Risk-Based Approaches to Regulatory Oversight and Compliance

David J. Horowitz, Esq.
Deputy Associate Commissioner
for Compliance Policy
Office of Regulatory Affairs
U.S. Food and Drug Administration

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Overview

- What is “risk” and “risk management”
- Relevance to FDA’s regulatory compliance work
  - FDA’s mission as it pertains to regulatory compliance
  - Supporting and inducing industry risk management
  - Directly managing risks with inspection and compliance tools
  - Prioritizing and focusing based on risk
    - Stages or levels of risk management
- Measuring risk management performance
- Selected risk management challenges and opportunities

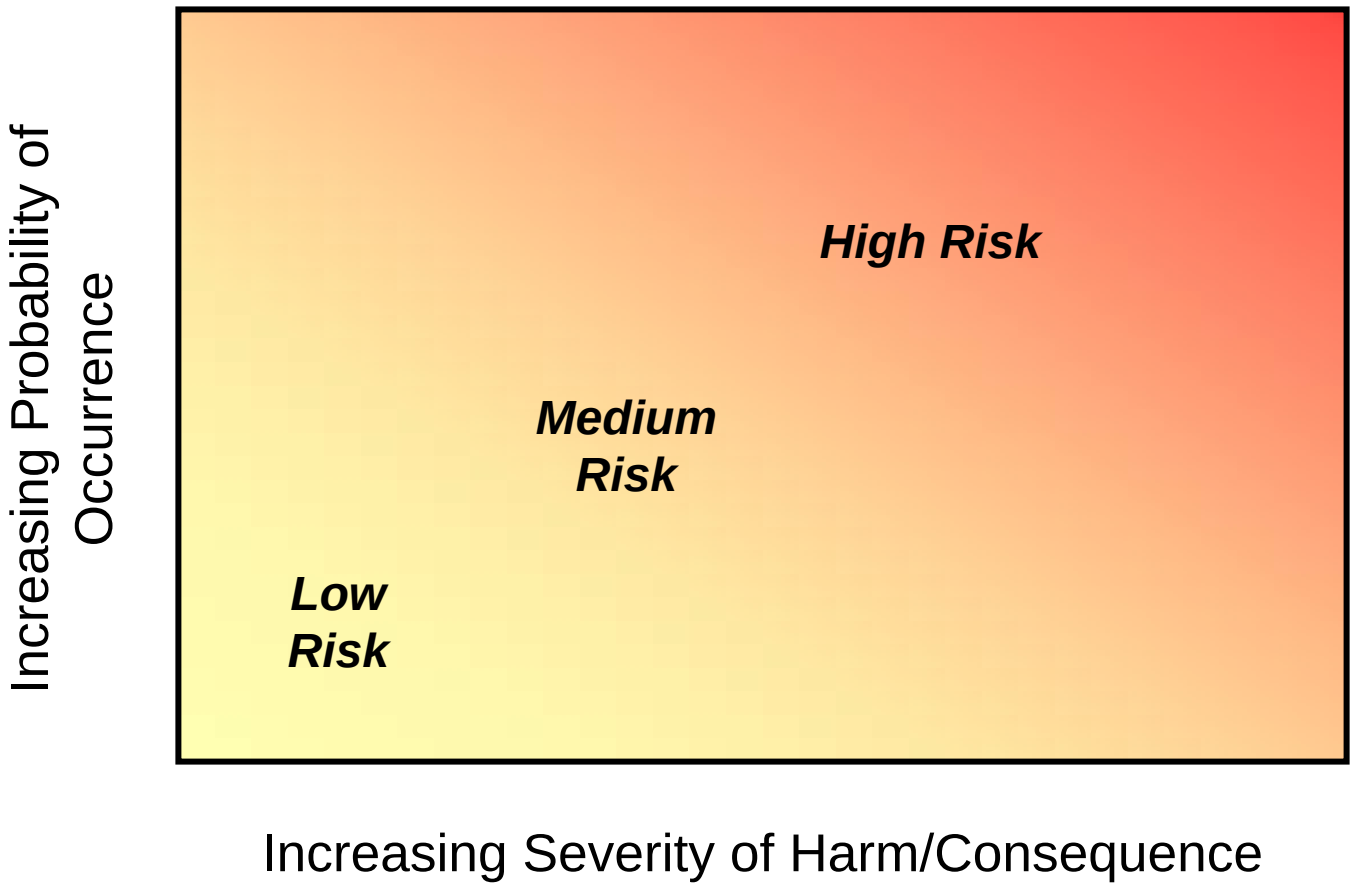
What is Risk?

