Moving Nanotechnology Forward: Performance Assessment

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FDA Perspective on Nanotechnology

- Nanotechnology has great potential for cancer diagnostics and therapeutics
  - Novel drug delivery systems
  - Imaging and therapeutic monitoring
  - New approaches in clinical diagnostics (proteomics; DNA microarrays)
  - Multi-component, targeted therapeutics
- Development Pathway (Critical Path) for Nanotechnology Products Must be Defined

Critical Path for Nanotechnology

- Critical Path: Defined steps and hurdles between a scientific idea and a commercial product.
- Performance in Several Dimensions:
  - Safety
  - Effectiveness
  - Industrialization (mass production)
- Nanotechnology an Element under Evaluation in FDA's Critical Path Initiative

Crucial Nanotechnology Hurdles

- Safety Assessment
  - Framework for common nanomaterials
  - Adequacy of current toxicologic screens for nano-scale materials
  - Potential for novel, unanticipated reactions
  - Environmental consequences of medical use
- Industrialization
  - Understanding the physical parameters that are crucial to product performance
  - Developing test methods and specifications to control product/process
  - Scale up to mass production
- Efficacy: No Experiences with Clinical Testing

Collaborations between NCI and FDA

- Inter-agency Oncology Task Force (IOTF)
  - Sub-committee on Nanotechnology
- Nanotechnology Characterization Laboratory (NCL) will define biological/physical characteristics of nano materials to:
  - Facilitate therapeutic/diagnostic development
  - Develop the science base to inform regulatory processes
  - Contribute to standards development for nanotechnology clinical assessment

Regulatory Issues for Nanotechnology Cancer Products

- Multifunctional nanoproducts – may have multiple functionalities (e.g. Imaging diagnostic plus drug delivery) embedded in one particle
- Combination products – functionality of a drug and a device
- Nomenclature: will need to develop standard nomenclature for these products