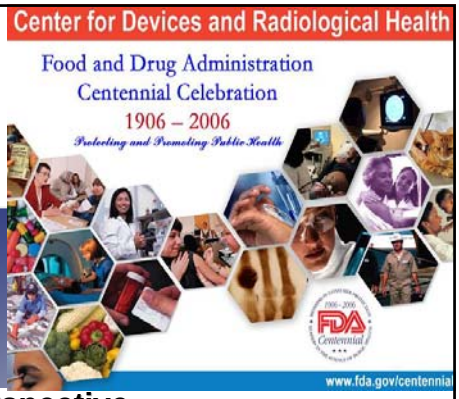
Implementing Risk Management to Your Advantage:



An FDA Perspective

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Points

- **FDA's role/objective in regulating medical devices to protect the public.**
- **Five principles – approaches in implementing risk management.**
- **Examples of FDA's implementation of risk management as a continuous process in the premarket, inspection and postmarket areas.**
- **Emphasis on using science-based, efficient, risk management in regulatory decisions and new initiatives.**

What is FDA's Role? Objective?

The role of FDA Center for Devices and Radiological Health is to establish reasonable assurance of the safety and effectiveness of medical devices marketed in the U.S.

Is our objective to eliminate risk?

Is our objective to control risk?

FDA's Approach – 5 Main Tenets *

1. **Base degree of control on risk**
2. **Weigh probable benefit vs. risk to determine safety and effectiveness**
3. **Use valid scientific evidence**
4. **Consider least burdensome means**
5. **Provide "reasonable assurance"**

** Center Director, Dr. Daniel Schultz, Washington DC 2006 May 18-19 Congress on Global Approaches to Risk Management: Current and Future Developments"*

1. Device Classification – "three categories based upon the degree of risk"

Class I: simple, low risk devices

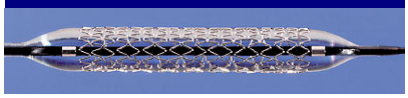
- General controls
- Most exempt from premarket submission

Class II: more complex, higher risk

- Subject to specific regulations or special controls
- Premarket Notification [510(k)]
- Substantial equivalence
- 10-15% require clinical data

Class III: most complex, highest risk

- Life-supporting, life-sustaining or important in preventing impairment of human health
- Data "soup to nuts"
- Premarket Application [PMA]
- Establish safety and effectiveness
- Bench - Animal – Human Studies
- May include post-approval study requirements



Exempt devices / Down classification

- **Exempt devices from premarket notification, 798 (47%)**
  - **Class I 729 (93%)**
  - **Class II 69 (9%)**
- **Reclassification**
  - **Identified risks**
  - **Summary of known potential benefits**
  - **Special controls**

2. Determination of safety and effectiveness

". . . the proposed legislation recognizes that products having the power to be useful in the healing arts also have the potential to do harm and that the is to carefully balance these considerations."

-- Report by the House Committee on Interstate and Foreign Commerce, to accompany the Medical Device Amendments of 1976

3. Use valid scientific evidence

Valid Scientific Evidence [§513(a)(3)]

- **Effectiveness is to be determined by:**
  - **Well-controlled investigations**
    - **1 or more clinical investigations**
    - **qualified experts**
  - **Other valid scientific evidence, if acceptable**

4. Consider least burdensome means

Risk management throughout the total product life cycle using the "Least Burdensome" means for industry.

- **Added by FDAMA (1997)**
- **Applies to PMA or 510(k)**
- **Guidance**

  The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry

  http://www.fda.gov/cdrh/ode/guidance/1332.html

5. Provide "reasonable assurance"

"No regulatory mechanism can guarantee that a product will never cause injury, or will always produce effective results. Rather, the objective of the legislation is . . . reasonable assurance that medical devices are safe and effective."

-- Report by the House Committee on Interstate and Foreign Commerce, to accompany the Medical Device Amendments of 1976

What is our objective?

