Office of the Chief Scientist and
Principal Deputy Commissioner
US Food and Drug Administration

Report on Status of Regulatory Science at FDA: Progress, Plans and Challenges

Frank M. Torti, M.D., M.P.H.

This report outlines the initiatives and efforts undertaken to ensure that the scientific base at the Food and Drug Administration is robust, effective, and targeted to its regulatory responsibility to protect and promote health through ensuring the safety and effectiveness of human and veterinary drugs, biologics, and devices and the safety of foods and cosmetics.

EXECUTIVE SUMMARY

The regulatory and public health decisions promulgated by the FDA are based upon the weight of scientific evidence. High quality scientific judgment applied by well trained physicians and scientists who have access to modern information and analytic systems will improve regulatory decisions, regulatory consistency and speed the approval of new products.

To achieve this vision the Office of the Chief Scientist has developed a scientific strategy guided by five principles:

I. FDA Must Develop an Overarching Scientific Strategy with an Accompanying Implementation Plan, Deliverables, Timetables and Budget.
II. The FDA Scientific Strategy Must be Preemptive
III. FDA Must Maintain and Enhance its Infrastructure, Core Expertise and Human Capital
IV. FDA Must Tell its Story
V. FDA Cannot do it Alone

FDA has initiated and developed a number of programs to strengthen the Agency's research programs, to improve recruitment and retention and to enhance the quality of regulatory science at FDA. These programs have been developed with the guidance of a number of reports and recommendations, including FDA's scientific advisory board (Science Board) report (*FDA Science and Mission at Risk*, November 2007) and the Institute of Medicine (IOM) reports (*The Future of Drug Safety: Promoting and Protecting the Health of the Public,* 2006 and *Challenges for the FDA: The Future of Drug Safety*, 2007) as well as ongoing interactions with the Science Board.

Scope and Intent of this Report

This report presents a number of efforts that FDA has initiated to define, or perhaps re-define, the future of the agency through the development of its scientific capability and infrastructure. The efforts and programs that have been initiated build on the recommendations of the FDA's Science Board report (*FDA Science and Mission at Risk*, November 2007), which suggested the establishment of scientific leadership, organization, and priority setting for investments, the development of the capacity and capability of its workforce, and the creation of an information technology infrastructure integrated with and supportive of science. These efforts also reflect the Institute of Medicine reports (*The Future of Drug Safety: Promoting and Protecting the Health of the Public,* 2006 and *Challenges for the FDA: The Future of Drug Safety,* 2007*)*, as well as the recommendations of stakeholders and constituencies that have testified before Congress, external reviews and workshops sponsored by the Brookings Institute, and many others. Perhaps most importantly, it reflects the duties of the Office of the Chief Scientist as outlined in the Food and Drug Administration Amendments Act of 2007.

The report focuses on the efforts the agency has made to develop a scientific vision and strategy as well as early steps toward implementation. It does not directly address the needs identified in the Science Board report for work force additions, which in part have been met by the agency's recent hiring efforts. During fiscal year 2008, FDA filled over 1300 positions, including backfills, in a variety of scientific, regulatory, public health, and support occupations. Further, the agency is implementing targeted, science based activities such as the Food Protection Plan (http://www.fda.gov/oc/initiatives/advance/food.html) and the Action Plan for Import Safety (http://www.fda.gov/oc/initiatives/advance/food.html) that are not discussed in this report.

Scientific Leadership

On May 15, 2008, Dr. Frank M. Torti was appointed FDA's first Chief Scientist, a position established by the Food and Drug Administration Amendments Act of 2007. He was simultaneously appointed Principal Deputy Commissioner. The appointment of a Chief Scientist signaled a new emphasis on the importance of science in the agency. It also enhanced the FDA's ability to direct and manage the complex and interrelated aspects of the regulatory science of medical product development from conception through post-marketing, as well as regulatory science related to human and animal food and nutrition, food additives and cosmetics.

In his presentation at the 100th Anniversary of the American Association for Cancer Research in Roswell Park, Dr. Torti stated, "The future of the FDA will be written in the quality of FDA science and scientists". This philosophy has guided his actions at FDA as he has engaged Center leadership to address the deficiencies outlined in the Science Board report and strengthen the science base of the Agency.

