What makes a standards a great standard

Industry View

September 2017 Ottawa, Canada

Elisabeth George – Philips Head of Global Regulations & Standards
MEDICAL DEVICE INDUSTRY PERSPECTIVE

- Introduction
- Value of standards
- Industry role in standards
- Considerations & Opportunities
- DITTA Priorities
Global Design, Manufacture, Distribution and Service

Healthy living

Prevention

Diagnosis

Treatment

Home care

Domestic Appliances

Rechargeable toothbrushes

Personal Health Solutions

Sleep & Respiratory Care

Mother and child care

Personal care

Kitchen appliances

Patient Care & Monitoring Solutions

Healthcare Informatics, Solutions & Services
Access & Time to Market: critical for healthcare system and business
- Country requirements (laws and regulations) vary
- Process and documentation requirements differ
- Scope of verification and validation is not unified
- Even definition of medical device varies by jurisdiction
- Supports harmonization in requirements and testing

THEREFORE:
International convergence of requirements through standards is KEY

Standards help by bringing:
- Common & agreed language across stakeholders
- Basis for international trade agreements
- Testable or auditable requirements (potentially without submitting data)
- Cost saving for healthcare: improve patient access
- Support common terms through the continuum of life with well being and prevention being critical
Why should we be interested in standards development?

- We are global manufacturers
- We are interested in high quality standards
- We want to be a responsible stakeholder – listen and learn from others
- We all have competence to share

Proper development of good consensus standards helps write the details that regulate our products

(Contributes to global regulatory convergence)

- EU: Directives & Harmonized Standards
- US-FDA: “Recognized Consensus Standards”
- Japan-MHLW: International Standards Adoption
- China: Voluntary & Mandatory (Timing Varied)
- India: under development
- LatAm: risk of diverging regulations or implementations
Recognition of standards by regulators varies
- Mandatory vs. voluntary
- Interpretation in supporting guidance documents
- Level of details in annexes of harmonized standards

Transition phase of standards varies
- Synchronization of multi-part standards
- Differing timeframes around the world
- Scope and implementation differences by jurisdiction

Note –
- Regulations: outcome of political process,
- Standards: outcome of technical discussions
CONSIDERATIONS FOR GOING FORWARD

• All stakeholders input is required in standards development
• Interests & needs may conflict across stakeholders
• Look out for best practices and lessons learned
• Limited resources: “too many standards projects” Let’s focus
• Long development time – Let’s get creative
• Transition, recognition & regulatory needs do not always align
SO WHAT CAN WE DO?

Standards Development Process Improvement

- Alternatives should be considered
  - Technology Opportunities
  - Sequencing / Concurrent Activities
- Purpose of Standard
  - Design vs. Conformity Assessment vs. Other

Cooperation & Engagement (within and across)

- Standard Developing Organizations (SDO’s)
- Regulators
- Industry
- Other Stakeholders: Patients, Caregivers, Consumers

A valuable thing to do is to leverage from other industries
Goal: Facilitate efficient and timely market access for member products by developing and promoting the use of appropriate standards.

Advance Smart Dose Program: In order to continue the success of XR-29, MITA needs to continue to focus on supporting and promoting the Smart Dose program and tying it to the other standards efforts.

Industry Groups to be recognized thought leader:
- Understand relevant SDO’s for participation and alignment
- Review standards under development and potential standards to prioritize their development to open markets and add value to members.
- Coordinate and provide oversight into standards development within specific industry group
- (MITA) Developing a standard (annex) for radiology symbols not identified in existing standards. This will allow members to use these symbols without accompanying text per FDA rules.
- Engage with FDA to provide input on the Accreditation Scheme for Conformity Assessment (ASCA) program
THANK YOU!

www.globalditta.org

Questions:
Elisabeth George
elisabeth.george@philips.com
978-902-6135