Using Standards to Enable Product Approval

Don Marlowe

Office of the Commissioner

Office of Science and Health Coordination

Outline

- FDA and Voluntary Consensus Standards
- History of FDA Participation in the Development and Use of Standards
- Getting a Product to Market
- FDA and Nanotechnology Standards

FDA Policy

- FDA employs voluntary consensus standards (VCS) wherever possible to enable the regulatory process
  - Describe measurement process
  - Test methods
  - Terminology and nomenclature

FDA's Commitment to Standards

- National Technology Transfer and Advancement Act (NTTAA) (PL104-113)
- OMB Circular A119
- FDA Commitment to international harmonization (1995 FR Notice)
- Key link in the "Critical Path"

FDA's History with Standards

- Every FDA Center works with specific SDOs to develop standards
  - > 160 SDOs have programs with FDA
- Committees meeting this week in Reno
  - ASTM E 20 Temperature Measurement
  - ASTM F04 Medical and Surgical Implants and Materials
  - ASTM F29 – Anesthetic and Respiratory Equipment

FDA's Uses Standards to Enable Product Development

- Biologics – CCLS, ASTM
- Drugs – USP, ICH, HL7, ASTM
- Devices and Radiological Health – AAMI, ASTM, CCLS, ISO, IEC
- Foods and Cosmetics – CODEX, ISO
- Veterinary Medicine – VICH, CCLS
- FDA is an ANSI member

FDA Standards Management

Roles of FDA Offices

- Office of Science and Health Coordination is responsible for coordinating consensus standards development and developing internal FDA procedures
- Office of International Programs is responsible for coordinating international activities, including standards participation, as they relate to the agency's international policy issues

FDA's Strategic Standards Vision

- Reinforce the Standards Policy
- Standards Coordination
  - Develop and operate a unified technical standards system
  - Establish FDA Standards Management System
  - Embody a Strategic Standards Manager
  - Greater internal coordination and communication

