BME 301

13 - Design, Test, & Sell

Design

- Simplified view of the design process
- Making Door knobs

1 - What the Customer Wants

- Red, White and Blue
- Child of 5 can open them
- Dog proof
- Cheap
- Cheap

2- What does this mean for the Developer

- Red, White and Blue
  - What are the ranges of each color to satisfy this need?
- Child of 5
  - Size of knob
  - Minimum torque needed to turn knob
- Dog Proof
  - What materials can be used to be resistant to dog gnawing on the the knob?

3 - After some research develop requirements that can be tested

- Color Requirements
  - Pure Hue ±5%
- Child Requirements
  - 4 “ diameter
  - .25 pound-inches
- Dog Requirements
  - No wood
  - Must support Child Requirements
  - Possibilities: Use plastic with compressive strength greater than 14,000 psi

How do I prove that I met what the customer needs

- Test the color using a matching scheme or a spectrophotometer
- Test the door knob with a caliper
- Test the torque with a torque wrench
- Test the material composition and strength

Testing with humans

- Informed Consent
- IRB

Research on Humans
Testing with Humans

- The Federal Regulations for the Protection of Human Subjects
  - Title 45 Part 46 of the Code of Federal Regulations (45CFR46)
  - Title 21 Part 50, 56, 312, 812 of the Code of Federal Regulations (21 CFR 50,56, 312, 812)
- State Law
- Local IRB policies and procedures

Infamous Cases, Ethical Violations in Research Involving Humans

- Nazi War Crimes of Medical Nature
- The Willowbrook Studies
- The Tuskegee Syphilis Study
- Radiation Test on Mentally Impaired Boys
- The Jewish Chronic Disease Hospital Study

Belmont Report

- **The *Belmont Report – Ethical Principles and Guidelines for the Protection of Human Subjects* was published in 1978**
- **The principles of The Belmont Report govern all research involving human subjects at this institution.**

The three ethical principles of The Belmont Report

- Respect for persons
  - that individuals should be treated as autonomous agents,
  - that persons with diminished autonomy are entitled to protection.
- Beneficence
  - do not harm
  - maximize possible benefits, and minimize possible harms.
- Justice
  - fairness in distribution
  - Willing participants

The Institutional Policy

- **Applies to all research activities involving human subjects conducted by Investigators, or staff.**
- Requires that all research activities involving human subjects follow the ethical principles of The Belmont Report and the legal requirements of 45 CFR 46 and or 21 CFR 56.
- Collaborations with other researchers in human subjects' research activities at other institutions is subject to the requirements of the Institution's Policies.

Your Responsibilities

- Research investigators have a fundamental responsibility to safeguard the rights and welfare of the people participating in their research activities.
- Therefore, when conducting research involving humans, federal regulations, institutional policy and the Institution's policies require prospective and continuing review and approval of the research by a committee called an **Institutional Review Board** (IRB).

IRBs

- IRBs have one paramount responsibility: **to protect the rights and welfare of human research subjects**.
- IRBs are very important to the conduct of human subjects research at this institution and other research institutions, both inside and outside the U.S.
- IRB review and approval relieves us of making that onerous decision and obviates our potential conflict of interest.
- IRBs take into account national and, when appropriate, international ethical standards of research on a study-by-study basis. Protecting human research subjects is their sole responsibility.
- IRBs rarely disapprove proposed research activities. Instead, they strive to work interactively with investigators to assure that the research design is optimal, that risks are minimized benefits maximized, and that outlined study procedures are adequate.
- The IRB staff and IRB Chairpersons are available to assist you. If you need advice or guidance, contact your IRB.