Dr Torti received his B.A. and M.A. degrees from Johns Hopkins University, his M.D. from Harvard Medical School (*cum laude*), and his M.P.H. from the Harvard School of Public Health, where he trained in cancer epidemiology and nutrition. He was an intern and resident at the Beth Israel Hospital, Boston and a fellow in medical oncology at Stanford University. While on the Stanford faculty, he served as Executive Officer of the Northern California Oncology Group and Associate Director of the Northern California Cancer Program, and was instrumental in the development and oversight of the data management functions and overall administration of that clinical cooperative group and its regional network in northern California. He was tenured at Stanford, where he led one of the most active genitourinary programs in the country. He joined Wake Forest University School of Medicine in 1993 as the Charles L. Spurr Professor of Medicine, Director of the Comprehensive Cancer Center, and Chair of the Department of Cancer Biology. At Wake Forest, he developed and is principal investigator on a training program in cancer biology for Ph.D. students and M.D. and Ph.D. postdoctoral fellows.

He has published in *Science, the Journal of Biological Chemistry, Molecular and Cellular Biology, Proceedings of the National Academy of Sciences of the United States of America (PNAS), The Journal of Immunology, Journal of Clinical Oncology, Cancer Research, The New England Journal of Medicine, Annals of Internal Medicine, Cell,* and other highly respected journals. He has served on or chaired a number of national study sections, including those of the National Institutes of Health (NIH), Department of Veterans Affairs, Department of Defense, and American Institute of Clinical Research. He also served on the NIH Council for the National Center for Complementary and Alternative Medicine.

Dr. Torti is a noted clinician and clinical investigator, as well as an accomplished research scientist. He is the recipient of a MERIT award from the NIH, an honor bestowed on only 2% of all NIH grantees.

Scientific Organization and Priority Setting:

The five principles developed by Dr. Torti will be presented in the following pages:

Principle # I: FDA Must Develop an Overarching Scientific Strategy with an Accompanying Implementation Plan, Deliverables, Timetables and Budget.

Principle # II: The FDA Scientific Strategy Must be Preemptive

Principle # III: FDA Must Maintain and Enhance its Infrastructure, Core Expertise and Human Capital

Principle # IV: FDA Must Tell its Story

Principle # V: FDA Cannot do it Alone

Principle # I: FDA Must Develop an Overarching Scientific Strategy with an Accompanying Implementation Plan, Deliverables, Timetables and Budget.

The Office of Chief Scientist has taken several steps to develop, coordinate and ensure quality of the science programs within the Agency.

I (a): Process: Define scientific priorities and implementation strategy
Dr. Torti has met with the Center Directors individually and as a group throughout the Fall and Winter of 2008, and has worked with them to identify those areas of science that most directly intersect with their regulatory functions, and to define those areas across Centers where priorities overlap. These areas are identified below [I(b)] and form the basis of a detailed scientific plan to be presented to the Science Board in February, 2009.

I (b): Output: Agency overarching scientific priorities
A product of the deliberations with Center Directors and their scientific staff has been the development of the **FDA's overarching scientific priorities**.

1. *Rapid Detection*: Development and implementation of rapid, sensitive, high throughput methodologies to detect and identify microbial or other contamination in human derived materials, animals and regulated products and in manufacturing and production sites.
2. *Adverse Event Detection and Analysis:* Development, implementation and qualification of improved methods for detection and analysis of adverse events associated with use of marketed products.
3. *Biomarkers:* Development and implementation of new or improved biomarkers, models and methods to predict safety and efficacy of regulated products including drugs, biologics, devices and foods.
4. *Clinical Trial Design and Analysis:* Implementation of clinical trial design and analysis methodologies to more rapidly and efficiently evaluate safety and efficacy of FDA regulated products.
5. *Microbial Ecology and Contamination Mitigation Strategies:* Development and implementation of programs to reduce or eliminate the contamination of products by microbial pathogens based on a characterization of routes of contamination and transmission and an understanding of microbial ecology.
6. *Manufacturing Science:* Development and implementation of innovative, novel technologies in manufacturing science to enhance manufacturing efficiency and product safety, quality and traceability.
7. *Personalized Medicine and Nutrition:* Development of individualized approaches to therapeutics and nutrition, such as toxicogenomics, pharmacoselection, and complex prognostic and predictive devices, and the use of these techniques to accelerate product development and provide enhanced product and food safety.

