QUALITY ENGINEERING FOR REGULATED MEDICAL TECHNOLOGIES - CERTIFICATE

Quality engineering principles are mandated by federal and state regulations for clinical facilities and for the design, testing and manufacture of medical technologies (such as pharmaceuticals and imaging, diagnostic and therapeutic devices). Different and complimentary quality regulations apply to both clinical and pre-clinical facilities involved in testing and validating new technologies. Completion of this certificate requires specific instruction in both quality engineering and regulation of medical technologies; moreover, candidates must go beyond understanding concepts by demonstrating appropriate use of quality engineering principles in a medically-related internship. Given the challenge to achieve both improved outcomes and lower costs in medical care, candidates for this certificate are expected to be entering a high-growth job market for biomedical engineers.

Program Requirements

Code	Title	Semester Credit Hours
Required Internship		
Select one of the following:		3
Internship (position must be approved by certificate faculty to meet experience needs)		
Bioinnovation I-Summer Clinical Fellowship		
Required Courses		
Select from the following:		6-9
BMEN 604	FDA Good Laboratory and Clinical Practices	
BMEN 606 or BMEN	Medical Device Path to Market or Entrepreneurial Pathways in Medical Devices	
ISEN 614	Advanced Quality Control	
Elective Courses		
Select from the following:		0-3
BMEN 643	Risk Based Development and Testing of Medical Devices	
ISEN 616	Design and Analysis of Industrial Experiments	
VTMI 629/ SCSC 629	Laboratory Quality Systems	
Total Semester Credit Hours		**12**