



# FDA's Regulatory Science Educational Activities

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# Overview of FDA's Initiatives

- Background on Regulatory Science
- Educational Resources on FDA Website
- Speakers at Conferences
- Regulatory Science Discussions
- FDA Training Programs
- Regulatory Science Curriculum
- Benefits of Regulatory Science Initiatives

# Background on Regulatory Science

- FDA published “Advancing Regulatory Science,” 2010
  - FDA’s Regulatory Science definition – development and use of new tools, standards and approaches to more efficiently develop products and to more effectively evaluate product safety, efficacy and quality
  - FDA’s role – work with partners to strengthen field, both within the agency and throughout the Nation

# Background on Regulatory Science

- Regulatory Science Workforce
  - Industry
  - Academia
  - FDA

# Educational Resources on FDA Internet

- For students, academia and industry:  
Consolidation of training and informational resources from one web site
  - <http://www.fda.gov/Training/default.htm>
- Course materials for educators
  - CDRH

# Educational Resources on FDA Website

- On-line education examples
  - FDA 101
  - CBER OCTGT Learn
  - CDER Learn
  - CDRH Learn
  - CFSAN Foods
  - CTP Retailor Training and Enforcement
  - CVM Veterinary Drug Regulatory Life Cycle
  - NCTR Array Track Tutorials
  - ORA University
- <http://www.fda.gov/Training/learningportal/ucm417483.htm>

# FDA Speakers at Conferences

- Invited presenters at conferences and meetings
- FDA sponsored workshops
  - <http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/default.htm>
  - FDA Science Forum, May 27-28, 2015

# FDA Participation in Regulatory Science Discussions

- Institute of Medicine - “Strengthening a Workforce for Innovative Regulatory Science in Therapeutics”
- UMD CERSI - “Degree Programs in Regulatory Science”
- PhRMA Foundation, University of Rochester and Georgetown University - “Regulatory Science Core Competencies and Curricular Guidelines”



# Training Programs

- Students Programs - Examples
  - ORISE Research Participation Program for Students
  - all Centers
  - FDA Regulatory Science Student Internship
  - CDRH Student Internship
  - CDER Experiential Pharmacy Program
  - CVM Veterinary Clerkship
  - JIFSAN Student Internship
  - NCTR Science Student Internship
- <http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/ucm395746.htm>

# Training Programs

- Post-Graduate Fellowship Programs - Examples
  - ORISE Research Participation Program - all Centers
  - FDA Service Fellowship Plan – all Centers
  - FDA Commissioner’s Fellowship Program
  - FDA – NCI/NIH Inter Agency Oncology Fellowship Program
  - CDRH Medical Device Fellowship
  - CTP Regulatory Science Fellowship
- <http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/ucm395747.htm>

# Regulatory Science Academic Programs

- Centers of Excellence in Regulatory Science and Innovation
  - University of Maryland
  - Georgetown University
  - University of California SF – Stanford
  - Johns Hopkins University
  - <http://www.fda.gov/scienceresearch/specialtopics/regulatoryscience/ucm301667.htm>

# Regulatory Science Academic Programs

- Instructional strategies that involve the classroom and hands on experience
  - Educational strategies such as case studies
  - Hands on experience - Industry and Academia
    - Internships and Fellowships that include interactions with FDA
      - » Industry and academia perspective of product approval

# Benefit of Regulatory Science Initiatives to FDA, Academia and Industry

- Through training programs the development and use of new tools, standards and approaches
- Scientists who:
  - Are prepared to work in areas of product development and approval
  - Need less time to be oriented and trained



**Thank you.**