Strengthening a Workforce for Innovative Regulatory Science in Therapeutics Development: An Institute of Medicine Workshop

September 20–21, 2011

National Academy of Sciences
Keck Building, Room 100
500 5th Street, N.W.
Washington, DC 20001

Background:
The Food and Drug Administration (FDA) has defined regulatory science as the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products (FDA 2010). The FDA Science Board, in Science and Mission at Risk (FDA Science Board, 2007), described regulatory science as a science-based decision-making process needed to fulfill the responsibilities of a public health agency: “FDA must have the scientific staff and resources to undertake the regulatory research that will provide a basis to: 1) improve capacity for safety and efficacy evaluations and monitoring of candidate and licensed products; 2) modernize current regulatory pathways; and 3) develop new regulatory pathways where there are currently none.” According to the report, this capacity is important because “decisions made in regulation development, pre-market approvals, legal actions and related public health emergencies must be based on understanding of contemporary and emerging science within the context of the risk analysis paradigm.” A number of gaps in the regulatory science discipline and infrastructure have been identified. They include: workforce and resource constraints; cultural differences and systemic barriers to collaboration and exchange among the agency, academia, and industry; and deficiencies in the network and infrastructure necessary to forge the collaboration and communication needed to advance regulatory science. There has been recognition that collaborative approaches are necessary to advance regulatory science. In early 2010, FDA and the National Institutes of Health (NIH) announced a unique collaboration, with establishment of a joint FDA-NIH leadership council to enable cross-agency efforts to improve regulatory science.

This workshop will explore issues related to strengthening a workforce for innovative regulatory science in therapeutics development. The workshop will: (1) consider opportunities and needs for advancing innovation in the discipline of regulatory science for therapeutics development through an interdisciplinary regulatory science workforce; and (2) examine specific strategies for developing a discipline of innovative regulatory science through development of a robust workforce within academia and industry and at FDA.

Meeting Objectives:
• Define and discuss the current regulatory science workforce, with particular attention to discussion of the disciplines involved and professional training opportunities.
o Identify gaps between the essential components of a workforce that will produce innovation in regulatory science and the current reality.
• Consider workforce development needs in areas identified as key components of a robust discipline of innovative regulatory science in therapeutics development.
• Examine application and advantages of collaborative (multisector and multidisciplinary) approaches for strengthening of a robust national regulatory science workforce.
  o Identify and discuss specific opportunities for enhancing collaboration and coordination – among relevant federal programs and between FDA and the extramural community – to strengthen a regulatory science workforce supporting innovation in therapeutics development.
  o Identify barriers to implementation of collaborative models, and discuss potential solutions to address those identified barriers.
• Explore the resources and stakeholder engagement needed, not only within FDA and other federal agencies, but also throughout the extramural sector, to build the discipline and establish career paths in the area of regulatory science innovation for therapeutics development.

September 20, 2011

8:30 a.m. Welcome and Introductions

BARRY COLLER, Workshop Co-Chair
Vice President for Medical Affairs and Physician-in-Chief
David Rockefeller Professor
Rockefeller University

ELAINE GALLIN, Workshop Co-Chair
Principal
QE Philanthropic Advisors

SESSION I: DEFINING A DISCIPLINE OF REGULATORY SCIENCE

Session Objectives
• Discuss the promise of and role for innovative regulatory science in therapeutics development.
• Define the discipline of regulatory science in therapeutics development.

8:40 a.m. Keynote Address, Food & Drug Administration

VICKI SEYFERT-MARGOLIS
Senior Advisor for Science Innovation and Policy
Office of the Commissioner
Food and Drug Administration
9:00 a.m. Keynote Address, National Institutes of Health

STORY LANDIS
Director
National Institute of Neurological Disorders and Stroke
National Institutes of Health

9:20 a.m. Keynote Address, Industry

ANDREW DAHLEM
Vice President & Chief Operating Officer, Lilly Research Laboratories
Eli Lilly & Co.

9:40 a.m. Keynote Address, Academia

RALPH SNYDERMAN
Chancellor Emeritus
Duke University

10:00 a.m. Panel Discussion with Keynote Speakers: *Components of a Robust Academic Discipline of Regulatory Science*

Objectives:

- Define “innovation” in regulatory science. What are the benchmarks and metrics of success in a discipline of regulatory science?
- Propose and discuss the essential, core components of a robust discipline of innovative regulatory science in therapeutics development.
- List key skills, techniques, and areas of expertise needed by a regulatory science workforce.

