



Skill Building for Reviewers in CDER

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CDER Forum for International Drug Regulatory Authorities

Skill Building for Reviewers in CDER



Overview

- Background
- Competency-Based Reviewer Education
- Current Educational Program
- Summary



CDER Forum for International Drug Regulatory Authorities



Background

- Purpose of our educational program:
 - To provide CDER reviewers with the knowledge and skills needed to accomplish CDER's mission
- Focus on improving science-based regulatory decision making



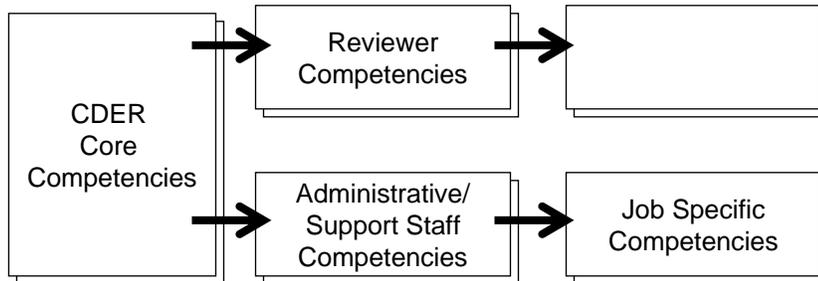
Background

- Multidisciplinary approach and internal program development/delivery
 - Educational specialists and medical professionals within the Division of Training and Development
 - Volunteer faculty from CDER (more than 200 in 2004-2005) and throughout FDA
 - "Visiting professors" from academia, industry, international colleagues



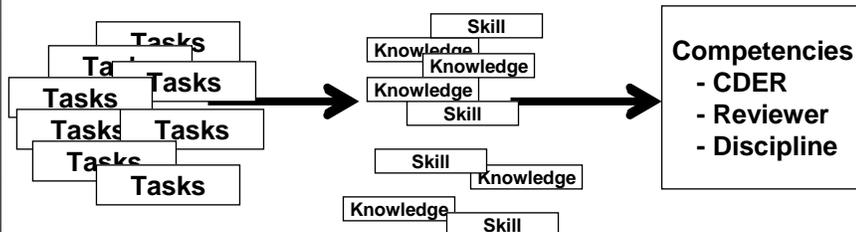


CDER's Competency Program



Competency-Based Reviewer Education

- Developed by CDER staff based on critical work





Sample Task and Knowledge

- Task: Review and evaluate Investigational New Drug (IND) submission
 - Knowledge of:
 - Types of submissions
 - Drug classes
 - Clinical trial design and protocols
 - Drug development process
 - Drug reviewer requirements
 - FDA regulations, CDER guidances
 - Discipline-specific data (pharmacology/toxicology, clinical pharmacology, chemistry, microbiology, biostatistics)



Sample Task and Skills

- Task: Review and evaluate Investigational New Drug (IND) submission
 - Skill in:
 - Evaluation, comparative analysis
 - Critical thinking
 - Data organization
 - Interpersonal communication
 - Conflict management





Sample Competencies

Communication:	Facilitates an open exchange of ideas in a variety of forums; makes clear convincing presentations.
Critical Thinking:	Uses problem solving and decision making skills to analyze data and form sound regulatory decisions.
Drug Review Process:	Explains the influence of regulations, guidances, and CDER operating procedures on the drug review process.
Medical/Pharmacologic Principles:	Applies basic concepts of disease processes and drug classifications to the drug review process.



Current Educational Program

- Components of the current educational program:
 - Foundational Programs
 - Advanced Programs
 - Special Programs





Foundational Programs

- Topics include:
 - Drug development process
 - FDA regulations
 - Drug review process
 - Discipline-specific review requirements
 - Scientific requirements outside their discipline (e.g., statistics for medical officers)
 - Communication, focusing on technical writing and presentations



Advanced Programs

- Topics are selected to:
 - Provide advanced and continuing education to CDER reviewers
 - Enhance the science base of CDER reviewers
 - Expose reviewers to a diversity of opinions
 - Introduce reviewers to new technologies
 - Strengthen science-based regulatory decision making





Advanced Programs

- Sample courses include:
 - Pharmacokinetic Toxicokinetic Concepts & Applications in Drug Development and Regulation
 - Survival Data Analysis
 - Use of Nanotechnology in Drug Development
 - Antisense and Oligonucleotide Therapeutics
 - Glycobiology



Advanced Programs

- Scientific Seminars
 - 8 – 10 lectures per month
 - Speakers are invited from academia, industry, clinical practice, and experts within FDA
 - Lectures are recorded using digital audio recording technology for computer archiving and playback





Special Programs

- CDER shares its expertise with others
- CDER learns from others
 - International Forum
 - Workshops co-sponsored with interested associations and universities



Summary

- Competency based program
 - For new reviewers
 - Based on critical work
- Three components of the program
 - Foundational Programs
 - Advanced Programs
 - Special Programs