Applications

- Applications of the general principles to the conduct of research leads to consideration of the following requirements:
  - **informed consent,**
  - **risk / benefit assessment**
  - **the selection of subjects of research**

Sell

- FDA Processes
- Standards


U.S. Department of Health & Human Services
www.hhs.gov
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A - Z Subject Index A B C D E F G H I J K L M N O P Q R S T U V W X Y Z #
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Multistate Outbreak of Listeriosis
FDA: Apple Juice is Safe To Drink
Hurricanes: Health and Safety
Drug Shortages
Food Safety Modernization Act
Minority Health
FDA on Flickr and Facebook
FDA-TRACK
More Public Health Focus
Spotlight
Globalization Report
FDA Strategic Priorities 2011-2015
Medical

FDA's Mission Statement

- *"The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health."*

http://www.fda.gov/AboutFDA/CentersOffices/default.htm

What FDA Regulates

- ***"Biologics***
  - *safety of the nation's blood supply, licensing, product standards and develop improved testing methods*
- ***Cosmetics***
  - *Safety, labeling*
- ***Drugs***
  - *product approvals, OTC and prescription drug labeling, drug manufacturing standards*
- ***Foods***
  - *Labeling, safety of all food products (except meat and poultry), bottled water"*
- ***Medical Devices***
  - *premarket approval of new devices*
  - *manufacturing and performance standards*
  - *tracking reports of device malfunctioning and serious adverse reactions*
- ***Radiation-Emitting Electronic Products***
  - *radiation safety performance standards for microwave ovens, television receivers, diagnostic, x-ray equipment, laser products, ultrasonic therapy equipment, mercury vapor lamps, and sunlamps, accrediting and inspecting mammography facilities*
- ***Veterinary Products***
  - *livestock feeds, pet foods, veterinary drugs and devices*

http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm

What FDA Does Not Regulate

- ***Advertising***
- ***Consumer Products.***
- ***Drugs of Abuse***
- ***Health Insurance***
- ***Meat and Poultry***
- ***Pesticides***
- ***Restaurants and Grocery Stores***
- ***Water***

http://www.fda.gov/AboutFDA/WhatWeDo/WhatFDADoesntRegulate/default.htm

Devices


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Key Topics
Device Advice
Device Classification
Guidance Documents
Medical Device User Fees
Approvals and Clearances
CDRH Learn
Radiation-Emitting Products
Regulatory Research
Consumer Resources
Lab Tests
Hearing Aids
LASIK
Glucose Testing Devices
Safety, Recalls & Alerts
Recalls
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FDA Patient Safety News
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More Information on Medical Devices
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E-mail Updates
RSS Feeds
RSS Help
FDA Basics
FDA Basics
FDA Basics For Industry
Spotlight
Globalization Report
Science & Research
Combination Products
Critical Path Initiative
Sentinel Initiative
Public Health Focus
Multistate Outbreak of Listeriosis
FDA: Apple Juice is Safe To Drink
Minority Health
FDA on Flickr and Facebook
FDA-TRACK

Device Advice

History of the FDA and Medical Devices

- 1906 – "the FDA enacted its first regulations addressing public health" although did not address medical devices directly.
- 1938 – Passage of the Federal Food, Drug and Cosmetic (FFD&C) Act to regulate medical devices
- Mid 60's – Electrical Engineers began designed devices for medical applications
- 1969 – the Cooper Committee was formed to address issues with medical devices.
- 1976 – the FDA created amendments to the FFD&C "to assure that medical devices were safe, effective and properly labeled for intended use.
- 1978 – using these amendments, the FDA issued good manufacturing practices (GMPs)
- 1990 – "the Safe Medical Devices Act (SMDA) was passed by Congress to give the FDA authority to add preproduction design validation controls the GMPs".
- 1996 - the new medical device reporting (MDR) regulation was enacted

"Design of Biomedical Devices and Systems", 2nd Edition, King & Fries, CRC Press, 2009.

Device Classes

- "*Class I - General Controls – Non Life Sustaining -* ***Most exempt from Pre-Market Notification***
  - *Class I devices are subject to the least regulatory control.*
  - *minimal potential for harm to the user and are often simpler in design than Class II or Class III devices.*
  - *Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.*
- *Class II - Special Controls – Non Life Sustaining Most require -****Pre-Market Notification (501k)***
  - *Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness*
  - *Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes.*
- *Class III - Premarket Approval - Life Sustaining or Life Supporting -* ***Most require Pre-Market Approval 501k Plus Clinical Data***
  - *Class III is the most stringent regulatory category for devices.*
  - *Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls.*
  - *Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.*
  - *Premarket approval is the required process of scientific review to ensure the safety and effectiveness of Class III devices.*
  - *Examples of Class III devices which currently require a premarket notification include implantable pacemaker pulse generators and endosseous implants.* "