I (c): Regulatory Science Projects that target the Overarching Priorities:
Within priority areas identified by each Center, specific scientific projects with deliverables, budgets and timetables have been developed that directly address key issues within the priority area. The titles of the projects are provided in Appendix I of this document.

I (d): External peer review: Science Board engagement
The FDA Science Board (Science Board) is an external group of experts who provide advice to the FDA Commissioner and Chief Scientist on complex and technical issues as well as emerging issues within the scientific community. A subcommittee of the Science Board has been established to review each project within the Centers' scientific priorities and provide feedback. The subcommittee will provide an initial report to the Science Board in the Spring, 2009.

I (e): Coordination with budget process: science priorities have been coordinated with the FY 2009 budget execution and outyear budget formulation process
Within FDA, Dr. Torti has met with Center leadership to discuss opportunities and options for funding science projects within the constraints established by Congress. In addition, Dr. Torti is actively engaged in agency outyear budget deliberations.

I (f): Project implementation:
Funding for some of the projects described above began in January 2009. Full implementation of these projects awaits the Science Board recommendations.

Principle #II The FDA Scientific Strategy Must be Preemptive

FDA needs to better anticipate future scientific regulatory needs and to develop a cadre of scientific professionals with expertise in "cutting-edge" science. This can only be accomplished with investment in new science and programs that address emerging regulatory issues. Some (but not all) of the initiatives developed to enhance a preemptive approach to science under Dr. Torti's leadership are highlighted below.

II (a): Rapid Risk Based Assessment of Economically Motivated Contamination:
Within the previous two years, pet food and infant formula have been found to be adulterated with melamine, which had been added to increase the apparent protein content. During the October 2008, Science Board meeting the FDA announced the establishment of a Science and Policy working group and presented the challenges of and strategies for preemptively identifying economically motivated contaminants. This group is soliciting information internally, from industry and from other governments about the factors that may lead to economic adulteration, with the aim of anticipating, to the extent possible, the next "melamine" and proactively developing tools to deal with future economic adulteration.

II (b): Task Force for Minority Health:
Responding to a recommendation of the Science Board, FDA senior leadership is forming a cross-Center Task Force on minority health that will specifically examine the science related to the differential responses to drugs and biologics of people from different racial and ethnic groups.

II (c): Genomics coordination:
In June 2008, FDA held a symposium to assess "omics" (including genomics, proteomics and metabolomics) needs across the Agency and to develop recommendations for use of and development of "omics" data at FDA. One of the recommendations of this symposium reiterated the need for formal coordination of "omics" across the Agency as identified in the Science Board Report. An Agency-wide Genomics Coordinator has been recruited as of February 1, 2009, to integrate "omics" across the Agency. This person will facilitate "omics' efforts and will establish a core group including at least 3 bioinformatics experts to provide cross-Center expertise in large data set analyses.

II (d): Combination Product Coordination:
Combination products include a diverse range of products including cells and scaffolding materials. These products represent a unique challenge for FDA regulation on a number of fronts, including the complexity of the science of precursor cell differentiation, the physical properties of the scaffolds on and in which the cells adhere, grow and differentiate, as well as the coordination of the Centers (Drugs, Biologics and Devices) that regulate these products. An FDA Commissioner's Fellow with extensive expertise in science and science policy will work in the Office of the Chief Scientist focusing on issues of regenerative

medicine, particularly in regard to the coordination among government agencies, in this rapidly evolving field.

