

Fay W. Boozman College of Public Health
 Graduate Certificate in Regulatory Sciences
 Department of Environmental Health Sciences
 Program Director: Mitchell R. McGill
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 Advisee's Name

 Student ID Number

 Faculty Advisor

PLAGIARISM TRAINING	Completion Date
Certification Test	
WRITING MILESTONE	
Skills Certification	

Plagiarism Training Requirement: All students in the COPH must adhere to the highest standards of professional and ethical conduct. Among these standards is the recognition that student written work must be original and appropriately cited. In order to facilitate understanding of this standard, all students must complete the on-line course “*How to Recognize Plagiarism: Tutorials*” at <https://plagiarism.iu.edu/tutorials/> and complete the Certification Test at <https://plagiarism.iu.edu/certificationTests/index.html>. Upon

successful completion of the test, students must provide a copy of the Validation Certificate to the COPH Office of Student and Alumni Affairs at cophoffice@uams.edu. The requirement must be completed by the first day of classes.

Writing Milestone Requirement: All students who enter the College of Public Health are required to complete a Writing Skills Assessment at the beginning of their first semester. The Assessment will identify strengths and weaknesses and highlight opportunities for improvement. Students who do not meet a predetermined score will be required to complete an online COPH 5000 Public Health Writing Workshop course. This course will address the fundamentals of good writing, writing with scholarly sources, revision strategies, and other topics in the interest of improving student writing skills. This is a non-credit curriculum requirement.

ALL CRGH OPTIONS

CORE (REQUIRED) – 12 Credit Hours		Credit Hours	Grade	Year	Semester
REGS 60133	FDA Regulations	3			
REGS 60233	Methods in Risk Assessment and Management	3			
REGS 51073	Design and Management of Clinical Trials	3			
REGS 61003	Good Regulatory Practices	3			

MINIMUM TOTAL HOURS = 12

Curriculum approved: Aug. 12, 2011

Form Updated: Sept. 12, 2024

GCRS COMPETENCIES

Graduate Certificate in Regulatory Sciences <i>At the completion of the course, students will be able to demonstrate the following competencies:</i>		
Competency	Learning	Assessment
1. Describe FDA structure and the structure of the US FDA and how the FDA works with other agencies to regulate products.	REGS 60133 FDA Regulations Week 1	Quiz. Students answer questions regarding the current structure, leadership, and functions of the US FDA. Grading will be performed following the rubric in the course syllabus.
2. Describe major US compliance rules, laws, regulations, policies, and practices for medical the regulation of food, drugs, dietary supplements, and medical devices products.	REGS 60133 FDA Regulations Weeks 1-5	Exam. Students answer questions about major food and drug related legislation and about FDA regulatory policies and approaches. Grading will be performed following the rubric in the course syllabus.
3. Assess drugs, medical devices, or related products to determine if their safety, efficacy, risk, and labeling or regulation are is sufficient for these products to meet regulatory standards or receive regulatory for approval.	REGS 60233 Methods in Risk Assessment Weeks 2, 3, 5, and 9	Essay. Students are given information regarding select a major regulatory decisions made for a specific product and must assess the information on which those decisions were based and determine if they agree with one of the decisions or discuss how a better decision could be made. Grading will be performed following the rubric provided by the course instructor.
4. Design a course of action to move a new drug or medical device product through the regulatory process.	REGS 61003 Good Regulatory Practices Weeks 2-4	Unit challenge. Students design a protocol to assess the safety and/or efficacy of a drug that would meet requirements for US FDA submission of a new drug or medical device. Grading will be performed following the rubric in the course syllabus.
5. Use resources to help stay current with the evolving regulatory landscape.	REGS 60133 FDA Regulations Week 10	Homework. Students select several cosmetics products from their homes or nearby stores and write about the ingredients contained within and the completeness and accuracy of the product labeling. Students also find and provide links to the FDA website with current information about the ingredients or products, demonstrating familiarity with FDA resources and showing that they can find relevant, up-to-date information on their own. Grading will be performed following the rubric in the course syllabus.