GCRA–MD

The University of South Florida's Industrial & Management Systems Engineering department offers a **Graduate Certificate in Regulatory Affairs–Medical Devices** 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 program develops the requisite compliance skills by combining current regulatory approaches and quantitative techniques in a balanced curriculum, which strengthens compliance credentials and develops professional competence.

The Industrial and Management Systems Engineering Department also offers Graduate Certificates to upgrade professional skills in other areas.

Current Graduate Certificates offered:

- Total Quality Management
- Technology Management
- Regulatory Affairs (Medical Devices)

For more information and application, visit http://www.outreach.usf.edu/gradcerts/a

GCRA–MD

Preparing a qualified workforce for the medical device industry

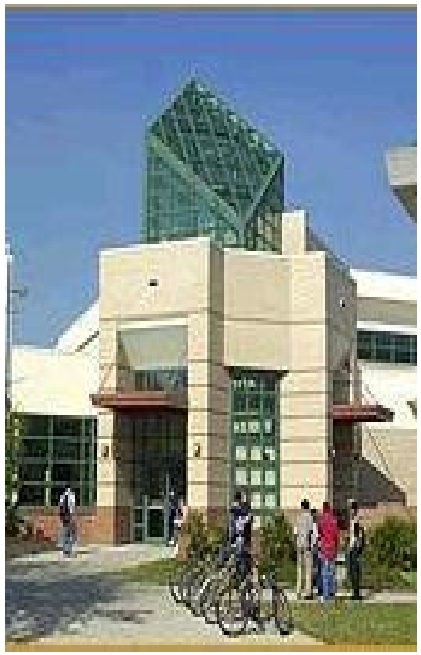
GCRA–MD
The Master of Science Program in Regulatory Affairs is under development. This certificate program develops the requisite compliance skills by combining current regulatory approaches and quantitative techniques in a balanced curriculum, This program is available on campus and to you anytime, anywhere, through distance learning at USF.

University of South Florida
4202 East Fowler Avenue
ENB 118
Location: ENC 2400
Tampa, Florida 33620-5350

Phone: 813-974-2269
Fax: 813-974-5953
Department's web page:
http://imse.eng.usf.edu
E-mail: imse@eng.usf.edu
For more information, please contact
Prof. Dolores Gooding
Phone: 813-974-5582
E-mail: gooding@eng.usf.edu

USF
UNIVERSITY OF SOUTH FLORIDA

Graduate Certificate in Regulatory Affairs–Medical Devices



Preparing a qualified workforce for the medical device industry

GCRA–MD
The Master of Science Program in Regulatory Affairs is under development. This certificate program develops the requisite compliance skills by combining current regulatory approaches and quantitative techniques in a balanced curriculum, This program is available on campus and to you anytime, anywhere, through distance learning at USF.

Graduate Certificate in Regulatory Affairs

This certificate will accommodate individuals with technical backgrounds from the medical device / pharmaceutical / regulated industries or other engineering environments who will occupy professional regulatory affairs positions, or who are involved in the design, development and manufacturing of medical devices. This program develops the requisite compliance skills by combining current regulatory approaches and quantitative methods which strengthens compliance credentials and develops professional competence.

Application Requirements:

1. An earned bachelor's degree from a regionally accredited college or university is required.
2. 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.
3. There is no specific test requirement for admission to the certificate.

Required Coursework:

Overview of Regulated industries (medical device concentration) 3 credits

Regulated Quality Systems and Control 3 credits

Regulated Product Approval Process 3 credits

Human Factors Engineering for Medical Devices 3 credits

Design Controls for Medical Devices 3 credits

Additional course: International Regulations – Medical Devices (Available for those individuals who need 18 hours teaching concentration.)

The coursework presented here was developed in collaboration with the Florida Medical Manufacturers' Consortium (FMMC) and with the input of staff at San Diego State University where a successful program in Regulatory Affairs already exists for the pharmaceutical and medical manufacturers in the State of California. Most, of a handful of programs in existence today, are heavily concentrated toward the pharmaceutical industry. According to the FMMC and the Cannon Company, this program will be a first of its kind. It will concentrate on medical devices and will be offered by a college of engineering. The longer range plan will be a proposal for an MS in Regulatory Affairs.

Curriculum Description:

1. EIN 6430 Overview of Regulated industries (medical device concentration)

Provides students with information on regulated industries , with particular emphasis on medical .

2. EIN 6431 Regulated Quality Systems and Control

Provides students with information to design and maintain quality systems for regulated industries.

3. EIN 6432 Regulated Product Approval Process

Provides students with information to collaborate effectively with regulatory agencies to navigate the product approval process, with particular emphasis on medical devices.

4. EIN 6433 Human Factors Engineering for Medical Devices

Provides students with information for the ergonomic design and operability of medical devices.

5. EIN 6434 Design Controls for Medical Devices

Provides students with information to establish and maintain procedures to effectively control the design requirements and specifications for medical devices.

6. EIN 6435 International Regulations-Medical Devices

Provides students with information regarding the major global and region-specific compliance issues related to medical devices.

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, FAO 100B
Tmapa, 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

Information on taking classes through distance learning (APEX), can be found at:
http://apex.eng.usf.edu/index.html

Department Contact

For additional information contact:

IMSE Certificate Director
(813)974-2269
imse@eng.usf.edu