- Everyone intuitively knows what it means, but it doesn't have the same meaning to everyone.
  - Greater clarity and transparency are needed.
- It's a term that can be defined, but it's also a concept that cannot be fully grasped and applied through a simple definition.
  - More description and explanation is needed to appreciate what it means and how it relates to different aspects of FDA's work.

Definition of Risk

- Informally used to mean a “chance” of something bad happening
  - Used (in error) as a synonym for probability
- Risk is defined as the *combination* of
  - the **probability** (or likelihood) of the occurrence of **harm;** and
  - the **severity** of that **harm**.
- Includes concepts of **hazard** and **exposure**

Definition of Risk (cont'd)



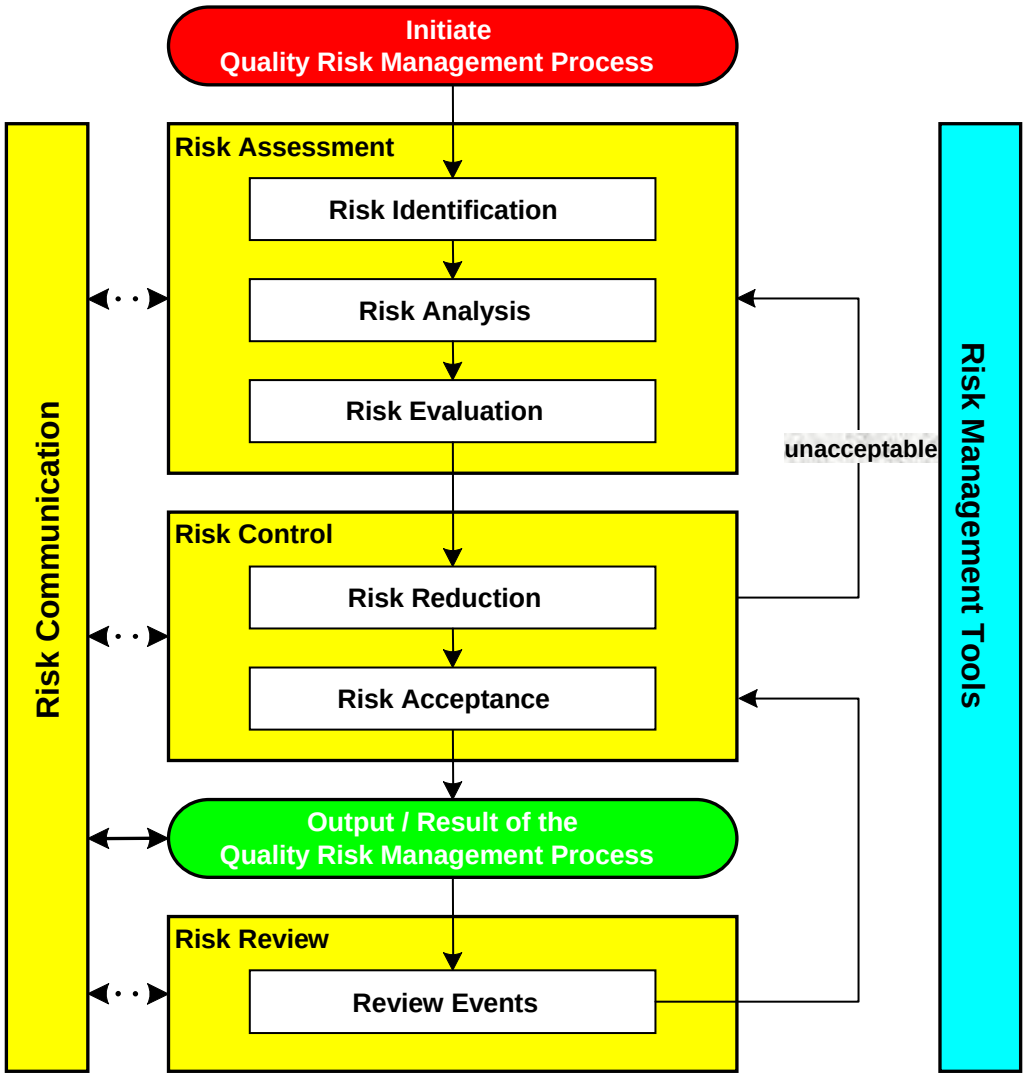
Definition of Risk (cont'd)

- The risk to what?
  - The meaning of risk is dependent on the "harm" on which you focus.
  - For FDA, we usually focus on damage to health/safety (associated with unsafe foods or unsafe/ineffective medical products) as the primary "harm".
    - Innate toxicities associated with a medical product vs. other "harms" that FDA must address to protect public health.
  - Compliance risk as a surrogate for public health risk?

