FAU | FLORIDA ATLANTIC UNIVERSITY
DEPARTMENT OF BIOLOGICAL SCIENCES

Introduction to Drug Development

This course provides the basics in US FDA drug regulations, facilities and process qualification and the processes involved in drug discovery and development. Students will learn how specific activities fit into the overall scheme of drug development and evaluate the impact of each activity on the overall progression of a new drug candidate. The principles of current good manufacturing practices (cGMPs), quality control and quality assurance are introduced. The basics of regulatory compliance, the global nature of regulations and their importance of validation in the Pharmaceutical and Biotechnology Industries will be presented.

Topics include:

- Drug Discovery and Non-clinical Development
- Early Phase Formulation and Analytical Development
- Requirements for Investigation New Drug (IND) Approval
- Quality and Regulatory Requirements in GMP Development
- Phase I Clinical Development
- Phase II Clinical Development
- Phase III Clinical Development
- Chemistry Manufacturing and Controls (CMC) required for NDA Filing
- Process and Analytical Validation
- FDA Pre-Approval Inspection (PAI)

Course information: BSC 6936/BSC 4930

Term: Spring 2018 (January 6 – April 23)

Time: Wednesday, 9:00-11:50 AM

Location: SC141 (Boca) and RF119 (Jupiter)

For additional information, please contact Dr. Shailaja Allani at skesaraj@fau.edu.