ELLEN SIGAL, panel moderator
Chair and Founder
Friends of Cancer Research

Panelists:
- Keynote speakers (FDA, NIH, Industry, and Academia represented above)
SESSION II: CORE COMPETENCIES OF AN INNOVATIVE REGULATORY SCIENCE WORKFORCE

Session Objectives

- Consider the core components of an innovative regulatory science discipline and essential competencies of a regulatory science workforce.
- Through case studies, provide examples of the practice of regulatory science and the needed skill set of the workforce involved.

STEVEN GALSON, session chair
Vice President for Global Regulatory Affairs
Amgen Inc.

Case Studies: Components and Application of Innovative Regulatory Science

10:30 a.m. Therapeutics Development

MARY DWIGHT
Vice President for Government Affairs
Cystic Fibrosis Foundation

10:50 a.m. Drug Safety

MUNIR PIRMOHAMED
Deputy Director
MRC Centre for Drug Safety Science, University of Liverpool

11:10 a.m. Components of Regulatory Science Through the Lens of Translational Science

BARRY COLLER
Vice President for Medical Affairs and Physician-in-Chief
David Rockefeller Professor
Rockefeller University

ROB CALIFF
Director, Duke Translational Medicine Institute
Professor of Medicine
Vice Chancellor for Clinical and Translational Research
Duke University Medical Center
11:45 a.m.  **Panel Discussion: Perspectives on Core Competencies for a Regulatory Science Workforce**

*Session Speakers and Additional Discussants:*

**STEVEN GALSON, panel moderator**  
Vice President for Global Regulatory Affairs  
Amgen Inc.

**MARY DWIGHT**  
Vice President for Government Affairs  
Cystic Fibrosis Foundation

**CLIFFORD LANE**  
Deputy Director for Clinical Research and Special Projects  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health

**MUNIR PIRMOHAMED**  
Deputy Director  
MRC Centre for Drug Safety Science, University of Liverpool

**MELINDA WHARTON**  
Deputy Director, National Center for Immunization and Respiratory Diseases  
Centers for Disease Control

12:40 p.m.  **LUNCH**

### SESSION III: EDUCATION AND TRAINING OF A REGULATORY SCIENCE WORKFORCE

**Session Objectives**

- Discuss education and training opportunities needed to develop a robust workforce in regulatory science in therapeutics development. Identify gaps between those needed components and the current reality.
- Identify and discuss specific opportunities, including collaborative approaches, to strengthen education and training opportunities for a regulatory science workforce.
- Examine barriers to implementation of those strategies and discuss potential solutions to those identified barriers.

**ALASTAIR WOOD, session chair**  
Partner & Managing Director  
Symphony Capital LLC
1:40 p.m. **Overview of Existing Training Programs in Regulatory Science**

CARL PECK  
Professor, Pharmacology and Medicine  
University of California, San Francisco

2:00 p.m. **Education and Training: What is Needed and How Do We Get There?**

2:00 p.m.  
EMMA MEAGHER  
Director, Translational Research Education  
Institute of Translational Medicine and Therapeutics  
University of Pennsylvania Perelman School of Medicine

2:15 p.m.  
ANNETTE MOLLET  
European Center of Pharmaceutical Medicine  
University of Basel, Switzerland

2:30 p.m. **Panel Discussion with Speakers**

ALASTAIR WOOD, *panel moderator*  
Partner & Managing Director  
Symphony Capital LLC

3:00 p.m. **BREAK**

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### SESSION IV: REGULATORY SCIENCE CAREER DEVELOPMENT AND ADVANCEMENT: CAREER PATHS WITHIN AND OUTSIDE ACADEMIA

**Session Objectives**

- Discuss career and career development opportunities that currently are available, or that would need to be available, to strengthen and support research and practice of regulatory science in therapeutics development.
- Discuss regulatory science careers outside academia, including industry, FDA, and other federal agencies. Focus on career tracks in innovative regulatory science (as distinguished from regulatory affairs and compliance).
- Identify and discuss specific opportunities, including collaborative approaches, to encourage the career development for a workforce in regulatory science in therapeutics development. Examine barriers to implementation of those strategies and discuss potential solutions to those identified barriers.

3:20 p.m. **Session Overview and Introductory Remarks**

LESLEY BENET, *session chair*  
Professor, School of Pharmacy  
University of California, San Francisco
Panel 1:  Regulatory Science Career Paths in Academia

3:25 p.m.  WILLIAM CHIN
Executive Dean for Research
Harvard Medical School

3:35 p.m.  DAVID DEMETS
Professor, Department of Biostatistics & Medical Informatics
University of Wisconsin

3:45 p.m.  KATHY GIACOMINI
Professor and Co-Chair, Department of Bioengineering and Therapeutic Sciences
University of California, San Francisco

Panel 2:  Regulatory Science Career Paths Outside Academia

4:00 p.m.  LESLIE WHEELOCK
Office of the Chief Scientist
Food and Drug Administration

4:10 p.m.  JONATHAN WIESE
Director for Training and Education, Center for Cancer Research
Office of Training and Education, National Cancer Institute
National Institutes of Health

4:20 p.m.  HENRIETTA UKWU
Senior Vice President for Global Regulatory Affairs
PPD, Inc.

