Practical Application of International Standards – Industry experience

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Why standards are important to industry

Compliance with international standards enhances our ability to bring products to the global marketplace by:

Making our regulatory submissions more uniform, faster and more cost effective.

We have seen that the use of standards reduces regulatory submission review and approval times.

Using standards enables us to design a single product which may be sold worldwide.

Standards assist companies in the production of products with the greatest possible reliability and quality.

Industry's opinion is supported by these standards related stakeholders

- The use of [internationally]-recognized consensus standards can increase predictability, streamline premarket review, provide clearer regulatory **expectations**, **facilitate market entry** for safe and effective medical products, and promote international harmonization.[1]
- Standards are the building blocks for **innovation** and competitiveness. [2]
- By participating in standards development activities – and by implementing standards and conformance tools – organizations are able to **streamline processes**, trim costs, earn and maintain market access, and boost their bottom line. [3]

[1] FDA Guidance: Recognition and Withdrawal of Voluntary Consensus Standards
[2] Patrick Gallagher, Director of the National Institute of Standards and Technology, 2010
[3] Standards Boost Business – American National Standards Institute

Regulatory bodies are increasing their reliance on standards as part of the approval process

- The MDSAP (Medical Device Single Audit Program) is a specific example of this reliance. This program allows for a single audit of a manufacturer's compliance with the quality management standard (ISO 13485) which is then usable in five jurisdictions (US, Canada, Australia, Japan, and Brazil). There are additional countries observing the program. [EU, UK, Argentina, Israel, South Korea & Singapore] [1]
- Many companies participate in MDSAP.
- The FDA has announced that it will be moving away from GMPs and towards compliance with ISO 13485.
- The EU has harmonized ISO 13485 to their Medical Device Regulation.

1 https://www.fda.gov/medical-devices/cdrh-international-affairs/medical-device-single-audit-program-mdsap

Participation in international standards creation & revision

IMDRF recognizes the value of international standards development, which led to the initiation of the IMDRF Standards Liaison Program[1]

Companies consider international consensus standards so important that they encourage employees to participate in international standards committees

Participation ensures practical implementation experience is considered by all stakeholders including regulators when designing standards

Participation allows manufacturers to anticipate future standards requirements for conformity assessment

1 https://www.imdrf.org/sites/default/files/2022-05/IMDRF%20Final%20Document%20-%20IMDRF%20Standards%20Liaison%20Program%20Framework.pdf

THANK YOU