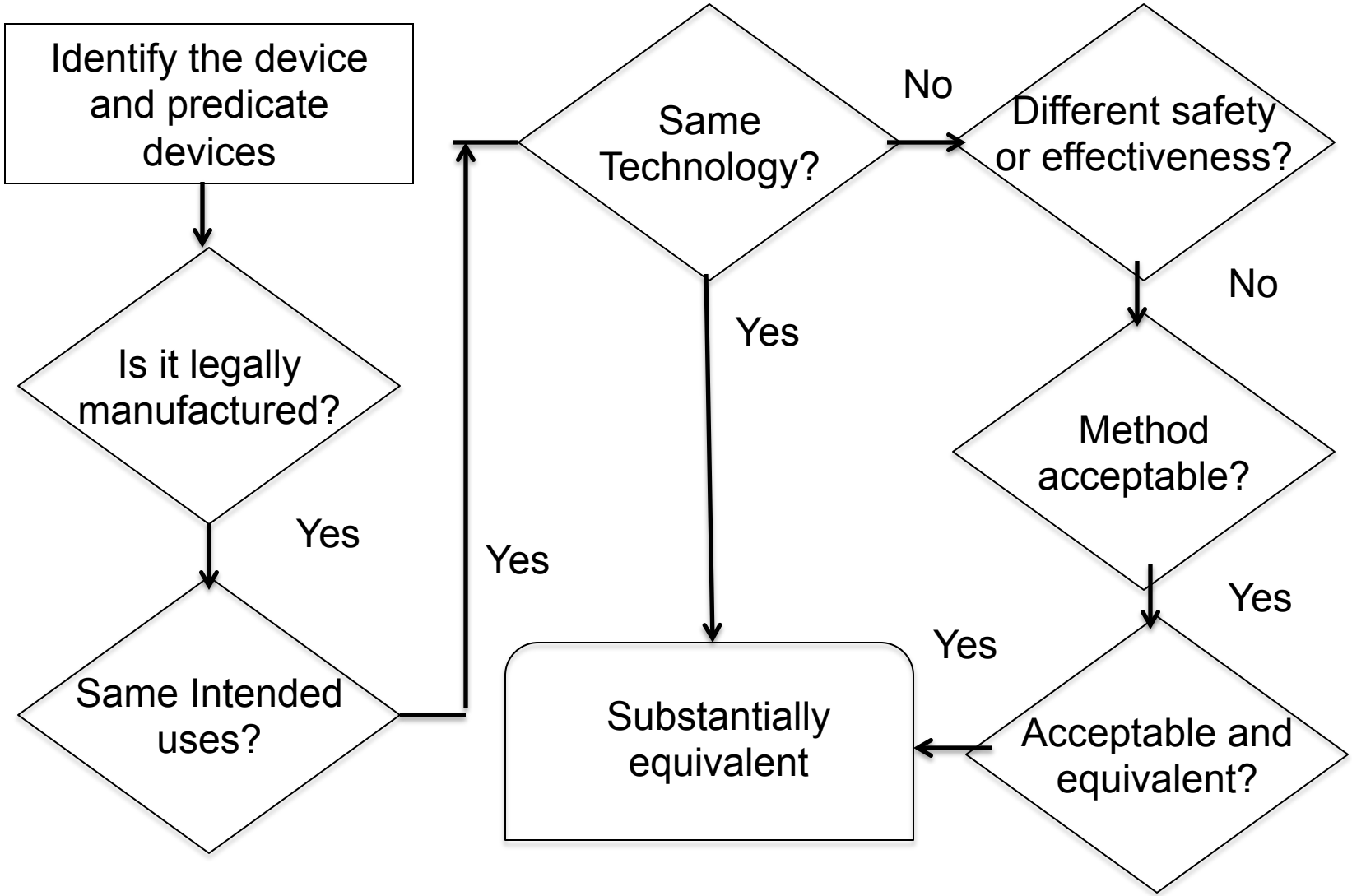
Registration and Listing
Section 510 of the FFD&C

