IOM Workshop on the Regulatory Science Workforce

Regulatory Science Career Paths in Academia

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Critical knowledge ecosystem requires robust interactions between FDA, industry and academia
Critical Factors
Academic Career Decision-Making

- Clear definition of the field. Important questions. Tools and technologies to approach answers.
- Training in desired field.
- Role models.
- Career development and promotion opportunities in an academic home. Career track is clear.
- Availability and sustainability of research funding.
- Alternative career pathways.
Pizzo: “The nature of academia does not lead itself to a regulatory mindset.”*

- Definition: broad and elusive
- Cultural: applied science as a perjorative
- Role models are rare
- Development of educational and research programs will require time, resources and institutional commitment
- Academic homes are uncertain
- Funding climate unsupportive

PhD Training Program in Therapeutics [Tracks]
MS in Regulatory Science

• **Required courses:** Molecular approaches to drug action, discovery and design; human physiology and pathology; experimental design; quantitative methods
• **Electives:** principles and practice of drug development; bio-devices; stem cells as therapeutics; human pharmacology; statistics and probability; systems biology; systems pharmacology; toxicology; drug metabolism
• **CTSA Courses:** Introduction to clinical investigation; Intensive training in translational medicine
• **Nano courses:** how to get new drugs in the pipeline; how to run a clinical trial; how to get FDA approval; getting drugs to market; animal models of disease, etc.
• **Internships:** collaborations with industry and government
Current Academic Homes for Regulatory Scientists

- Pharmaceutical science: Schools of Pharmacy
- Pharmacology; clinical pharmacology
- Toxicology
- Drug disposition: PK/PD
- Genetics: P-genetics, P-genomics
- Bioinformatics: in silico modeling
- Applied statistics: clinical trial design, modeling
- Epidemiology: P-epidemiology
- Regulatory affairs; health care policy
- Others: P-vigilance, P-economics, decision sciences, preventive medicine, ethics, law, comparative effectiveness, post-market studies
Regulatory Science: Future Career Path Opportunities in Academia?

- Personalized medicine, with more precise diagnoses using state-of-the-art diagnostics
- Regenerative medicine
- Gene therapy
- Clinical investigation; innovative clinical trial design
- Bioinformatics
- Bio-engineering
- *Translational science and therapeutics
- *Regulatory science

*New interdisciplinary programs
An Example: Biologically Inspired Engineering

• A emerging discipline that applies biological principles to develop new engineering solutions.

• Based on convergence of life sciences and medicine with engineering and physical sciences.

• Develops new bioinspired technologies and translates them into products that meet real world needs.
Biomimetic Microsystems

• Engineer microchips containing living cells that reconstitute human organ functions for drug screening, diagnostic and therapeutic applications.

• ACCELERATE drug development & REPLACE animal testing

Don Ingber
George Whitesides
Kit Parker
Ali Khademhosseini
Dave Weitz

Biomimetic Heart

Biomimetic Spleen

Biomimetic Lung
Regulatory Science: Opportunities in Improve Visibility in Academia

- Training
- Institutional investment and commitment to translational science, therapeutics and regulatory science; use of translational science/medicine as a template
- Industry-academic interactions
- NIH-FDA collaboration; FDA COEs
- Other government funding of regulatory science research
- CTSA; NCATS