II (e): Critical Path:
Among the high priority Critical Path projects are the following:

- Sentinel Initiative: Launched in May, 2008, the goal of the Sentinel Initiative is to create a national, integrated, electronic system (the Sentinel System) for monitoring medical product safety. The Sentinel System, which will be developed and implemented in stages, will ultimately enable FDA to access the capabilities of multiple, existing data systems (e.g., electronic health record systems, medical claims databases) to augment the Agency's current capability to detect adverse events.
- Clinical Trials Transformation Initiative: Effective, well designed clinical trials are the basis for most FDA regulatory decisions. In November 2007, as part of FDA's Critical Path Initiatives, FDA in collaboration with Duke University Medical Center announced the creation of a Public-Private Partnership to improve the quality and efficiency of clinical trials. In May 2008, a 12 member Executive Board including representatives from academia, industry, government and patient advocacy was named.
- Biomarker Qualification: The ability to define useful biomarkers will improve efficacy of medical products, enhance safety and usher in the era of personalized medicine. In June 2008, the Critical Path Institute, co-founded by FDA, announced the qualification of seven urinary biomarkers of kidney injury for use in certain regulatory decisions. This was a collaborative effort with preclinical data provided by Novartis, Merck, Harvard Medical School and FDA.

II (f): Other Public-Private Partnerships:
FDA has several partnerships with academic, for-profit and non-profit institutions; two of these are detailed below:

- FDA/Alliance for NanoHealth Initiative: FDA and eight academic institutions have completed a Memorandum of Understanding (MOU) to collaborate in the development of efficient nanoengineered products.
- Drug-Induced Liver Injury Program: Liver injury represents the single largest reason for withdrawal of drugs in late development or shortly after approval. The current animal models are inadequate for predicting whether a drug will induce liver injury. FDA has engaged academic investigators and Entelos, a company nationally recognized for systems modeling of pathways, to explore whether drug induced liver injury is predictable based on examining the activation of cellular pathways. FDA and Entelos entered into a Cooperative Research and Development Agreement (CRADA) to develop a computer model of drug-induced liver injury.

Principle # III: FDA Must Maintain and Enhance its Infrastructure, Core Expertise and Human Capital

Dr. Torti has taken several steps to recruit high quality scientific talent, to create scientist career development programs and to provide professional development opportunities. Working with the Office of Operations, the agency has also undertaken information technology (IT) improvements.

Infrastructure

III (a): Core research facilities:

A proposal has been developed to establish core research facilities in nanotechnology, flow cytometry, and imaging. Other core facilities are actively under consideration. We are currently working on the design and integration of these core facilities into existing FDA buildings at White Oak, those under construction, and those at NCTR, as well as identifying the requisite equipment for these facilities.

III (b): Information Technology development

The 2007 FDA Science Board report (*FDA Science and Mission at Risk)* noted that progress in IT had been initiated but advocated significant investment to support regulatory science. FDA recognizes the need for significant investment and plans substantial investments to improve IT infrastructure and computational sciences over the next 5 years (2009-2013).

In addition to the centralization of FDA's IT personnel and resources, which occurred in May of 2008, the Bioinformatics Board (BiB) with representatives from each Center and operational unit is working to upgrade the current IT system to enable electronic data submissions, data mining, and analysis and to ensure Agency-wide compatibility and interoperability. These enhancements will improve Computational Science (a term which broadly represents FDA's needs in the area of advanced analytics) and will provide essential tools for scientific review and analysis, improve assessment of manufacturing and product quality, and strengthen pre- and post-approval regulatory actions, including post-approval surveillance and safety. In addition, these improvements will support electronic prescribing and improve clinical decision support.

FDA's IT modernization includes efforts to improve efficiency and effectiveness of IT Infrastructure Operations. Some examples of this effort include: Janus (an Agency-wide program to improve how the FDA manages and accesses structured scientific data), Automated Laboratory Management (a program to enhance laboratory data capture, analysis and data sharing) and IT collaborations with other organizations (including the National Cancer Institute (NCI) and the Centers for Disease Control and Prevention) to strengthen FDA's scientific computing capabilities and to promote data sharing. Dr. Torti is committed to ensuring that IT work is fully compatible and interoperable with standards and datasets developed by the NCI as part of the caBIG (cancer Bioinformatics Grid) initiative.

