The Regulatory Science Workforce

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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.”
Perspectives

• Critical Need—global and US specific
• Multiple layers with different goals
• Major overlap with clinical and translational science
• Specific needs in each segment
• Need for clinical research skills and decision science understanding greatly underappreciated
Global and Local

• We are now in a global marketplace and global scientific development community
  – Regulatory dysharmony is a major cause of excess cost and reduced investment (too much uncertainty and risk)
• But the US has created a singularly non-competitive environment
  – Almost NO evidence based regulation
  – Probably too much emphasis on useless regulation
  – Probably not enough emphasis on critical regulations to the public health
Regulatory Science Workforce

- All Healthcare Providers
- All Clinical and Translational Researchers
- Regulatory Specialists
- Regulatory Scientists and Policy Makers
Regulatory Science for All

• All practitioners
  – Enhanced understanding of regulations, why they are there and what they mean

• All clinical and translational researchers
  – Deep understanding of regulatory requirements
  – Instilled ethos of evaluation of regulations for purpose of improving the system

• Regulatory specialists
  – Detailed understanding of the regulatory systems and their requirements
  – Commitment to a “learning regulatory system”

• Core of academic regulatory specialists and policy makers
  – Focused on applying scientific and policy methods to regulations to improve them
  – Teaching at multiple levels, including PhD
All Trainees in Health and Biological Science Disciplines

Clinical Research Specialty Training

PhD Training in Those Interested in Translation

Regulatory Specialists

Regulatory Scientists and Policy Makers
Medical Products Industry

• Currently too often “on the job training”
• Tremendous and growing need
• Global need
• Organizations like Regulatory Affairs Professional Society (RAPS) have established a basis for education and training
FDA Employees

- Over 13,000 employees
- Although training systems exist, they could be improved
  - Especially if there was a track that prepared people before coming to FDA
- Need for lifelong education
- Enhance the pipeline by improving career attractiveness
Clinical Research

- Clinical investigators
- Biostatisticians
- Informaticians
- Coordinating Center
  - Site managers
  - Data managers
  - Regulatory specialists
- Clinical research sites
  - Clinical Research Coordinators (CRCs)
  - Data managers
  - Regulatory specialists
- IRB members
- “Decision scientists”—statistics, economics, psychology, sociology
Healthcare Quality Experts

• If we move to a learning healthcare organizational framework, regulatory science and clinical quality improvement will have substantial overlap

• Examples include the FDA’s sentinel project, cluster RCTs within health systems and use of data warehouses for comparative effectiveness
Regulatory Science is a Natural Partner with the Clinical and Translational Science Enterprise