

The Value of International Standards for Conformity Assessment – Industry Perspective

Greg LeBlanc – Director, Regulatory Affairs and Quality Systems
Cook (Canada) Inc.

DITTA Standards Workshop – Ottawa, September 18, 2017



www.cookmedical.com

Disclaimer

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

Introduction

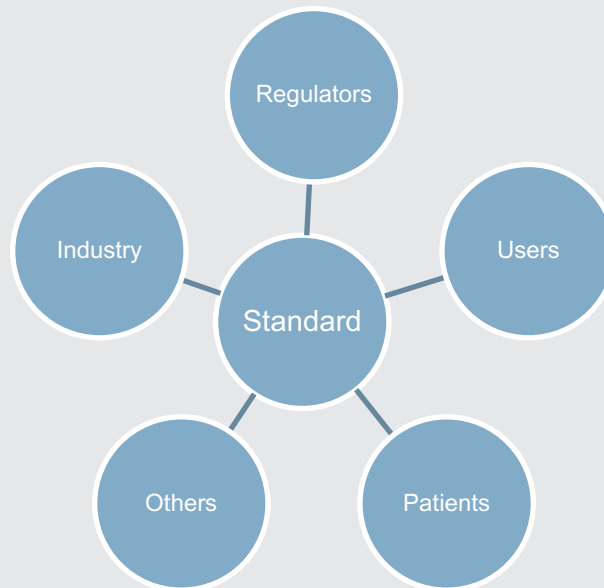
- From ISO: *“A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose”*
(<http://www.iso.org/iso/home/standards.htm> -*“What is a standard?”*)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

Greg LeBlanc – Director, Regulatory Affairs and Quality Systems
Cook (Canada) Inc.

E-mail: greg.leblanc@cookmedical.com



www.cookmedical.com
