

UNIVERSITY OF SOUTH FLORIDA

GRADUATE
CERTIFICATE

Regulatory Affairs
(Medical Device Concentration)

The University of South Florida's Industrial & Management Systems Engineering Department offers a certificate in Regulatory Affairs (Medical Device Concentration) for individuals with technical backgrounds from the medical device/pharmaceutical/regulated industries or other engineering environments who will occupy professional regulatory affairs positions.

This certificate will also be of value to individuals involved in the design, development and manufacturing of medical devices. This certificate program develops the requisite compliance skills by combining current regulatory approaches and quantitative techniques in a balanced curriculum.

The required fifteen (15) semester hours in five (5) courses will assist in strengthening compliance credentials and developing professional competence. Courses are offered on the Tampa campus or on-line via Florida Engineering Education Delivery System (FEEDS).

Additionally, graduate students in the Colleges of Engineering, Medicine, Nursing, Public Health and Arts & Sciences will also be served by these courses. Individuals seeking the certificate need not be accepted to a specific program at USF to earn the certificate. Students who wish to apply these courses toward a degree program should contact that department for information and prior approval.



<http://www.outreach.usf.edu/gradcerts/a>

USF UNIVERSITY OF
SOUTH FLORIDA

Course Requirements (15 Semester Hours)

Required Coursework: A concentration of fifteen (15) semester hours in five (5) courses is required. The student must obtain a grade of "C" or better in each class for it to be applied toward the certificate. Students pursuing a graduate certificate will be required to meet the same academic requirements as those defined for degree-seeking students to remain in "good standing," which includes maintaining a 3.0 GPA average.

Required Coursework: (15 semester hours) Select five courses from the following list:

EIN 6271	Overview of Regulated Industries (Medical Device Concentration)	3 Credit Hours
EIN 6272	Regulated Quality Systems and Control	3 Credit Hours
EIN 6273	Regulated Product Approval Process	3 Credit Hours
EIN 6274	Human Factors Engineering for Medical Devices	3 Credit Hours
EIN 6275	Design Controls for Medical Devices	3 Credit Hours
EIN 6276	International Regulations— Medical Devices	3 Credit Hours

These courses are all available both on the Tampa campus and on-line via Florida Engineering Education Delivery System (FEEDS).

Application Requirements

An earned bachelor's degree from a regionally accredited college or university is required.

Candidates interested in the Certificate in Regulatory Affairs (Medical Device Concentration) must notify the department of their intent to pursue the Certificate prior to exceeding six (6) credit hours. A personal statement of purpose and letter from your employer will be required. A personal interview by the certificate director may also be required.

There is no specific test requirement for admission to the certificate.

Certificate Program Courses Applied Toward Graduate Degree

Up to 12 semester hours may be applied contingent upon department approval.

Prospective Master of Science in Engineering Management (MSEM) students must meet all entrance requirements for the MSEM program before the course(s) will be transferred. Additionally, no class will be considered unless at least a "B" grade was obtained.

Registration and Applications

For information on this, or other Graduate Certificate programs, or to receive application materials please visit <http://www.outreach.usf.edu/gradcerts/admissions.asp> or contact:

Office of Graduate Certificates
University of South Florida
4202 E. Fowler Avenue, FAO100B
Tampa, FL 33620-7940
Phone: (813) 974-2442
Fax: (813) 974-7061
Email: gradcerts@admin.usf.edu
Website: <http://www.outreach.usf.edu/gradcerts/a>

For more information about College of Engineering certificates and degrees, follow the links on the web at <http://www2.eng.usf.edu/index.asp>
For more details about master's or Ph.D. programs, or financial aid, or to view the graduate catalog visit: <http://www.grad.usf.edu> or call 813-974-2846.

Department Contact

For additional information contact:
IMSE Certificate Director
(813) 974-2269
imse@eng.usf.edu

Registration Process for Individual Courses

Register through the IMSE department, located in ENC 2400 or by calling (813) 974-2269. Off campus students may register through the Florida Engineering Education Delivery System (FEEDS), by calling (813) 974-3783 or on the web at <http://feeds.eng.usf.edu>.

Time Limit for Completion of Certificate

Certificate course work should be completed within three years.

Fee Per Course/Credit Hour

Fees parallel those of standard graduate-level classes. For more information on current fees, visit: http://usfweb.usf.edu/pfs/tuition_cost.htm



STATEMENT OF ACCREDITATION AND NON-DISCRIMINATION

The University of South Florida is accredited by the Commission on Colleges of the Southern Association of Colleges and Schools to award degrees at the baccalaureate, master's, specialist, and doctoral levels, including the Doctor of Medicine.

Events, activities, programs and facilities of the University of South Florida are available to all without regard to race, color, marital status, sex, religion, national origin, disability, age, Vietnam or disabled veteran status, sexual orientation as provided by law and in accordance with the University's respect for personal dignity.