4:30 p.m.  Panel Discussion with Speakers: Career Development Pathways: What is Needed and How Do We Get There?

  LESLIE BENET, panel moderator
  Professor, School of Pharmacy
  University of California, San Francisco

5:30 p.m.  ADJOURN
8:30 a.m. Welcome and Introductions

*Workshop Co-Chairs*

**BARRY COLLER**  
Vice President for Medical Affairs and Physician-in-Chief  
David Rockefeller Professor  
Rockefeller University

**ELAINE GALLIN**  
Principal  
QE Philanthropic Advisors

### SESSION V: INTERNATIONAL APPLICATIONS

**ELAINE GALLIN, session chair**  
Principal  
QE Philanthropic Advisors

8:35 a.m. Regulatory Science Workforce Needs to Maintain a Robust Global Therapeutics Pipeline

**XAVIER LURIA**  
Head, Safety & Efficacy of Medicines  
Human Medicines & Evaluation  
European Medicines Authority

8:55 a.m. Regulatory Science Workforce Needs to Support Therapeutics Development for Global Neglected Diseases

**MICHAEL BRENNAN**  
Senior Advisor for Global Affairs  
Aeras Global TB Vaccine Foundation
SESSION VI: COLLABORATIVE MODELS AND NEW PARADIGMS FOR SUPPORTING REGULATORY SCIENCE RESEARCH AND PRACTICE

Session Objectives

- Discuss funding opportunities that would need to be available to strengthen and support research and practice of regulatory science in therapeutics development. What institutions, public or private, could offer research funding and other support to create an infrastructure and habitat for innovative regulatory science? Outline a sustainable funding model.
- Identify and discuss specific opportunities for enhancing collaboration and coordination to strengthen a regulatory science workforce supporting innovation in therapeutics development.
- Identify barriers to implementation of funding strategies and collaborative models, and discuss potential solutions to address those identified barriers.

BARRY COLLER, session chair
Vice President for Medical Affairs and Physician-in-Chief
David Rockefeller Professor
Rockefeller University

9:15 a.m.  GIGI HIRSCH
Program Director, NEWDIGS
Executive Director, Center for Biomedical Innovation
Massachusetts Institute of Technology

9:30 a.m.  WILLIAM GREENLEE
President & CEO
The Hamner Institutes

9:45 a.m.  THEODORE REISS
Research Professor of Medicine
Vanderbilt University School of Medicine

10:00 a.m.  Panel Discussion Led by Workshop Co-Chairs: Fellowship/Exchange Programs

FDA CTP Regulatory Science Fellowship (pilot)

LAWRENCE DEYTON
Director
Center for Tobacco Products
Food and Drug Administration
**FDA Commissioner’s Fellows Program**

**UROS DJEKIC**
Commissioner’s Fellow (2008–2010)
Senior Regulatory Reviewer/Policy Analyst
Center for Biologics Evaluation and Research
Food and Drug Administration

**Visiting Lecturer/Expert Programs at FDA**

**KATE AHLPORT**
Executive Director
Health Research Alliance

**FDA Rotation for Clinical Research Fellows at the NIH Clinical Center**

**JUAN LERTORA**
Director
Clinical Pharmacology Program
NIH Clinical Center

10:45 a.m.  **Q&A with Panelists**

**SESSION VII: SETTING THE AGENDA**

**Session Objectives**
- Explore resources and stakeholder engagement needed to build the discipline and establish career paths in the area of regulatory science innovation for therapeutics development.
- Discuss specific next steps for stakeholders to strengthen a workforce for innovative regulatory science in therapeutics development.

11:00 a.m.  **Discussion with Panelists and Workshop Attendees Led by Workshop Co-Chairs**

**BARRY COLLER, Workshop Co-Chair**
Vice President for Medical Affairs and Physician-in-Chief
David Rockefeller Professor
Rockefeller University

**ELAINE GALLIN, Workshop Co-Chair**
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QE Philanthropic Advisors

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WILLIAM GREENLEE
President & CEO
The Hamner Institutes

THEODORE REISS
Research Professor of Medicine
Vanderbilt University School of Medicine

12:00 p.m.   ADJOURN