

Regulatory Affairs Minor

The Regulatory Affairs Minor covers FDA regulations, laws and regulatory document processes related to medical devices, medical device development, and project/facility management. The program provides students with an understanding of applications such as obtaining approval for medical devices, pharmaceuticals, and biologics, and marketing and implementing medical devices in hospital/clinical settings. The minor prepares students particularly for careers in regulatory affairs, but also for the healthcare industry in general.

Students majoring in biomedical engineering can count no more than 9 hours from their major towards this minor. Students may not receive both the clinical engineering and regulatory affairs minors.

Program Requirements

Code	Title	Credit Hours
Required Courses		
CPB 448	Hospital Rotation	3
CPB 402	Introduction to Clinical Engineering	3
CPB 452	Introduction to FDA Regulations and Medical Device Laws	3
CPB 453	Medical Device Development and Regulatory Considerations	3
Select two from the following:		6-7
MGT 453	Quality Management Systems	
STA 308	Introduction to Programming and Scripting for Data Analytics	
STA 301	Applied Statistics	
or STA 261	Statistics	
CMR 224	Medical Terminology	
KNH 209	Medical Terminology for Health Professionals	
PHL 375	Medical Ethics	
NSG 343	Health Care Informatics	
KNH 381	Biodynamics of Human Performance	
CIT 431	Health Information Technology I	
SOC 357	Medical Sociology	
NSG 435	Challenges in Health Care Delivery	
NSG 321	U. S. Health Care System and Culture	
CPB 428	Engineering Principles in Medical Device Design	
CPB 328	Bioinstrumentation	
ECE 411	Sensors and Data Fusion with Robotics Applications	
ECE 414	Design and Modeling of Robotic Systems	
ECE 425	Digital Signal Processing	
ECE 426	Biomedical Signal Analysis	
ECE 429	Digital Image Processing	
CSE 432	Machine Learning	
CSE 466	Bioinformatics Computing Skills	
CSE 488	Image Processing & Computer Vision	

Select one from the following: 3

EGM 411	Leading and Managing Projects
MGT 291	Introduction to Management & Leadership
MGT 295	Introduction to Operations and Supply Chain Management

Total Credit Hours 21-22