What Is Risk Management?

- International Conference on Harmonization (ICH) Q9, based on ISO definitions:
  - "the systematic application of … **policies, procedures, and practices** to the tasks of **assessing, controlling, communicating, and reviewing risk**."
- Risk management is an umbrella term that includes **assessing** and **controlling** risks.
- For our purposes, usually synonymous with "risk-based approaches."

ICH Q9 Risk Management Process



Relevance to FDA's Regulatory Compliance Work

- **FDA 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.

- How do we "protect" public health?

Relevance to FDA's Regulatory Compliance Work (cont'd)

- **ORA Vision Statement:**
  - All food is safe; all medical products are safe and effective; and the public health is advanced and protected.
- **ORA Mission Statement:**
  - ORA **protects consumers and enhances public health** by maximizing compliance of FDA-regulated products and ***minimizing risks*** associated with those products.

Relevance to FDA's Regulatory Compliance Work (cont'd)

- FDA's been in the business of risk management for over 100 years!
  - Increasingly important in addressing limited resources in the face of expanding responsibilities
- FDA's mission is about protecting public health by controlling risk.
- FDA is a science-based agency, and risk management is about making the best use of that science to achieve our mission.

Relevance to FDA's Regulatory Compliance Work (cont'd)

- One of main risk management functions we perform involves overseeing and encouraging industry to properly use risk management concepts and tools (e.g., HACCP, FMEA, and quality systems).
  - One way we control risk is by creating the necessary incentives to ensure that industry does a good job managing risk.
  - Compliance and enforcement tools are important to maintain those incentives.

Relevance to FDA's Regulatory Compliance Work (cont'd)

- Our surveillance and compliance activities can be viewed as a risk control enterprise
  - Surveillance activities (e.g., inspections) can be viewed as *risk assessment* activities
    - They involve identifying risks, analyzing them, and evaluating them
  - Compliance activities (e.g., seizure) can be viewed as *risk control* activities
- FDA/ORA manages risk by reducing consumer exposure to unsafe and/or ineffective products through prevention, detection, and interception.

Relevance to FDA's Regulatory Compliance Work (cont'd)

- Most of our risk management activities, until more recently, have been informal and empirical.
- Modern risk management concepts and tools allow us to be more **systematic** and **transparent** in our approaches
  - Facilitate greater consistency and uniformity across organizational and geographic boundaries
  - Facilitate peer review and continuous improvement

Relevance to FDA's Regulatory Compliance Work (cont'd)

- Risk management can also be viewed as *a lens to focus and prioritize our work of minimizing risk*
  - Limited resources; expanding responsibilities.
- Risk concepts and tools can help us:
  - prioritize and manage discretion (e.g., *what* we work on and *how* we do it);
  - prioritize risks and make sure we're getting the biggest risks (and "risk concentrations") before we divert too much attention to the smaller ones;
  - Maximize our impact on public health protection
- Concepts/tools applied at different levels

