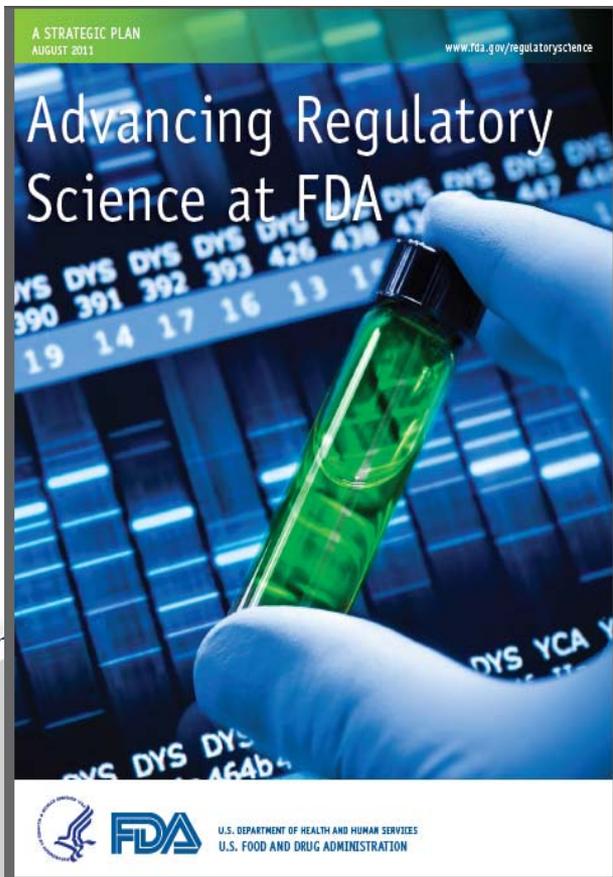


Advancing Regulatory Science at FDA: Strategic Plan



Jesse L. Goodman, MD, MPH
Chief Scientist, FDA
FDA Science Board
August 19, 2011



U.S. Food and Drug Administration
Advancing Regulatory Science

VISION STATEMENT

“FDA will advance regulatory science to speed innovation, improve regulatory decision-making, and get safe and effective products to people in need. 21st Century regulatory science will be a driving force as FDA works with diverse partners to protect and promote the health of our nation and the global community”



U.S. Food and Drug Administration
Advancing Regulatory Science

Purpose

- Identify and communicate priority opportunity areas of regulatory science where new or enhanced engagement/collaboration is essential to the success of FDA's public health mission
- Develop/use the 21st century regulatory science tools and approaches needed for development and evaluation of 21st century products
- Promote innovation through targeted and collaborative approaches to regulatory science that enable new technologies and product development paradigms – *getting needed products to people, safely*
- Build FDA's scientific capacity, infrastructure, culture and collaborations, including through scientific and professional development of FDA's scientists

How was the Plan Developed?

- Science and Innovation Strategic Advisory Council (SISAC, includes Center Directors +1 Senior Scientist, Chief Scientist) set priority areas
- Senior Science Council took leadership role in developing plan with support from the Office of the Chief Scientist
- Writing Teams from SSC, including additional subject matter experts, drafted plan
- Review and feedback provided by SISAC and OCS
- Final draft



What the Plan Is and Is Not

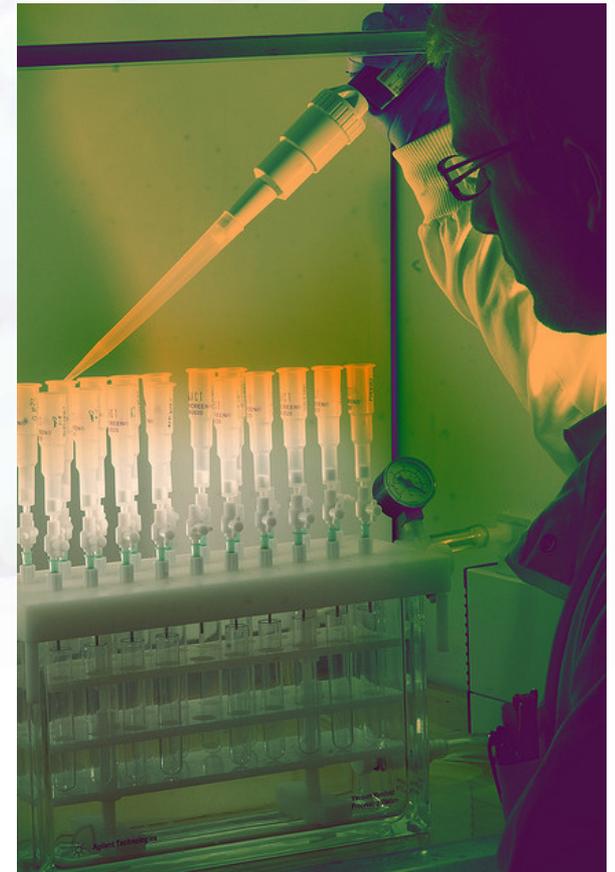
- It is FDA's current view of high priority cross-cutting opportunities and needs, and action areas for implementation
- It is intended to help guide our cross-agency scientific focus, resources and activities
- It is a living document to be revisited and modified as appropriate
- It is not just for laboratory science but also to support scientists and scientific needs in review, manufacturing, population and behavioral sciences
- It does not reflect all FDA science activities driven by our mission and responsibilities. FDA Centers/ORA field offices engage in other activities, and in many cases have specific scientific plans
- Its goals cannot, and should not, be accomplished by just FDA
- While resources affect how much we can do, we recognize the budget environment and believe we can engage with diverse partners and help enable real progress with existing resources

Eight (8) Priority Areas

- Modernize Toxicology to Enhance Safety
- Stimulate Innovation in Clinical Evaluation & Personalized Medicine
- Support new Approaches to Improve Product Manufacturing and Quality
- Ensure FDA Readiness to Evaluate Emerging Technologies
- Harness Diverse Data through Information Sciences to Improve Health Outcomes
- Enable a Prevention Focused Food Safety System
- Facilitate Development of Medical Countermeasures to Protect US and Global Health and Security
- Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions

1. Modernize Toxicology to Enhance Product Safety

- Develop better models of human adverse response
- Identify and evaluate biomarkers and endpoints that can be used in non-clinical and clinical evaluations
- Use and develop computational methods and in silico modeling



2.

Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development and Patient Outcomes

- Develop and refine clinical trial designs, endpoints and analysis methods
- Leverage existing and future clinical trial data
- Identify and qualify biomarkers and study endpoints
- Increase the accuracy and consistency, and reduce inter-platform variability of analytical methods to measure biomarkers
- Develop a virtual physiologic patient

3.

Support New Approaches to Improve Product Manufacturing and Quality

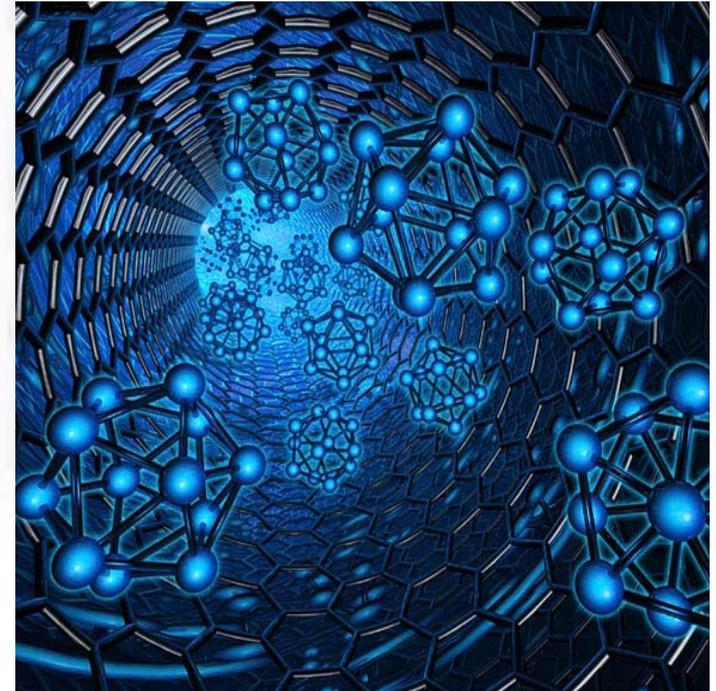
- Enable development and evaluation of novel and improved manufacturing methods
- Develop new analytical methods
- Reduce risk of microbial contamination of products



4.

Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

- Stimulate development of innovative medical products while concurrently developing novel assessment tools and methodologies
- Develop assessment tools for novel therapies
- Assure safe and effective medical innovation
- Coordinate regulatory science for emerging technology product areas



5. Harness Diverse Data through Information Sciences to Improve Health Outcomes

- Enhance information technology infrastructure development and data mining
- Develop and apply simulation models for product life cycles, risk assessment, and other regulatory science uses
- Analyze large scale clinical and preclinical data sets
- Incorporate knowledge from FDA regulatory files into a database integrating a broad array of data types
- Develop new data sources and innovative analytical methods and approaches



6. Implement a New Prevention- Focused Food Safety System to Protect Public Health



- Establish and implement centralized planning and performance measurement processes
- Improve information sharing internally and externally
- Maintain mission critical science capabilities
- Cultivate expert institutional knowledge

7.

Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security

- Develop, characterize, and qualify animal models for MCM development
- Modernize tools to evaluate MCM product safety, efficacy, and quality
- Develop and qualify biomarkers of diseases or conditions
- Enhance emergency communication



8.

Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products

- Know the audience
- Reach the audience
- Ensure audience understanding
- Evaluate the effectiveness of communication about regulated products

Key Implementation Components: Collaboration, Professional Development

- *Goals: leverage expertise, resources, enhance culture of collaboration, promote scientific and career development*
- Partnerships with Government Agencies
- Staff Scientific Training and Professional Development and exchanges
- Direct Funding Mechanisms
- Public-Private Partnerships



Summing Up

- We intend this plan as a foundation that is both realistic and aspirational
- Multi-sectoral and global engagement and collaboration is essential and a given
- We seek and we see present and future outcomes that include:
 - New knowledge
 - New scientific tools, pathways, approaches and guidance to improve and speed product development, evaluation, manufacturing, quality and monitoring
 - FDA scientific staff engaged in cutting edge technologies and innovators with better tools for and understanding of product evaluation
 - Needed products to people faster, safer, and more efficiently, including in emergencies
 - Product use tailored to maximize benefit and minimize risk to every person
 - **Improved health, safety and security**
- *We welcome discussion and continuing engagement*

Acknowledgements

Writing Team Leads

- Jeanne Anson
- Thomas Colatsky
- Lawrence Dusold
- Jan Johannessen
- Michelle McMurry-Heath
- Steve Pollack
- David White
- Carolyn Wilson
- Don Zink
- Carlos Pena

FDA Organizational Components & Working Groups

- SISAC (Center Directors)
- Foods Program Science and Research Steering Committee
- Office of the Chief Scientist
- Office of External Affairs
- Office of Minority Health
- Office of Women's Health
- Science and Innovation Senior Advisory Council
- Senior Science Council
- Scientific Computing Board