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## *Standards Development : US Regulatory Participation*

## *Standards: What Are They?*

*“A standard is a common language that promotes the flow of goods between buyer and seller and protects the general welfare.”*



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## *US Standards System*

- n Voluntary, market-driven, and led by the private sector
- n Requires cooperation among stakeholders:
  - Standards organizations
  - Industry and users/consumers
  - Academia
  - Government representatives
- n Stakeholders needs must be met:
  - Protect health, safety and environment
  - Enhance industry competitiveness
  - Facilitate global trade



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## *Types of Standards*

- n **Company Standard**
  - n Consensus among the employees of an organization.
- n **Consortium Standard**
  - n Consensus among a small group of organizations; usually like-minded companies forced to undertake an activity that is beyond the resources of any one member.
- n **Industry Standard**
  - n Consensus among the many companies within an association or professional society.
- n **Government Standard**
  - n May reflect many degrees of consensus. Some are written by individuals within government agencies, many are now being developed in the private sector and then adopted by reference as mandatory.
- n **Voluntary Consensus Standard**
  - n Consensus is developed by representatives of all sectors that have an interest in the use of the standard. These sectors can include producers, users, and those having a general interest (government and/or academia), as well as ultimate consumers. Consensus standards, with their broad input, are considered by many as the most technically sound and credible documents. They are often used as the basis for commercial and regulatory action.



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## *NTTAA & OMB A-119*

### **n** What are they?

- National Technology Transfer and Advancement Act (NTTAA) (PL104-113).
  - n** Passed by Congress in 1996, signed by President Clinton.
  - n** 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, )
  - n** Issued several times previously, dating back to the late 1970s.



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## *Benefit to Government*

- n** Eliminate/reduce costs of developing standards
- n** Decrease costs of goods purchased
  - Commercial off-the-shelf procurement
- n** Promotes efficiency and economic competition
- n** Relies on the private sector to meet needs
  - Access to industry experts and technology
  - Process is faster and more dynamic



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## *Impact on Government*

- n The NTTAA gives an agency discretion to use other standards, e.g. those developed with non-government organizations or government-unique standards, in lieu of voluntary consensus standards where use of the VCS would be "inconsistent with applicable law or otherwise impractical."



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## *US Government as a User of Voluntary Consensus Standards*

- n **Incorporation by Reference:** An agency may adopt a voluntary standard (without change) by incorporating the standard in a regulation by listing (or referencing) the standard by title.
- n **As a Basis for Rulemaking:** The agency reviews a standard and makes changes to match their needs.
  - During a rulemaking, an agency must publish in the Federal Register its intent to incorporate a standard or to make a revision to an existing standard part of a rule.
  - Public comments may result in changes to the proposed rule before it is instituted.



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## *US FDA Involvement: Why?*

### **n** Standards

- Address elements of the FDA Performance Plan
- Optimize the utilization of FDA resources
- Accomplish international trade commitments
- Enable cooperation between governments
- Encourage partnering with manufacturers
- Enable improvements in industrial productivity by basing requirements on accepted standards
- National Technology Transfer Act (PL104-113) & OMB Circular A119



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## *FDA Standards Activity*

### **n** Foods

- CODEX
- ISO TC 34
- >60 product type SDOs
- 3A Sanitary Standards

### **n** Medical Devices

- >20 SDOs
- >500 committees, WGs
- >230 participants

### **n** Drugs

- HL 7
- ASTM
- CCLS
- ISPE
- ICH
- USP

### **n** Veterinary Medicine

- CCLS
- VICH

### **n** Biologics

- Tissue Engineered Medical Products
- CCLS



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## *Acronyms Defined*

- n CODEX – Codex Alimentarius Commission (WHO creation)
- n HL 7 – Health Level 7
- n CCLS – Conference for Clinical Laboratory Standards
- n ISPE – International Society for Pharmaceutical Engineering
- n ICH – International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
- n USP – US Pharmacopoeia
- n VICH – International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medical Products



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## *US FDA Use of Standards*

- n Participation in development does not connote adoption
  - Does the standard address science or regulatory concerns/issues?
- n Uses
  - Cite by FDA in Regulation and Guidance
  - Cite by sponsor as part of documentation
  - As forum to discuss science with industry



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## Internal FDA Implementation

- n Standards Program within CDRH:
  - <http://www.fda.gov/cdrh/stdsprog.html>
  - database of the non-governmental standards used by the Center  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>
- n FDA centers handle implementation differently, although CDRH & CDER have many efforts facilitated through the Office of the FDA Commissioner via the Standards Administrator (Donald Marlowe)



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## What is ASTM?

- n A proven and practical system
  - Established in 1898
  - 140 Committees & 12,000+ Standards
  - 30,000 members
    - n 5,500+ International Members from 125 countries
    - n 3,000 ASTM standards used in 60+ countries
  - ‘Audited Designator’ accreditation: American National Standards Institute (ANSI)
  - Process complies with WTO principles: Annex 4 of WTO/TBT Agreement
  - All stakeholders involved (Public & Private Sector Cooperation)
  - Neutral forum
  - Consensus-based procedures
- n Development and delivery of information made uncomplicated
- n A common sense approach: industry driven
- n Market relevant globally
- n No project costs



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# *Standards for Manufacture of Pharmaceutical Products*

## **n** ASTM International Committee E55

<http://www.astm.org/COMMIT/COMMITTEE/E55.htm>



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# *ASTM Committee E55*

- n** Organized December 2003 by Industry
- n** Current Roster: 294 Individuals & Organizations
- n** 5 Approved Standards
- n** 12 Work Items Under Development
- n** 4 Technical Subcommittees
  - E55.01 on PAT System Management
  - E55.02 on PAT System Implementation & Practice
  - E55.03 on General Pharmaceutical Standards
  - E55.91 on Terminology



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## *Standards for Medical & Surgical Materials & Devices*

### nASTM International Committee F04

<http://www.astm.org/COMMIT/COMMITTEE/F04.htm>



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## *ASTM Committee F04*

- n Organized December 1962 by Industry
- n Current Roster: 826 Individuals & Organizations
- n 261 Approved Standards
- n 5 Divisions
  - Division I - Resources
  - Division II - Orthopedic Devices
  - Division III - Medical/Surgical Devices
  - Division IV - Tissue Engineered Medical Products
  - Division V - Computer Assisted Surgical Systems



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## *Standards for Anesthetic & Respiratory Equipment*

### n ASTM International Committee F29

<http://www.astm.org/COMMIT/COMMITTEE/F29.htm>



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## *ASTM Committee F29*

- n Organized December 1983 by Industry
- n Current Roster: 105 Individuals & Organizations
- n 29 Approved Standards
- n 11 Subcommittees
  - F29.10 Anesthesia Workstations
  - F29.11 Gas Monitors
  - F29.12 Airways, Bronchoscopes and Laryngoscopes
  - F29.14 Ventilators
  - F29.15 Harmonization of Alarms
  - F29.16 Terminology
  - F29.17 Medical Surgical Suction and Drainage
  - F29.18 Operating Room Fire Safety
  - F29.19 Patient Warming Equipment
  - F29.20 Medical Gas Systems
  - F29.21 Devices in the Integrated Clinical Environment



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# *Questions?*



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