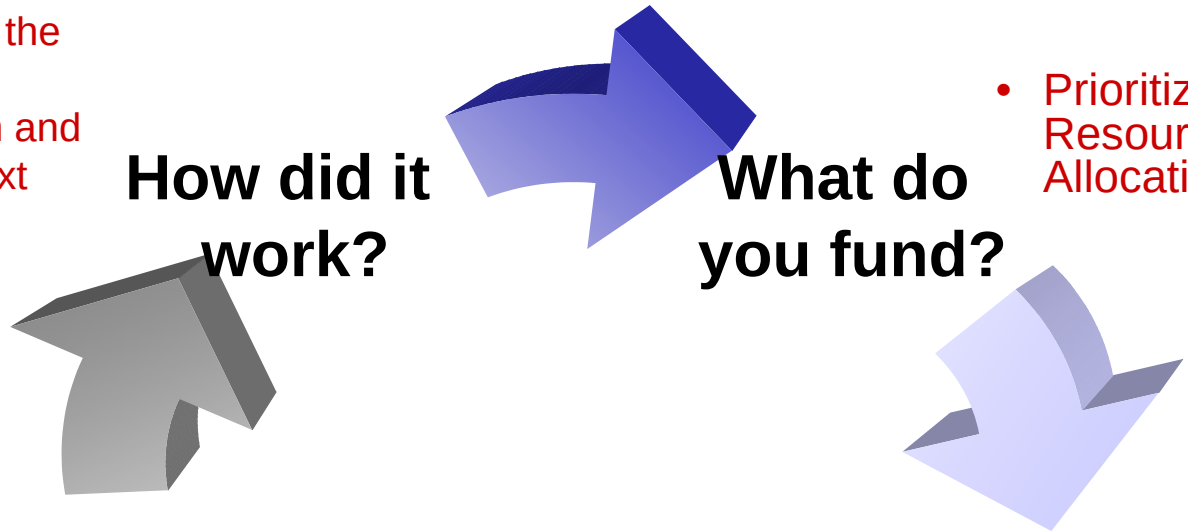
Stages of Risk Management

- Assessment of the prior year's implementation and changes for next cycle

How did it work?

What do you fund?

- Prioritizing Resource Allocation



- Prioritizing Regulatory Response

What do you do about it?

Where do you go?

- Prioritizing Site Selection

What do you look at?

- Prioritizing the subject matter of inspection/analysis

Stages of Risk Management

1. **What you fund? (*Prioritizing resource allocation*)**
   - Which compliance programs and activities achieve the greatest risk-reduction?
     - Balanced against longer-term investments
   - Work planning and resource allocation
   - Strategically allocate resources based on rigorously developed/updated priorities

Stages of Risk Management (cont'd)

2. **Where you go? (*Prioritizing sites*)**
   - Which inspection sites are expected to lead to the greatest risk reduction?
   - Site selection; consumer complaint response; inspectional assignments
   - Risk-based prioritization of inspection sites using risk tools

Stages of Risk Management (cont'd)

3. **What you look at? (*Prioritizing the subject matter of the inspection/analysis*)**
   - Which subjects of inspection/analysis are expected to lead to the most risk reduction?
   - Compliance programs; sample collection and analyses; field exams; import screening
   - Scope, focus, and intensity of inspection/analysis
   - Prioritizing by products, processes
   - Fully explore violations that appear most connected with public health risk

Stages of Risk Management (cont'd)

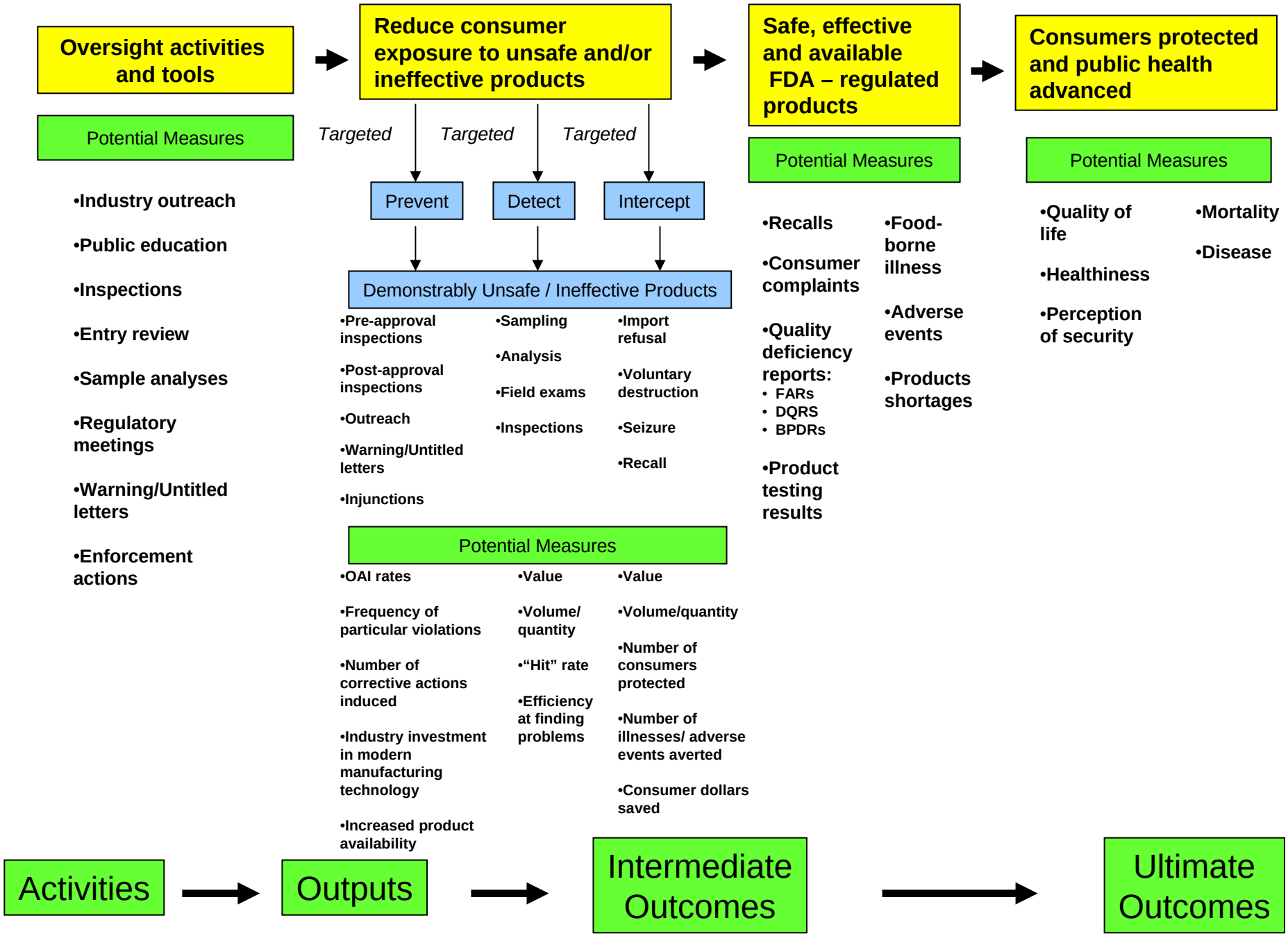
4. **What you do about it? (*prioritizing response*)**
   - Which compliance tools/options are expected to lead to the most risk reduction?
   - Outreach, guidance, 483s, violation letters, regulatory meetings, enforcement
   - Interpreting the significance of observations
   - Aligning:
     - the resources consumed by the regulatory response; and
     - amount of risk-reduction that can be achieved.

