Standards and Its Benefits – MedTech Perspective

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The medical technology business is **highly regulated**. The world keeps changing: **regulations are becoming more stringent**, e.g. EU MDR. Industry must **comply with** the regulations (it’s the law!). Industry must **understand** the regulations and applicable standards – interlinked. Industry can and must **influence** the contents of upcoming standards. Industry must be **timely aware** of new standards and regulations. Standards are **recognized** by regulators (EU: Harmonized, USA: Consensus Standards etc.). Standards give **presumption of conformity** with regulations. Standards are used in **business-to-business** economy. Standards represent **state-of-the-art** technology. Standards ensure **global market accessibility**. Standards and how it is applied, **essential for career development**.
### Products & Standards

**Blood Glucose Meter**

- **ISO 15197:2013**
  - In vitro diagnostic test systems -- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

- **USFDA Guidance (Oct. 11, 2016)**
  - Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use

- **NCCLS* EP9-A2 Vol. 22 No. 19**
  - Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition

- **ISO 14971:2012**
  - Application of risk management to medical devices

- **ISO 13485:2016**
  - Quality management systems. Requirements for regulatory purposes.

**X-Ray**

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
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<tbody>
<tr>
<td>IEC 62304 (Edition 1.0, 2006)</td>
<td>Medical device software – Software life cycle processes</td>
</tr>
<tr>
<td>ISO 14971: 2012</td>
<td>Medical devices – Application of risk management to medical devices</td>
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<tr>
<td>USFDA Guidance (May 11, 2005)</td>
<td>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices</td>
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<tr>
<td>USFDA Guidance (February 3, 2016)</td>
<td>Applying Human Factors and Usability Engineering to Medical Devices</td>
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<td>USFDA Guidance (September 1, 2016)</td>
<td>Guidance for the Submission of 510(k)’s for Solid State X-ray Imaging Devices</td>
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<tr>
<td>ISO 13485:2016</td>
<td>Quality management systems. Requirements for regulatory purposes.</td>
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*NCCLS: National Committee for Clinical Laboratory Standards

**Note:** Not exhaustive list
Standards development process

- **EDUCATE** industry stakeholders *early* about Standards & that they **CAN WRITE THE STANDARDS!!**
- **But only during** the development process, **not after** publication!!
- Industry stakeholders can participate at different levels:
  - *in the national mirror committees* (from a distance, only reviewing official drafts)
  - *in working groups/technical committees* (discussing working drafts, writing the official drafts)
  - *as convener/chairman of working groups* (“holding the pen”)
Challenges & Issues

• **INFLUENCE (TIME) = MONEY !!!**
  – Travel costs are **limited**, but business burden can be **HUGE**
  – Investments are **limited**, but business benefits are **HUGE**

• International vs. National Participation?

• Do we have experts to participate? Team effort!!

• Development of experts takes time & $$

• Business Focus = Speed to Market
Evolution of Medical Technology

- Deep Brain Neurostimulators
- Cochlear Implants
- Cardiac Defibrillators/Pacemakers
- Gastric Stimulators
- Insulin Pumps
- Foot Drop Implants

Meet iQ.
Whole body imaging. Under $2k.

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Competency Development Process

• Domain technical experts – knowledgeable & experienced
• Evolving Medical Technology
  – Rapid convergence of multiple-domains of expertise
  – Opportunities for more new/revisions of standards/regulations etc..
• Career pathway – upstream (e.g. R&D, manufacturer) and downstream (e.g. commercial)
  – Roles & responsibilities differ
  – Competencies differ
  – No One-Size-Fits All approach
• Competency timely matched to Company’s focus and requirements ($$$) – Team effort!!
Thank You!

Q & A