In August, 2008, Science Board member Dr. Sangtae Kim, a computational expert, reviewed the agency's progress in implementing IT improvements and the associated impact on FDA's bioinformatics capabilities. Dr. Kim noted FDA's commitment to a centralized IT structure and the significant progress in enhancing infrastructure. Since August, 2008, Dr Kim has continued his dialogue with scientific and IT leadership of the FDA, most notably the prioritization outcomes of the BiB Strategic Retreat. Dr. Kim has reviewed seven projects that were selected as the top funding priorities and these have received his endorsement as consistent with the findings and recommendations of the Science Board Science and Technology IT Subgroup.

Core Expertise and Human Capital

III (c): FDA Commissioner's Fellowship Program:

Central to the future of the FDA is the recruitment of the best and brightest people to the Agency. In October 2008, the first group of 50 fellows selected from over 1000 highly qualified applicants began the 2 year Fellowship curriculum. Selected fellows have doctoral level (Ph.D., M.D. or D.V.M.) or engineering degrees and expertise in diverse fields including physics, environmental science, pharmacology, cell biology and neuroscience. The Program is designed to expose highly qualified and selected fellows to FDA regulations, science and policy related to devices, drugs, biologics, foods, and cosmetics. The Program combines rigorous didactic coursework with the development, investigation, and completion of a regulatory science project in conjunction with a senior FDA scientist-preceptor. It is expected that interaction of fellows and preceptors, formally and informally, will enhance the expertise of FDA scientists through exposure to new ideas, emerging areas and techniques. The Program is integral to the broader agenda of enhancing the scientific capabilities of FDA. To enhance its scientific knowledge base and workforce and to keep up with rapid scientific and technological advances, FDA needs to attract and retain outstanding scientists. Thus, FDA is working to develop career paths for fellows so that they will have the opportunity to continue their public health careers at FDA after the successful completion of this program.

III (d): Quarterly FDA wide "Science First" symposium series:

Topics for these symposia will be in areas of emerging science and will be relevant to FDA's overarching scientific priorities as defined by the Center Directors. FDA is planning a regulatory Nanotechnology Symposium with speakers from the US, Europe, Australia, Canada and Japan in April 2009.

III (e): FDA Distinguished Speakers Series:

Invited external speakers are identified by the Committee for Advancement of FDA Science (CAFDAS). Seminar topics will be focused on FDA's overarching scientific priorities as identified by the Centers. On February 25, 2009, the first speaker, Mr. Shaun Kennedy, will give a talk in the area of Rapid Detection entitled "Threat Assessment of Food Contaminants in the Farm-to-Fork

Continuum and Potential Solutions". Mr. Kennedy will spend a day interacting with FDA scientists and fellows.

III (f): Enhanced library capacity:

In August 2008, the FDA library purchased access to the Science Direct Freedom Collection. This expanded the number of Elsevier titles from 150 to approximately 2500 and increased the total number of electronic journals FDA scientists can access from approximately 2,000 to 4,400. FDA scientists now have journal access comparable to NIH scientists. Further enhancements of FDA library capacity are being considered.

III (g): Professional development opportunities:

Mini-sabbaticals: In September 2008, scientists from 5 FDA Centers were funded by the Office of the Chief Scientist to attend a 5 day workshop in systems biology at the Hamner Institute in North Carolina. Dr. Torti has recently implemented a mini-sabbatical program where scientists and reviewers exchange positions between Centers.

III (h): Career development plan for Office of Oncology Drug products:

Oncology physician retention and career development has been identified as a high priority for the Agency. Working closely with the oncology division's leadership, Dr. Torti encouraged the development of a professional development plan with a mechanism to reward world class physicians and scientists who do not choose a managerial tract for promotion. Included in the oncology career development plan is the hiring of 30 new medical officers to allow time for FDA oncology physicians and scientists to engage in professional development activities. If successful, this approach will serve as a model that can be adopted by other groups within the FDA.

III (i): Cross FDA Working Groups

To enhance scientific collaboration across the agency, Dr. Torti has supported and encouraged cross-agency working groups, including Neurology Across FDA, Cardiology Group, Nanotechnology Working Group, and the Genomics Working Group.

III (j): Scientific Achievement Awards

The number of Scientific Achievement awards has been increased from seven to ten with the addition of three new group awards for scientific achievement. The Scientific Achievement Awards include monetary recognition for scientific achievement.

