FDA’s Initiatives to Closing the Regulatory Science Knowledge Gap

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Overview of FDA’s Initiatives

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

• Announced with FDA’s initiative to fast-track innovations to the public (2010)

• Initiative involves:
  – Translational science – shaping of basic scientific discoveries into treatments
  – Regulatory science – development and use of new tools, standards and approaches to more efficiently develop products and to more effectively evaluate product safety, efficacy and quality
Educational Resources on FDA Website

• 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](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](http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/default.htm)
Regulatory Science Curriculum

• FDA and 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 Curriculum

• Considerations for curriculum
  – Industry teachers
  – Instructional strategies so that application, analysis, synthesis and evaluation achieved
  • Case study, collaborative learning
  – Collaborations with Industry for student, Fellow and Senior Scientist training programs that include interactions with FDA
  • Formal meetings between FDA and Sponsors/Applicants
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

• [Link](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
Benefit of Regulatory Science Initiatives to FDA, Academia and Industry

• Scientists who:
  – Are prepared to work in areas of product development and approval
  – Need less time to be oriented and trained
  – Develop new tools, standards and approaches
Thank you.