The Nuts and Bolts of Consensus Standards

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It doesn’t fit

The process of standardization is always a political struggle with winners and losers. Had the screw not been standardized, the entire economy of the American economy might look different.

From left: precut from 1800 to 1950. Sellers flathead.
The Whitworth thread

The Sellers thread
Overview for today

Executive Directives re Use of Standards by government Agencies
U.S. government use of standards
Brief overview of the U.S. Food and Drug Administration
US and EU use of standards in Regulation
U.S. Government Use of Standards

- National Technology Transfer and Advancement Act (NTTAA; PL 104-113)
- OMB directive (OMB A-119)
- Interagency Committee on Standards Policy (ICSP) – more info at http://standards.gov/icsp/query/index.cfm
- Annual Report on Federal Agency Use of Voluntary Consensus Standards and Conformity Assessment produced by National Institute of Standards and Technology (NIST)
What are they?

National Technology Transfer and Advancement Act (NTTAA) (PL104-113).

passed by Congress in 1996, signed by President Clinton.

This statute codified an existing OMB directive

Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities (OMB Circular A-119, )

issued several times previously, dating back to the late 1970s.
What does FDA do?

FDA’s mission, simply stated, is to:

• promote and protect the public health by helping safe and effective products reach the market in a timely way;

• monitor products for continued safety after they are in use; and

• help the public get the accurate, science-based information needed to improve health.

= Risk Management
What does FDA regulate?

Wide array of products - From common food ingredients, medical devices, cosmetics, drugs to radiation-emitting consumer and medical products.

$1 trillion a year - FDA-regulated products account for about 25 cents of every consumer dollar spent.

Variety of regulatory approaches –

New drugs and complex medical devices must be proven safe and effective before companies can market them.

Other products, such as x-ray machines and microwave ovens, must measure up to mandatory performance standards.

And some products, such as cosmetics and dietary supplements, can be marketed with no prior approval.
The problem of risk management

Science-based, efficient risk management allows FDA to provide the most health promotion and protection at the least cost to the public.

No regulated product is totally risk-free, so these judgments are important. FDA will allow a product to present more of a risk when its potential benefit is great -- especially for products used to treat serious, life-threatening conditions.
So, voluntary standards?

FDA uses regulations to define specific requirements manufacturers must follow to assure product safety and to provide accurate information to health professionals and consumers. - WHAT

FDA uses standards to describe how manufacturers might meet the requirements. - HOW
FDA Policies re Standards

- 21 CFR 10.95 – Commissioner encourages participation in standards development
- 60 FR 53078 (Oct. 11, 1995) - OIP Policy Statement – Policy regarding the development and use of standards with respect to international harmonization of regulatory requirements and guidelines
- FDA Policy on Standards – Develop and use consensus standards whenever possible
- SMG 9100.1 – Internal guidance on participation in standards development
FDA Use of Standards

FDA Centers use voluntary consensus standards to varying degrees, depending on the product and regulatory approach.

FDA Center experts actively participate in dozens of standards development organizations and hundreds of committees and working groups.

Each Center may have a preferred standards forum, depending on history, statutory requirements and experience.
Regulation

• Regulation is Risk Management
• Regulatory models
  – US model
  – EU model
• Regulatory harmonization
US vs EU Models

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US Regulation

FD&C Act

Pharmaceuticals
  Pre-market review

Medical Devices
  General controls
  Standards
  Pre-market approval
EU Regulation

Pharmaceuticals
Medicines
Medical Devices
Medical Device Directive
Active Implantable Medical Device Directive
In-Vitro Diagnostic Medical Device Directive
US Standards System

- Voluntary System
  - operates under the ANSI umbrella
- Unique in the world
  - >600 SDOs
    - Each SDO has a different operational model
  - Not understood by the rest of the world
Consensus – the collective opinion of all interested parties

Majority, not necessarily unanimity
Role NIST Plays

- Maintains standards of metrology for USA
- Participant on many SDO committees
- Permanent seat on ANSI Board of Directors
- Implements NTTAA (PL104-113)
- Research supports technology for standards development
  - Develops and markets Standard Reference Materials
- DOES NOT WRITE STANDARDS
Medical Device Standards

- Horizontal Standards
- Device Specific Standards
Medical Device Standards

- Regulation = Risk Management
  - Is the device safe to use
  - Is the device effective - Does it do what is claims to do
  - Risk vs. Benefit - the eternal question
Important Horizontal Standards

- Risk Management – ISO 14971
- Biological Evaluation – ISO 10993 or ASTM F748
- Electrical Safety – IEC 60601
- Sterility – ISO 13408
- Quality System Requirements - ISO 13485
Useful Internet Websites

- www.cdrh.fda.gov/science/standards/constand/organization
- www.astm.org
- www.aami.org
- www.ihs.com
- www.standardslearn.org
  - Why Standards Matter
  - US Standards - Today and Tomorrow
I’m from the gummament.
I’m here to help.
QUESTIONS AND DISCUSSION