eHealth Technologies and the FDA

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Emerging Technology Trends

CDRH TECHNOLOGY FORECAST

- Computer-related Technology
- Molecular Medicine
- Home- and Self-care
- Minimally Invasive Procedures
- Device/Drug Products
- Organ Replacements and Assists

http://www.fda.gov/cdrh/ost/trends/toc.html

Survey Participants

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Medical Device Technology Drivers

- Demographic trends
- Economic trends
- Technology trends

Computer-related device trends

- Substantial new product development 5-10 yrs
- Integrated patient medical information systems
- Smart cards
- Computer-aided medical decisionmaking
- Smart artificial organ implants
- Miniaturized biosensors & sensor “fusion”
- Customized microprocessor devices

Homecare technology trends

- Substantial new product development 5-10 yrs
- Limited expectations for advanced technologies
- Monitoring -- blood, urine, drug concentrations
- Simplified drug delivery systems
- Telemedicine
- Smart devices

Home Care Technologies for the 21st Century

- NSF-FDA Workshop
  - 150 participants
  - Industry
  - Academia
  - Government
  - Clinicians
  - Providers

21st Century Home Care Technology

- Prevention-oriented devices
- Consumer health model
- Noninvasive sensors
- Smart devices
- Customized products, flexible configurations
- Data analysis tools for medical decisions
- Electronic patient records
- Wearable products
- Wireless net-linked systems

US Food & Drug Administration

- Center for Drugs
- Center for Food Safety and Applied Nutrition
- Center for Biologics
- Center for Veterinary Medicine
- Center for Devices and Radiological Health
- National Center for Toxicological Research
- Office of Regional Affairs

CDRH Focus

Ensuring the safety and effectiveness of medical devices

FDA's Mandate for Regulation

- Medical Device Amendments (1976)
- Regulations implementing FD&C Act
  - Title 21 Code of Federal Regulations (21CFR) Parts 800 – 1299
- Safe Medical Devices Act (1990)
- FDA Modernization Act (1997)

What is a medical device?

- Diagnosis, cure, mitigation, treatment or prevention of disease or condition
- Affects the structure and function of the body
- Does not achieve intended use through chemical reaction
- Is not metabolized

Device Classification

- 1700 generic types of devices
- Three Classes
  - Class I
  - Class II
  - Class III
- intended use; intended user
- Classification determines extent of regulatory control

Device Classification

	Risk
Class I *- General Controls*	Low
Class II *- General Controls and Special Controls*	Medium
Class III *- General Controls and Premarket Approval*	High

Premarket approval – 510k

- Marketing for first time, or significant change to existing device
- Demonstration of Substantial Equivalence (SE) to legally marketed device in U.S.
- SE means "As safe and as effective"
  - *engineering*
  - *clinical outcome*

Premarket approval – PMA

- Only applies to Class III devices
  - New device
  - Device found not substantially equivalent
- Proof of safety and effectiveness with clinical data
- Investigational Device Exemption (IDE) may be desired or required

Investigational Device Exemption

- Used for clinical trials
- Significant risk devices
- Protection of human subjects
- Allows sponsor to recoup R&D costs

FDA's Framework --
The traditional strategy

- Regulatory gatekeeper
- Unilateral responsibilities
- Reactive orientation

FDA's Framework --
The emerging strategy

- Multifaceted, information-based strategy
- Collaborative multi-party harmonization
- Anticipatory orientation

eHealth Technology Issues

- What's a Device?
- Labeling
- "Smart Devices"
- Tele-health
- Interacting Systems of Devices
- Architectural Considerations
- Environmental Factors

Action Groupings