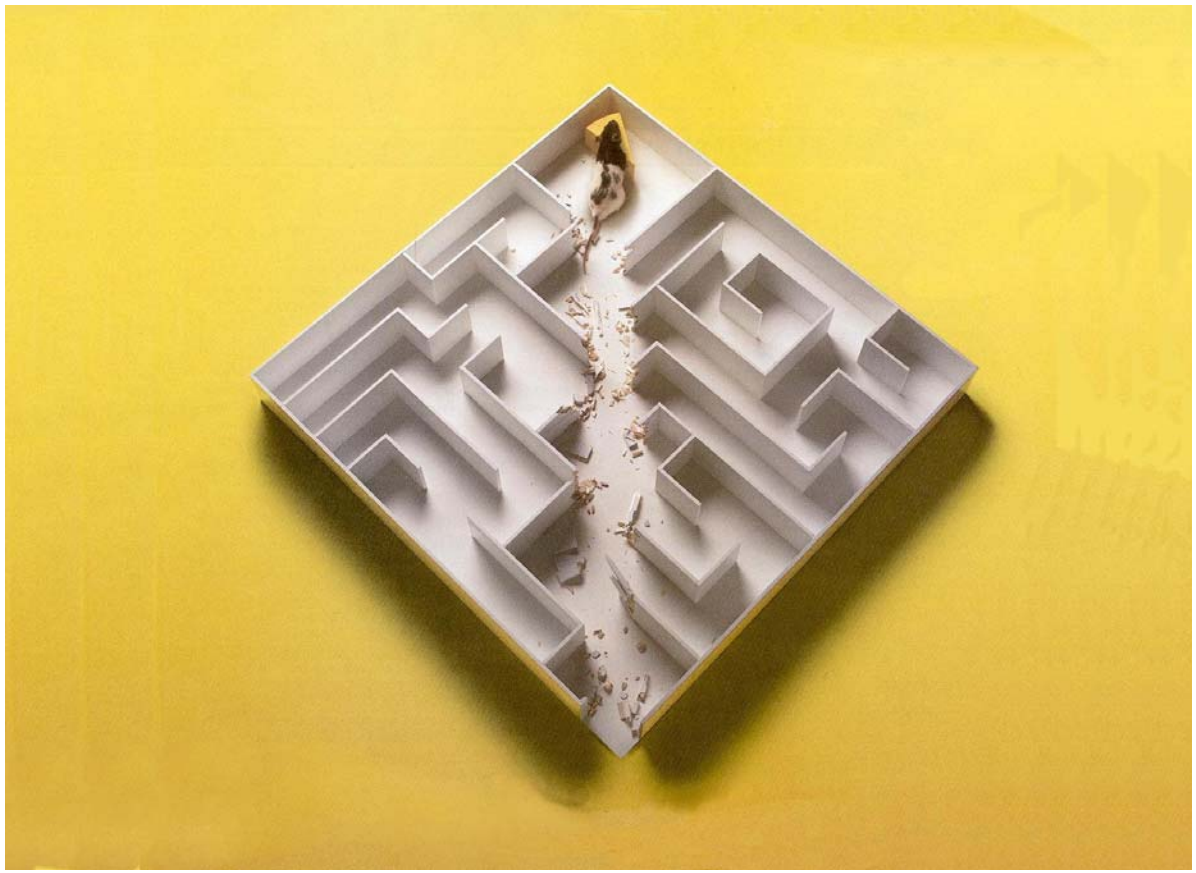
Rationale behind the Vision

1. Addresses the FDA's Performance Plan
2. Optimizes FDA and manufacturer's resources
3. Accomplishes International Trade Commitment
4. Strengthens cooperation between governments
5. Partners with manufacturers to reduce risks
6. Enables productivity improvements
7. Improves the quality of FDA participation

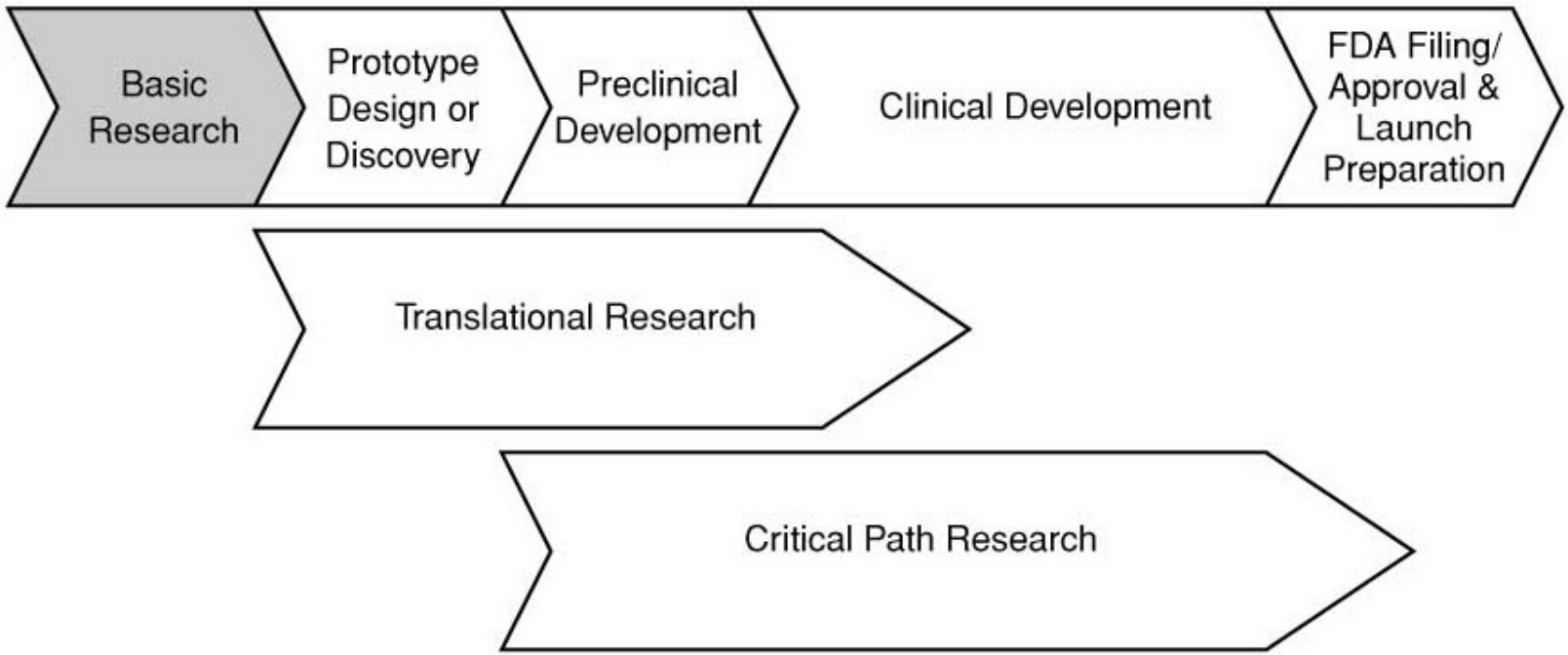
1) Addresses elements of the FDA Performance Plan

