REGULATORY AFFAIRS TRACK

The Regulatory Affairs Track is not currently accepting new students. Students who have elected the track in the Class of 2023 and the Class of 2024 may continue to pursue it using the curriculum specified.

Every drug, medical device, diagnostic test, and food sold in the United States and other countries throughout the world must meet rigorous standards that are intended to insure that all products satisfy a set of safety and performance objectives. Scientists must possess the knowledge and expertise to create and implement high-quality systems as well as understand the environment encompassing regulatory compliance. Other essential skills include project management and leadership, scientific tools that allow for proper risk assessment and risk management strategies, and the ability to clearly communicate the regulatory decisions made.

The Regulatory Affairs Track is an interdisciplinary program that may be combined with any departmental concentration. Four courses are required. The track covers a wide array of regulatory affairs topics, including complex issues involving food and drug law, ethics, clinical trials, epidemiology, risk analysis, and adverse event reporting requirements and systems.

TRACK REQUIREMENTS

BIS 575	Introduction to Regulatory Affairs	1

Three of the following:

CDE 650	Introduction to Evidence-Based Medicine and Health Care	1
EHS 511	Principles of Risk Assessment	1
HPM 559	Big Data, Privacy, and Public Health Ethics	1
HPM 564	Vaccination Policy and Politics	1
HPM 570	Cost-Effectiveness Analysis and Decision-Making	1
HPM 588	Public Health Law	1
HPM 595	Food and Drug Administration Law	1

COMPETENCIES

Each student in the Regulatory Affairs Track will master the core curriculum competencies and the competencies for the student's department/program. In addition, upon completion of the Regulatory Affairs Track, the student will be able to:

- Utilize the best scientific and ethical standards to insure that food, pharmaceutical, and medical and diagnostic devices meet quality and regulatory standards.
- Develop/use leadership and management skills for conducting/overseeing research and clinical studies that are required by regulatory agencies.
- Develop processes that insure clear and consistent decisions to the public and to regulatory agencies.

- Assess/develop risk management strategies that can be used to get new products to the market swiftly, while assuring the consumer and regulatory bodies that efficacy and safety have been preserved.