Education and Training: What is Needed and How do we Get There?

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Training a Workforce in Regulatory Science

• Delineate the audience
• Identify the needs
• Develop the program to address both
• Enumerate the core elements to meet the needs
• Integrate as an opportunity to minimize resources and maximize collaboration
• Evaluate the efforts
Creating a Robust Workforce

Who is the Audience?

Target Audience for Regulatory Science

- Legal Profession
- Pharma/Biotech
- Federal Agencies
- For Profit Research Facilities
- Academia
- Research Support Staff
Needs Assessment for a Career in Regulatory Science

- Define the discipline
- Create mentored career development programs to educate the next generation of CRPs and Regulatory Scientists
- Create a visible flexible career path with appropriate education/training to support career trajectory
  - In FDA, NIH, Industry, Biotech and Academia
- Enhance the level of sophistication in approaches to drug development, evaluation and approval
Needs Assessment for a Career in Regulatory Science

• Provide a necessary understanding of research and scientific methodology

• Provide a necessary understanding of pharmacology, toxicology and therapeutics

• Provide a necessary understanding of the science that underpins the regulatory processes
Development of a Robust workforce Adaptive to Needs of Audience

Masters Program
- FDA Scientist
- Investigator
- Research Director
- Lawyer

Certificate Program
- Lawyer
- Research Director
- Project Manager
- Research Nurse
- Regulatory Coordinator
- Quality Assurance Specialist
Components of Regulatory Science
Current Reality Vs Future Opportunity

- Biological Sciences
  - Scientific Methods
- Biostatistics, Informatics
  - Clinical Trial Design
- Regulatory Compliance:
  - FDA, ICH, DHHS
- Clinical Trial Conduct & Management

Science & Regulation
Competency Areas

- Biostatistics, Decision Theory, IT
- Fundamentals of Pharmacology
- Scientific Methodology
- Clinical Trial Design
- Drug/Device Discovery & Development
- Clinical Research Conduct
- Monitoring & Quality Assurance
- Food, Drug & Device Law and Regulation
Integration into Existing Career Development Programs

INSTITUTE FOR TRANSLATIONAL MEDICINE AND THERAPEUTICS (ITMAT)

TRANSLATIONAL RESEARCH
- PATIENT ORIENTED RESEARCH CERTIFICATE
- TRANSLATIONAL RESEARCH CERTIFICATE
- MSc in TRANSLATIONAL RESEARCH

REGULATORY SCIENCE
- INTRODUCTORY (PENN CRC PROGRAM)
- REGULATORY SCIENCE CERTIFICATE
- MASTERS OF REGULATORY SCIENCE
Integrated Educational Program Scope

- Research Assistants
- Entry level Coordinators

Awareness/Exposure

- Coordinator
- Research Nurse
- Regulatory Coordinator
- Project Manager
- Lawyer

Certification

- Translational Scientists
- Faculty / Postdocs
- Project Managers
- Research Directors
- Lawyer

Masters
Program Elements: Opportunities for Collaboration

- 4 core courses
- 4 electives
- 2 internships
- Trainee designed mentored project
- Goal for completion: 2 years
Outcome Metrics of Training

• Global
  – *Increased ability of the research workforce to meet the needs of the regulatory science initiative*
  – *Creation of a viable career structure*
  – *Improved quality of research management with more formalized education*

• Individual
  – *Demonstrated knowledge in core concepts*
  – *Application of knowledge through completion of a mentored project designed to enhance the individual’s function in their professional life*
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