- Standards enable the FDA Critical Path Initiative
- FDA Standards Initiative relates to Strategic Mapping of FDA Activities to Outcomes
- The Standards Initiative supports the provision of clear standards, guidance and predictive analytic tools

What is the ”Critical Path”?



Critical Path to Product Approval



2) Optimizes FDA's and manufacturer's resources

- Reduce the overlap between standards and FDA regulatory development
- Strongly encourage standards development organizations to avoid overlapping activities
  - Intent: fewer company and FDA resources being used to participate in multiple venues

3) Accomplishes international trade commitments

- FDA seeks to increase FDA recognition of globally recognized standards, the backbone of international trade agreements

4) Strengthens cooperation between governments

- FDA's participation in multinational regulatory harmonization forums (e.g., GHTF, ICH, VICH and CHIC) will be strengthened
- Standards provide a common starting point on regulatory cooperation between governments

5) Partners with manufacturers of regulated products to reduce risks

- Identification of risks and their reduction to acceptable levels is the principle underlying good standards development for a product
- Strengthens FDA's partnership with the industry and other stakeholders in identification of the risks and addressing their management
- If necessary, FDA can adopt/recognize/use the standard but still develop additional requirements through guidance to meet its needs

6) Enables productivity improvements by regulated industry

- Basing FDA requirements on accepted global standards promotes health and facilitates commerce

7) Improve the quality of FDA participation

- Train FDA liaisons to SDOs in political and trade issues
- FDA sees value in consistent participation and deliberation
- Agency-wide coordination and trouble-shooting

Regulatory Pathways

- Premarket Approval
  - Drugs, high risk medical devices (Class III)
- Market Clearance
  - Moderate risk medical devices (510(k)), drugs manufactured to monographs
- Post-Market Review
  - Foods, cosmetics, low risk medical devices, dietary supplements

FDA Regulated Products

- Foods
  - All interstate domestic and imported, including produce, fish, shellfish, eggs, milk (not meat)
  - Bottled water
- Food additives
  - Colors
  - Food containers
- Cosmetics
- Dietary supplements
- Animal feeds
- Sterilants
- Pharmaceuticals
  - Human
  - Animal
  - Tamper resistant packaging
- Medical Devices
- Radiation Emitting Electronic Products
- Vaccines
- Blood products
- Tissues

FDA Regulation

- FDA regulates on a “Product by Product” basis
  - FDA regulates to the “claims” made by the product sponsor
- FDA anticipates that many nanoproducts will be “Combination Products”
  - “primary intended mode of action”

FDA, Standards and Nanotechnology

- Background – FDA believes that nanoproducts will be important in every product area we regulate
- Policy - FDA believes that the existing battery of pharmacotoxicity tests is probably adequate for most nanotechnology products that we will regulate. As new toxicological risks that derive from the new materials and/or new conformations of existing materials are identified, new tests will be required.

Nanotechnology Standards

- Participation
  - ANSI Nanotechnology Standards Panel
  - ASTM E56
- Website - www.fda.gov/nanotechnology

FDA's Issues w.r.t. Nanotechnology

- A high percentage of new applications will be "Combination Products"
- FDA regulates products, not "technology".
- FDA has limited authority over some products

Examples of Potentially Applicable ASTM Standards

- C 1274 Test Method for Advanced Ceramic Specific Surface Area by Physical Adsorption
- F1877 – Practice for Characterization of Particles
- F1903 – Practice for Testing for Biological Responses to Particles *in-Vitro*
- F 1904 – Practice for Testing the Biological Response to Particles *in-Vivo*

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