Is our objective to eliminate risk?

Is our objective to control risk?

Incorporating Risk Management Principles

- **Premarket Review**
- **Postmarket Surveillance**
- **Inspections**
- **Communication of risk/benefit information**

The New 510(k) Paradigm

The New 510(k) Paradigm

Two optional approaches for obtaining marketing clearance

Abbreviated 510(k)

Special 510(k)

Premarket: Recognized Consensus Standards

- **FDA recognizes ISO 14971: 2000, *Medical devices – Application of risk management to medical devices (General).***
- **A declaration of conformity may be used to satisfy the risk management needs for a Special Premarket Notification or 510(k).**
- **If the risk management process indicates the need for a new safety standard, these results should be described in addition to the declaration of conformity.**

Risk Management and New Technology

- FDA regulates medical devices on a product-by product basis.
- FDA does not regulate technologies.
- ISO 14971 may no longer be enough to manage individual risks.
- Expect the manufacturer to document known information about risks:
  - Experience with similar products or materials

Risk Management and New Technology

- Use framework of 14971 to develop risk analysis for new risks.
- Develop an approach to handle unanticipated risks: structure of risk management approach will allow incorporation of new risks into the risk-benefit equation.

Risk Management and New Technology

- Decision-making will continue with standard review practices, including panel approach.
- Medical device review process is not static. As we learn more, we evolve the process.
- Work with reviewers to determine the needs.

Other Expectations

- Must also assure overall risk is acceptable
- Analyzing the risks will require top down and bottom up approaches.
  - Bottom up – induce a failure and determine the harm it can cause, e.g., FMEA failure mode and effects analysis
  - Top-down – select an undesired top-level event and identify the faults that can cause it, e.g. Fault Tree Analysis
- Risk control measures should be included in the analysis.

Postmarket

- Passive surveillance systems (Adverse event reporting): MDR
- Targeted surveillance systems: MedSun
- Condition of Approval Studies (Postmarket study)

Postmarket Components

Problem identification tools include:

- Medical Device Reporting (MDR)
- Targeted surveillance (MedSun)
- Inspections
- Recall notification reports
- Bio-research monitoring (BIMO) investigations
- User complaints and comments
- Competitors complaints
- International vigilance reports
- Manufacturers' reports of device modifications
- Post-approval studies

Risk communication tools include:

- Urgent alerts and notifications
- Multimedia outreach
- Publications
- Presentations

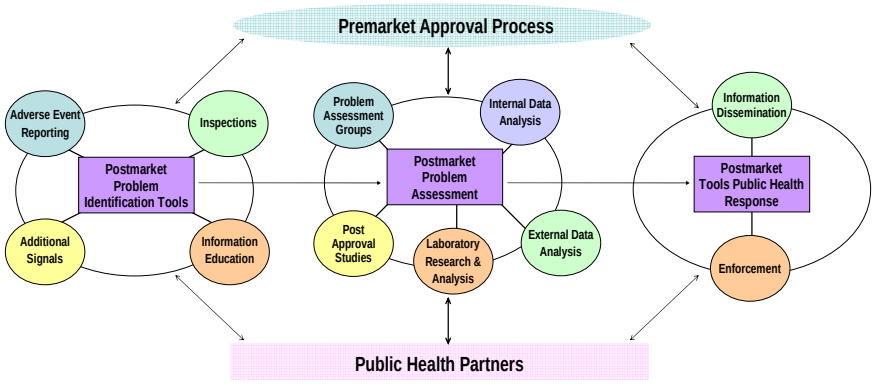
Enforcement actions include:

- Recalls
- Injunctions and seizures
- Detentions of imported products
- Civil Money Penalties