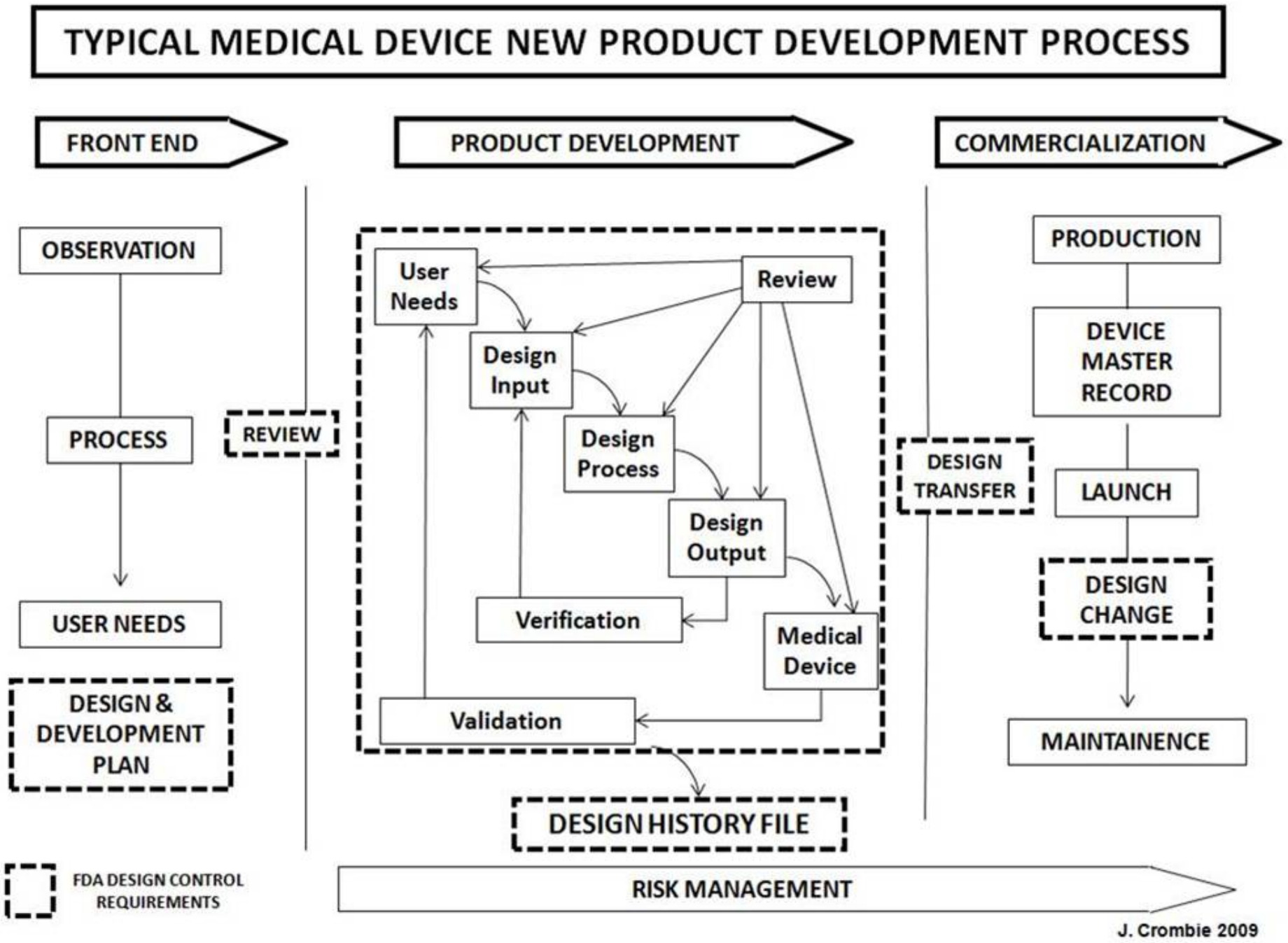
- Determine Substantial Equivalency
  - New device compared to marketed device
  - If comparable, then may get through without full testing.
- Regular 510(k) submission
  - Types
    - Identical
    - Equivalent but not identical
    - Complex devices or major differences
    - Software controlled devices
  - Format
    - Descriptor of device
    - Evidence of performance including both non-clinical and clinical testing and conclusions drawn from these tests
    - Certification
- Special 510(k)
  - E.g. Device Modification
- Special Approval for Class III Devices

"Design of Biomedical Devices and Systems", 2nd Edition, King & Fries, CRC Press, 2009.

