



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Role of Standards in the Evaluation of Medical Devices

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Agenda

- Introduction
- Type of standards
- Why standards are important?
- Role of standards in the evaluation of medical devices
- Take home message (Challenges and Opportunities)
- Q & A.

Definition of Standard (per ISO)

Technical:

'A standard is a document, established by a consensus of subject matter experts and approved by a recognized body that provides guidance on the design, use or performance of materials, products, processes, services, systems or persons.'

Less Technical:

'Standards are the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent – people such as manufacturers, sellers, buyers, customers, trade associations, users or regulators.'

Type of Standards and their Use

- Types of Standards
 - Horizontal - Apply across a wide range of devices and device types
 - Vertical - Apply to specific devices or device groupings
 - Test Methods - Consensus procedure that produces a test result
 - Material Specifications - Typically includes requirements for physical, mechanical & chemical properties, safety, quality, or performance criteria.
 - National - Produced by country SDO
 - International - Developed by a harmonized international SDOs
- Where are the standards used?
 - Clinical Issue, Labeling, Symbol, Device Identifier, Pre-Market, Post-Market
 - Radiological Health, Public Health Concern, Informed Consent, Study Subject Protection,
 - Manufacturing, QSR, GLP, Risk Management/Assessment, Human Factors, etc.

Value of Standards for Medical Devices

**Enhance
regulatory
science**

**Promote
quality and
Innovation**

**Improve
patient
access**

- Science-based, least burdensome regulatory approach
- Lowers the cost of and improves access to technology
- Promotes international trade
- Encourage innovation and competition among product developers
- More efficient to rely upon consensus-driven standards
- Enables “smart”, nimble, and responsive regulation
- Ensures the highest levels of safety and effectiveness of medical devices

Why Optimized/Consensus Standards?

- Reduce burdens on manufacturers by harmonization
 - Promote regulatory science
 - Speeds patient access to safe, effective devices
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- Fairness: Participation by all stakeholders
 - Conformance: Essential Principles for Medical Devices.
 - State of the Art: Standards represent the current state of the art
 - Efficiency: Reduce the regulatory burden on innovators
 - Completeness: Within its scope, a standard addresses all elements
 - Consistency: Terms and symbols across standards are as consistent
 - Clarity: Standards are clear, unambiguous, and easily understood.
 - Accessibility: Standards and associated documents available to all



Role of Standards in Evaluation of Medical Devices

- Regulation of medical devices is very complex (extremely wide spectrum)
- Demonstration of Essential principles (safety and efficiency) is very important
- Standards are essential in assessing medical devices and play a fundamental role in ensuring safety, quality, efficacy, and/or regulatory compliance.
- Standards make it possible to apply essential requirements in a uniform way
- Good medical device standards:
 - Have rational and clear scope, focus more on performance than specification, connect EP and regulatory requirement, differentiate between requirements and guidance, state of the art, and have means for demonstrating conformance,
- Involvement of Regulators, Industry leaders, and Users
- Voluntary vs Mandatory

Medical Devices Standards – Challenges and Opportunities

- Challenges
 - Rapid Innovation/Obsolescence – The average device life is 2-3 years
 - The regulatory framework to be developed such that it does not stifle innovation
 - The effectiveness of the device to a great extent depends on the skill of the deployer
 - Risk management plays is important - Risk arising due to the misuse of the device
- Opportunities
 - Develop Performance Standards versus Design Specific Standards
 - Foster innovation and healthy marketplace dynamics
 - Express a standard's requirements with references to performance, rather than Principle and technology-specific standards
 - The standard should be able to demonstrate conformance to EP of Safety & Performance
 - Regulations should encourage the use of standards or innovators' own validated standards

Good Standards Philosophy



Standards only where there is a need



Involvement of all the Stakeholders
(Users, Industry and Regulators)



Preference for global solutions--“*One standard, one test, worldwide*”



Systems approach—Address safety and efficacy across full product lifecycle

Note: Consensus standards are voluntary, and innovators are allowed to use their own validated standards



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Thank You