University Council

April 12, 2024

UNIVERSITY CURRICULUM COMMITTEE – 2023-2024
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Dear Colleagues:

The attached proposal from the College of Pharmacy for a new Area of Emphasis in Clinical Trials Management under the major in Pharmacy (M.S. Non-Thesis) will be an agenda item for the April 19, 2024, Full University Curriculum Committee meeting.

Sincerely,

Susan Sanchez, Chair

cc: Provost S. Jack Hu
Dr. Marisa Pagnattaro

PROPOSAL FOR AN AREA OF EMPHASIS

Date: February 23, 2024

School/College: College of Pharmacy

Department/Division: International Biomedical Regulatory Sciences

Program (Major and Degree): Pharmacy (M.S. Non-Thesis)

Area of Emphasis Title: Area of Emphasis in Clinical Trials Management

Which campus(es) will offer this program? Online

Proposed Effective Date: Fall 2024

CIP: 51200601

1. Area of Emphasis Description:

The Area of Emphasis in Clinical Trials Management is designed to enhance students' foundational skills in regulatory requirements essential in the safe and effective development, registration, and maintenance of medical products. In addition, students will learn skills and develop competencies in scientific, clinical, technical, and practical aspects of medical product development as well as how the different functions within the medical industry work to succeed in the regulated environment. Students completing the Area of Emphasis in Clinical Trials Management will have career opportunities in clinical research, clinical operations, clinical monitoring, or regulatory affairs, or as faculty in a regulatory sciences or clinical trials program.

2. Major Requirements:

The Area of Emphasis in Clinical Trials Management requires a minimum of 33 credit hours.

- BIOS(PHAR) 7100E, Biostatistical Applications for the Pharmaceutical and Biotechnology Industries (3 hours)
- PHAR 6010E, Pharmaceutical, Biotechnology, and Device Industries (4 hours)
- PHAR 6030E, Current Good Manufacturing Practices (3 hours)
- PHAR 6140E, Overview of Drug Safety Throughout Medical Product Lifecycle (4 hours)
- PHAR 6200E, Clinical Trials Design and Monitoring (4 hours)
- PHAR 6210E, Project Management in Clinical Trials (3 hours)
- PHAR 6310E, Good Clinical Practice Regulations for Drugs, Biologic Products, and Medical Devices (3 hours)
- PHAR 6950E, Master's Seminar in Regulatory Affairs (minimum of 3 hours)
- PHRM(HPAM) 7230E, Ethical Issues in Research (3 hours)

Choose at least one of the following:

- PHAR 6020E, Food and Drug Law (3 hours)
- PHAR 6130E, U.S. Marketing Applications for New Drugs, Biologics, and Medical Devices (4 hours)
- PHAR 6340E, European Pharmaceutical and Biologics Regulatory Sciences (3 hours)

Documentation of Approval and Notification

Proposal: Area of Emphasis in Clinical Trials Management under Pharmacy (M.S., Non-Thesis)

College: College of Pharmacy

Department: International Biomedical Regulatory Sciences

Proposed Effective Term: Fall 2024

School/College:

- College of Pharmacy Associate Dean for Science Education, Research, and Technology, Dr. Michael Bartlett, 2/23/24
- Graduate School Associate Dean, Dr. Anne Shaffer, 4/11/24