501(k) Determining Substantial Equivalency

Design of Biomedical Devices and Systems, 3rd Ed., King, et.al. CRC Press 2015




TYPICAL MEDICAL DEVICE NEW PRODUCT DEVELOPMENT PROCESS
FRONT END
PRODUCT DEVELOPMENT
COMMERCIALIZATION
OBSERVATION
PROCESS
USER NEEDS
DESIGN & DEVELOPMENT PLAN
REVIEW
User Needs
Review
Design Input
Design Process
Design Output
Verification
Medical Device
Validation
DESIGN HISTORY FILE
DESIGN TRANSFER
PRODUCTION
DEVICE MASTER RECORD
LAUNCH
DESIGN CHANGE
MAINTAINENCE
FDA DESIGN CONTROL REQUIREMENTS
RISK MANAGEMENT
J. Crombie 2009

Industrial Standards

Industrial Standards

- In addition to meeting design specs, products must met industry standards
  - Operational standards
  - Safety Standards
  - Quality Process
- US standards vs. International standards

Operational standards

- Examples of Operational Standards
  - EMI
  - EMC
  - EMP
- FCC
- ASTM Formerly a USA Standards Body now international
- NIST
- ASME
- ANSI/IEEE
- ISO International Organization for Standardization

Safety standards

- Examples
  - Electrical
  - Human Consumption
- FDA
- OSHA
- ADA
- UL Underwriters Laboratory
- ISO

Other Standard

- Operational
- Safety

Medical Device Standards

- ASTM American Society for Testing and Materials
  - Develops and publishes voluntary consensus technical standards for a wide variety of materials, products, systems and services.
  - astm.org
  - Book of Standards
  - Section: 13 Medical Devices and Services.

Medical Device Standards

- American Society of Mechanical Engineers
- Promotes the art, science, and practice of multidisciplinary engineering and allied sciences around the globe
  - asme.org
  - Bioprocessing Equipment

Medical Device Standards

- NIST The National Institute of Standards and Technology
  - Physical Sciences laboratory and non-regulatory agency of the US Dept of Commerce to promote innovation and industrial competitiveness
  - nist.gov
  - Biomaterials
  - Biomolecular characterization
  - Cell Biology
  - Bioprocessing

Medical Device Standards

- ANSI American National Standards Institute
- Oversees standards conformity assessment activities in the US
  - ansi.org
  - Biological Evaluation of Medical Devices

Medical Safety Standards

- OSHA Occupational Safety and Health Administration
- Large regulatory agency of the US Dept of Labor
  - osha.org
  - Biological agents
  - Handling Blood
  - Eye and face protection
  - First aid

Medical Safety Standards

- ADA American Disabilities Act of 1990
- Reasonable accommodations for employees with disabilities
- Information and Technical Assistance of the Americans with Disabilities Act
  - ada.gov
  - Medical Care for individual with mobility disabilities
  - Wheel chairs, Mobility Aids, Power Driven Mobility Aids

Quality

- How the product is made

Quality Process standards

- Does the company design and manufacturing processes meet quality standards
  - Are all design and manufacturing processes documented so that workers know how to do their jobs?
    - E.g., Mission, Goals,
  - Does the organization have a method of continuous quality improvement?
- ISO 9000
- Malcolm Baldrige
- Internal organization quality standards

Homework

1. What is the main prime mover of a design project?
2. What is the IRB and where do you find one?
3. What is the function of the FDA with respect to medical devices? What are the classes the FDA uses to define a medical device? What must a developer do to get FDA approval?
4. What are the areas of industrial standards that medical device may have to meet?
5. HONORS STUDENTS ADD THE FOLLOWING

   Go to the FDA website and research what Device Classification Panels are and how they are used. What is the classification code for a electrocardiograph?