Stages of Risk Management (cont'd)

- Selecting the best targets for regulatory attention
- Maximizing impact from regulatory action; not just numbers
- Risk Management does **NOT**:
  - Exempt industry from complying with regulatory requirements; or
  - Shift the burden to FDA to demonstrate actual harm;
    - » Prevention remains a highly effective RM tool;
    - » Elements of a quality system cannot be viewed in isolation to minimize their relevance to actual risk

Stages of Risk Management (cont'd)

5. **How did it work? (Assessment/Evaluation)**
   - Analyze data and information available
   - Assess implementation
   - Evaluate program effectiveness
   - Adjust targeting
   - Consider changes in resources and regulatory environment
   - Feed forward to the other stages of risk management
   - Invest in measurement and analysis


Oversight activities and tools
Potential Measures
•Industry outreach
•Public education
•Inspections
•Entry review
•Sample analyses
•Regulatory meetings
•Warning/Untitled letters
•Enforcement actions
Reduce consumer exposure to unsafe and/or ineffective products
Targeted
Targeted
Targeted
Prevent
Detect
Intercept
Demonstrably Unsafe / Ineffective Products
•Pre-approval inspections
•Post-approval inspections
•Outreach
•Warning/Untitled letters
•Injunctions
•Sampling
•Analysis
•Field exams
•Inspections
•Import refusal
•Voluntary destruction
•Seizure
•Recall
Potential Measures
•OAI rates
•Frequency of particular violations
•Number of corrective actions induced
•Industry investment in modern manufacturing technology
•Increased product availability
•Value
•Volume/ quantity
•"Hit" rate
•Efficiency at finding problems
•Value
•Volume/quantity
•Number of consumers protected
•Number of illnesses/ adverse events averted
•Consumer dollars saved
Safe, effective and available FDA – regulated products
Potential Measures
•Recalls
•Consumer complaints
•Quality deficiency reports:
• FARs
• DQRS
• BPDRs
•Product testing results
•Food-borne illness
•Adverse events
•Products shortages
Consumers protected and public health advanced
Potential Measures
•Quality of life
•Healthiness
•Perception of security
•Mortality
•Disease
Activities
Outputs
Intermediate Outcomes
Ultimate Outcomes

Selected Risk Management Challenges

- Balancing the targeting of known risks against the need for surveillance to identify and assess previously unknown risks.
- Balancing public health/safety focus with the need to preserve the integrity of regulatory systems and deter legal violations
  - Fraud and economic adulteration
  - Auditing low risk areas

Risk Management Opportunities

- FDA is aggressively working across a wide range of programs, developing and implementing more rigorous risk-based approaches to most effectively achieve our mission.
- Risk management, based on strong science, helps articulate the basis and relevance of our programs and activities.
- Risk management also provides a conceptual framework that helps unify and focus FDA's diverse activities—including compliance/enforcement work—in support of FDA's mission.

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