- These SDOs have Technical Committees (TCs) and Working Groups (WGs) that develop and maintain international "parent" standards for medical technology standards, e.g.:
  - ISO TC210
  - ISO TC212
  - IEC TC62

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- Some regulatory authorities may reference standards directly (e.g. FDA medical device standards database)
- Some regulatory authorities may only reference a national adoption of an international standard in the local language.
- It is a role of the NSBs to adopt the international standards
- ISO/IEC “parent” standards are made available in English, French, Russian.
- Spanish-language versions of these standards may be available where there is a sufficient number of P members (e.g. STTFs)
- Otherwise, the ISO/IEC “parent” standards are translated into Spanish and Portuguese at the national level.
- Spain’s NSB (UNE) has one of the highest levels of national adoption of ISO standards into Spanish – and agreements for LatAm NSBs to leverage.

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- The NSBs and their authorized administrators of mirror committees to must be open to all stakeholders.
- Regulatory authority and industry use of international standards is a form of reliance.
- Global and regional medtech regulatory convergence requires that all medtech interests participate in international standardization and via the local NSB TCs and WGs, voting to adopt international standards as national standards with a minimum of national deviations.
- The Coalition members can help facilitate this by:
  - Maintaining a relationship with their NSB
  - Shepherding the activities of their members in the NSB
  - Maintaining metrics of their engagements
  - Requesting any assistance from the IACRC

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THANK YOU

SANDRA LIGIA GONZÁLEZ

Executive Secretary

Sandra@interamericancoalition-medtech.org

LETICIA FONSECA

Deputy Executive Secretary
Executive Secretary Brazil

leticia@interamericancoalition-medtech.org

MARINA CARVALHO

GRP and Trade Lead
marina@interamericancoalition-medtech.org