Challenges for Careers in Academia

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Regulatory Sciences is Part of Translational Medicine and Therapeutic Sciences, TMAT

- Basic Pharmacology
- Pharmacokinetics/Pharmacodynamics/Pharmacometrics
- Genomics/Pharmacogenomics
- Biostatistics
- Medical Specialty, e.g., Cardiology
- Devices/Diagnostics
- Systems Pharmacology/Pharmacometrics
- Medical Informatics/Pharmacoinformatics
- Regulatory Sciences
- Regulatory law
- Pharmaco-Metrics
- Drug Safety
- Biostatistics
- Informatics Etc…
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Drug Development Sciences
Pharmacokinetics/Pharmacodynamics
2

Pharmacogenomics
Personalized Medicines:
Drug Safety/ Drug Efficacy
6

Computational and Systems Biology Pharmacology
6

Therapeutic Bioengineering
Drug delivery systems, tissue engineering, devices, diagnostics
4

Regulatory Sciences
Development of new tools/standards/approaches for drug product evaluation
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We offer core services and public/private outreach programs.

- American Course in Drug Development and Regulatory Sciences
- Pharmacokinetics for Industrial Scientists
- Center for Drug Development, UC Washington Center
- New Center in Quantitative Pharmacology
Challenges for Recruitment and Retention of a Regulatory Scientist

1. The Pipeline

2. Academic Sustainability
   --- NIH Funding for Research
   --- Department Homes
The Pipeline:
Few regulatory scientists are being trained for careers in academia

Clinical Pharmacology Postdoctoral Training Programs

- Pharmacokinetics/Pharmacodynamics
- Pharmacogenomics
- Drug Safety/Toxicology
- **Regulatory Sciences**
- Pharmacoepidemiology
- Device/Diagnostics/Biologics
- Clinical Trial Design/Analysis

NIH Funds a Total of 10 Small Clinical Pharmacology Training Programs in the U.S.
2. Academic Sustainability: Concerns that research in Regulatory Sciences will not be NIH fundable

Faculty in Pharmaceutical Sciences

UCSF: 7 mid-career pharmaceutical-oriented scientists left UCSF largely because of lack of NIH funds for research (1995-2000)

Encourage Innovative Research in Regulatory Sciences
Encourage Funding from NIH, FDA and Others
2. Academic Sustainability: There needs to be a department that recognizes, recruits, hires, mentors and retains regulatory scientists

Tenure Track Position in Quantitative Clinical Pharmacology: Pharmacometrics

1. Research directly applicable to problems in drug development
2. Interactions with industry and regulatory agencies highly encouraged
3. Funding for research from federal sources OR industry

   1. Pipeline was thin
   2. Research area not generally recognized as innovative in academia
We are looking ahead.

**Bioengineering and Therapeutic Sciences**

We need to develop the pipeline in the context of a larger discipline (TMAT)

NIH and other peer-reviewed funding mechanisms are needed to fund innovative research in regulatory sciences

We need academic homes that recognize, support and promote regulatory scientists