The Value of International Standards for Conformity Assessment – Industry Perspective

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DITTA Standards Workshop – Ottawa, September 18, 2017
Disclaimer

- Opinions/thoughts expressed are my own
- They do not necessarily represent views of my employer or any particular industry association
Introduction

- From ISO: “A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose” (http://www.iso.org/iso/home/standards.htm -“What is a standard?”)

- How do these documents impact industry?
  - Pros
  - Cons

- How can they be used effectively to promote safety, performance, and resource efficiency?
Introduction

• Horizontal vs. Vertical Standards
  – Horizontal standards are broad reaching and cover “overarching” topics across sectors
    • Examples: ISO 13485 (Quality Systems), ISO 14971 (Risk Management)
  – Vertical standards are product/sector specific
    • Examples: ISO 10555 (Intravascular Sterile and Single-Use Catheters), ISO 25539-1 (Endovascular Prostheses)
Global Standards Development

• How are they developed?

• Working groups consist of expert stakeholders
  – Variety of perspectives represented
  – Regulators, industry, users, patients
Global Standards Development

- Develop consensus documents that detail processes/requirements for best practices and/or safety/performance
Benefits of Standards

• When used as part of the conformity assessment process, standards can provide several benefits to regulators, industry, users and patients:
Benefits of Standards

• Benefits to Regulators/CABs:
  – Global expert consensus of best practice
    • What do the experts think is required in terms of safety/performance
    • Common, agreed-upon terminology, definitions, etc.
    • Allows for regulatory decisions based on this consensus perspective
  – Input from a variety of stakeholders
    • Consultative/collaborative development process ensures views of a variety of groups are represented
Benefits of Standards

• Benefits to Regulators/CABs:
  – Efficiency
    • During review, can be assured of safety/performance in areas that are addressed through the use of the standard and concentrate efforts in other areas
  – State of the Art
    • Standards go through a process of periodic review and updating, meaning they reflect current best practices – confidence
Benefits of Standards

• Benefits to Industry (remarkably similar):
  – Global expert consensus of best practice
    • Confidence in safety/performance of the product
  – Input from a variety of stakeholders
    • Will meet the needs of the various other stakeholders – regulators, users, patients
  – Efficiency
    • No need to start from scratch to cover requirements for areas addressed in the standard
  – State of the Art
    • Reflect current best practices - confidence
Benefits of Standards

• Benefits to Users and Patients (also remarkably similar):
  – Global expert consensus of best practice
    • Confidence in safety/performance of the product
  – Input from a variety of stakeholders
    • Their requirements have been taken into account
  – State of the Art
    • Reflect current best practices - confidence
Potential Pitfalls of Standards

• There are potential drawbacks from over-reliance on standards in some specific cases – some examples:
  – Cost
    • Testing required to demonstrate conformance may outweigh that for potential alternative approaches
  – Burden
    • May have requirements that are not relevant for a particular device within a broader family or particular safety/performance requirements might be more easily yet satisfactorily addressed through alternative means
How Can They Be Used Effectively?

- Recognition by Regulators:
  - The more regulatory agencies that participate in the development of standards, and that then recognize those standards, the greater the global benefits
  - International standards mean one set of requirements for multiple regulatory regions – efficiency of development and speed of access by patients
  - Transparency benefits – where an applicable standard is recognized, industry knows what is expected of them in regulatory submissions
How Can They Be Used Effectively?

• Recognition by Regulators:
  – Important! – “Recognize” not “Require”

• With few exceptions, conformance with standards should be one way, but not the only way, to demonstrate safety/performance for the reasons above
How Can They Be Used Effectively?

• Implementation by Industry:
  – As previously mentioned, efficiency of development and speedier pathway to market
  – Cover regulatory requirements of multiple jurisdictions
How Can They Be Used Effectively?

• Participation by Stakeholders:
  – More input means better standards
  – Ensure the needs of the various stakeholder groups are met in the standard
  – Standards-making bodies should continue to encourage broad participation
    • Directly
    • Through national bodies
  – Confidence in the products that conform to the standard
Summary – Benefits to the CA Process

• Front end benefits to industry
  – Reflection of state-of-the-art requirements for safety/performance of the product to guide development and submission preparation

• Submission review process
  – Reviewer confidence that safety/performance requirements have been met
  – Efficiency of review

• Post-review phase
  – Market confidence
Summary – Benefits to the CA Process

... and in the end, that’s really what it is all about:

Process

Product
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