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Engineering the extraordinary

Practical Application of International Standards – Our experience

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Why standards are important to Medtronic

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 Medtronic in the production of products with the greatest possible reliability and quality.**

Our opinion is supported by these standards related stakeholders

[1] The use of FDA-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.

[2] Standards are the building blocks for innovation and competitiveness.

[3] 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.

[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

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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 & Brazil). There are additional countries observing the program. [EU, UK, Argentina, Israel, South Korea & Singapore]
- Medtronic participates 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.

Other Examples

- Medtronic is considering using the FDA Accreditation Scheme for Conformity Assessment (ASCA) where the ASCA Summary Test Report (from an ASCA accredited test house) takes the place of a lengthy full report within a regulatory submission. This simplifies and speeds up a portion of the review process.
- The EU expects the use of standards in support of meeting the General Safety and Performance Requirements (GSPR) for a product.
- Standards harmonized the European MDR have annexes attached that help manufacturers map clauses within the standard to the text of the law and to the IMDRF essential principals.

Other Examples

There have been market issues that involve standards.

- We were able to effectively compete with a competitor who alleged to be “better” because of the breadth of standards they claimed compliance with.
- We are prepared for situations where bid documents require a complete list of standards our product(s) meet.
- There have been situations where bid documents require proof of meeting quality management standards.

Participation in standards creation & revision

- Medtronic considers international consensus standards so important that we encourage employees to participate in national and international standards committees.
- To that end, we have more than 150 employees who participate in international and domestic standards including some who hold leadership positions within IEC, ISO and AAMI
- Our participation ensures we have a chance to influence the results early on, we receive advance notice of what is coming, and we understand the language and intent of the standards
- Most importantly, we take part in creating something that benefits patients, users and the medical device industry
- All standards committees benefit from the participation of regulators!

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