Medical Device Postmarket Transformation Initiative

- **We are assessing the impact of our postmarket safety program and pinpointing areas that are in need of improvement.**
  - **We are looking at the tools we use to identify problems, analyze problems and take action, either regulatory or information dissemination (or both) → Postmarket Report http://www.fda.gov/cdrh/postmarket/mdpi.html**
  - **We are looking into how to better coordinate our efforts, so we can have a better understanding of how devices are performing in the market → *Action Steps***

We must connect the dots…



Postmarket Problem Identification **Postmarket Problem Assessment** **Postmarket Public Health Response**

Risk-Based Compliance Actions Inspection Work Plan

- **A cooperative planning process between ORA and Center**
- **Directs ORA inspectional resources to critical program areas:**
  - **GMP**
  - **BIMO**
  - **MQSA**
  - **RH**
  - **Imports**

Inspection Work Plan (Current Scheme)

- **PMAs -- Class III, typically high risk**
- **For Cause -- Significant safety issues; focused attention**
- **Statutory -- Class II & III; directs compliance program to risk areas and includes performance goals:**
  - **Domestic – 20% of inventory**
  - **Foreign – 7% of inventory**
- **Ad Hoc and special emphasis initiatives**

Correlating Inspection to Risk

- **Developing risk assessment criteria**
  Considers probability and severity of harm
- **Developing the inspection Work Plan**
  Focuses limited field resources on medical devices and manufacturers that present the greatest risk to public health

Risk Management and Quality Systems Regulations

The Quality System (QS) Regulations

- Assure device safety and effectiveness through design and manufacturing controls
- Enable tailoring the controls based on the type of device manufactured
- Are part of premarket review for Class III devices
- Are a key element of assuring postmarket safety for all devices

Risk management techniques

- Are being formalized through standards and training programs
- Are becoming more important to the oversight of devices at all stages of the product life cycle

Risk Management and Quality Systems Regulations

Harmonization

- FDA is involved in harmonization through GHTF
- Quality systems programs in regulations and standards globally are currently quite consistent with FDA QS Regulations

Communication of Risk/benefit Information

- Medical Device in Emergency Situations http://www.fda.gov/cdrh/emergency/index.html
- Medical Device Recalls - The redesigned website provides a web-friendly, plain language overview of medical device recalls http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/medicaldevicesafety/recalls.cfm
- Hospital Bed Safety http://www.fda.gov/cdrh/beds/index.html
- Phakic Intraocular Lenses http://www.fda.gov/cdrh/phakic/
- Maturity Health Matters www.fda.gov/cdrh/maturityhealthmatters/
- E-Consumer Initiative – New services available include email subscription management system and Real Simple Syndication (RSS) feeds

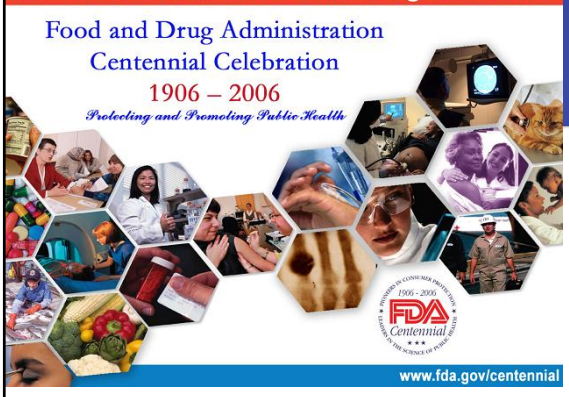
Summary

- Risk-based management is not a new concept; it has always been part of medical practice and our regulatory paradigm
- As medical devices change, the way we manage risk also changes
- As the world of medical devices becomes more complex, we are developing new tools to manage risk in the 21st century

Summary

- With new and better ways to reduce risks to public health, we create and promote efficient risk management.
- By using science-based, efficient risk management in regulatory activities, the agency's limited resources can provide the most health promotion and protection at the least cost for the public.
- Maintaining a strong science base to support FDA's risk management responsibilities builds a strong FDA.

Center for Devices and Radiological Health



Thank you!

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