III (k): Chief Scientist's "Challenge Grants" program:

Announced in December 2008, this program will award four to ten grants of up to $125,000 each for cross-center collaborative projects.

Principle # IV: FDA Must Tell its Story

To enhance understanding of regulatory decisions and the science behind them, FDA needs to communicate with the public and with fellow scientists. Providing this information will broaden the understanding of regulatory science and will build greater trust and confidence in the Agency.

IV (a): FDA Science Writers Symposium:

Working collaboratively with the Office of Public Affairs, the Office of the Chief Scientist hosted its first Science Writers Symposium in November, 2008. Attendees represented magazines including *Time* and *Business Week*, scientific journals such as *Science*, wire services including AP and Reuters, the *Los Angeles Times* and other daily newspapers, TV networks, as well as industry and trade publications. FDA scientists discussed a DNA vaccine for avian influenza, contaminated heparin, techniques for analyzing the safety of drug-eluting stents down to the molecular level, Salmonella outbreaks, melamine contamination of pet food, and nutrigenomics. The symposium also included a guided tour of the FDA's Office of Science and Engineering Laboratories, which conducts research in areas such as wireless technologies and nanobiophotonics, and an ultrasensitive detection method for trace agents using light and nanotechnology.

IV (b): Journal of Regulatory Science:

The Office of the Chief Scientist is planning to launch a new scientific journal provisionally entitled the *Journal of Regulatory Science*. Successful regulatory decision making requires the application of sound science to support those decisions. The journal will publish articles relevant to FDA regulatory science. It is expected that this journal will provide a forum for the science associated with product development in the context of the regulatory environment and bridge gaps in the scientific, trade association, and professional association publications currently addressing these subjects.

Principle # V: FDA Cannot do it Alone

It is neither technically feasible nor economically advisable for FDA to develop research programs and expertise in all areas - FDA must partner with external experts to a greater extent than it currently does. This will be cost effective compared to developing research agendas in all areas and will increase the transparency of regulatory decisions.

V (a): Leveraging FDA resources:
Dr. Torti has publicly stated that FDA needs to effectively partner with academia, industry and others in areas where their expertise can support and amplify the scientific base that underpins FDA regulatory decisions.

- Centers of Excellence with Academia:
  Within academic medical centers there is expertise in scientific areas that form the foundation of FDA regulatory science. Partnering with these centers is an important approach to developing the datasets that form the foundation of FDA regulatory decisions. FDA will identify through a competitive process academic centers that have depth and breadth of scientific expertise in areas critical to FDA's public health mission. Centers would be recipients of specific funding from the FDA to tackle FDA mission-critical scientific issues.
- Resource Networks with Biotechnology Firms:
  Small biotechnology firms represent a flexible resource. They are operationally and scientifically nimble and often have the capability to devote a large proportion of human capital to a single project. Biotech firms that have an interest in partnering to resolve mission-critical FDA questions will be identified and engaged through contracts and other funding mechanisms.
- Partnerships with industries in the "pre-competitive" space:
  We will explore how FDA can harness the extensive expertise of regulated industries in areas that are of mutual benefit, such as drug-induced liver toxicity [see II (f)]. Such partnerships with industry already exist in the area of safety assessment of kidney toxicity and the Sentinel initiative [see II (e)].

V (b): Engagement of the Science Board in review of FDA scientific planning:
The number of Science Board meetings has been expanded to four per year and the number of members will be expanded from 12 to 21. Dr. Torti has left some of these positions vacant to allow the incoming FDA leadership to have input in the selection of members. We will engage the Science Board to provide external comment on FDA's review of available scientific evidence and conclusions.
Recent Science Board meetings have addressed:

- Risk-based assessments of exposures to bisphenol A (BPA) in food (2008)
- Rapid, risk-based assessment of intentional and economically motivated contamination [October 2008, see Item II(a)]
- Rapid detection of Salmonella in food (October 2008)

Future Science Board meetings will address:

- Biospecimens for genomic and proteomic analyses.
- Peer review of the intramural research programs of the FDA Centers.

