

BIOSCIENCE ENTREPRENEURSHIP (BIOS)

BIOS 447. Regulatory Affairs for the Biosciences. 1.5 Unit.

This mini-course introduces students to the Food and Drug Administration (FDA) and the laws and regulations it enforces. A scientific regulatory agency with far reaching enforcement authority, FDA is the most powerful consumer protection agency in the world. This course will familiarize students with FDA's mission, philosophy and organizational structure, as well as policy and procedure it uses to ensure the safety and effectiveness of the food, drugs, biologics, cosmetics, medical devices and radiation-emitting products it regulates. Recommended preparation: Enrollment in the MEM Biomedical Entrepreneurship Track. Offered as BIOS 447, HSMC 447, and MGTE 447.