The Future of FDA Science: Challenges and Opportunities

FDA recognizes that the creation of a scientific vision and strategy and the initiation of a plan to achieve its strategic goals are just first steps toward strengthening the scientific foundation at FDA. FDA needs, in addition to strong support for science, consistent internal and external recognition of the fundamental role of science in the regulatory process and a commitment internally and externally to the revitalization of this science.

Appendix I

Projects within priority areas from: Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), Center for Food Safety and Applied Nutrition (CFSAN), Center for Devices and Radiological Health (CDRH), Center for Veterinary Medicine (CVM), National Center for Toxicological Research (NCTR), and Office of Regulatory Affairs (ORA):

CBER

Rapid Detection

Proactive Identification, assessment, monitoring of and response to Top Priority Pathogen Threats to Blood and Tissue Supply

Development of standards, reagents and assays to facilitate rapid response to emerging pathogens that threaten the blood and tissue supply

Harness new cutting edge science for pathogen detection to enhance prevention and rapid response to emerging and unknown threats and to improve product quality through in-process testing and process analytic technologies

Adverse Event Detection and Analysis

Enhanced analytic capability: Develop tools to more quickly and reliably identify adverse events caused by administration of biologics

Biomarkers

Build and apply genomics and personalized medicine to biologics safety.

Development and use of improved preclinical models to identify and assess biomarkers for the safety and efficacy of cellular therapies, including stem cells and engineered tissues

CDER

Adverse Event Detection and Analysis

Analysis of Medical Product Adverse Events Utilizing a Distributed Network: Efforts toward building a Sentinel System

Risk assessment of drug-induced phospholipidosis in the CNS

Effect of proton pump inhibitors (PPIs) on the pharmacokinetics and pharmacodynamics of clopidogrel: Impact of CYP2C19 genotypes and PPI class effects

Clinical Trial Design and Analysis

New Outcome Measures and Data Collection Methods for Improving CDER Bioresearch Monitoring Compliance Programs

Development of bioinformatic tools to improve drug safety and to consistently predict and assess complex drug interactions including genetic components

Development of an FDA-European Medicines Agency (EMEA) Collaboration Program for Good Clinical Practice Inspection of Clinical Trials Supporting Drug Development Worldwide

Manufacturing Science

Rapid screening of pharmaceutical products and ingredients

Implementation of Quality by Design Principles and Novel Process Analytical Technologies for Protein Therapeutic Manufacturing in the 21st Century

Inactivation Resistant Viral Contaminants: Risk of Human Transmission & Approaches for Elimination

CDRH

Rapid Detecion
Assuring the Safety of Ophthalmic Medical Devices
New Approaches to Analyzing Chemical Contamination at Medical Device Surfaces
Biomarkers
Computational Endpoints for Cardiovascular Device Evaluations
Clinical Trial Design and Analysis
Improving Clinical Trials for Imaging Devices

CFSAN

Rapid Detection
High Throughput Technology for Identification and Characterization of Microorganisms: Field trial of IBIS Biosensor
Rapid identification of food pathogens using high-throughput detection methods that target single-nucleotide polymorphisms (SNPs).
Microbial Ecology and Contamination Mitigation Strategies
Ecology and Control of Salmonella on Tomatoes
Manufacturing Science
High pressure processing as a new technology for producing safe shelf-stable foods

CVM

Rapid Detection
Simultaneous Detection and Identification of Multiple Foodborne Bacterial Pathogens Isolated from Animals and Foods by Bio-Plex Technology and Microarray.

NCTR

Rapid Detection
Validation of Advanced Technologies for Rapid Detection of Bacterial Contaminants
Biomarkers
Development of a non-invasive and translatable biomarker using PET imaging
Evaluation of biological impact of nanoscale materials and development of biomarkers of exposure and biomarkers of impact
Investigation of molecular markers in the mitochondria using toxicogenomic, proteomic and metabolomic technologies to predict early events of drug-induced cardiotoxicity
Liver Toxicity Biomarkers Study
Personalized Medicine and Nutrition
NCTR Healthy Challenge

ORA

Rapid Detection
Enhanced Preventive Analytical Capabilities
ORA Science Leveraging/Collaborations