UCI Division of Continuing Education

MEDICAL DEVICE DEVELOPMENT

CERTIFICATE PROGRAM • ONLINE

Emerging disruptive technologies, ever-changing regulations, and increased competition create many challenges for the medical device industry. This program provides comprehensive professional training in the successful research, conceptualization, development, and manufacturing of medical devices. Evaluated and developed in collaboration with governmental and industry advisors, this program meets the highest professional development standards for the medical device industry.

The newly updated curriculum addresses current industry trends and best practices in medical device design, development, and manufacturing. Coursework covers quality, safety, regulatory compliance, commercial and financial strategies, and post market surveillance. Updated EU-MDR requirements are now included in the Regulatory Requirements for the Medical Devices course.

WHO SHOULD ENROLL

- Regulatory professionals, such as those in regulatory affairs or quality assurance
- Research, development and engineering professionals involved in biomedical product design, development, validation, and manufacturing
- Manufacturing professionals
- Clinical managers and other healthcare professionals
- Field service engineers, commercial marketing and sales professionals
- Life science managers, such as research scientists and product managers

PROGRAM BENEFITS

- Gain the knowledge needed to design, create and manufacture medical devices
- Acquire an understanding of the medical device product development process and knowledge needed to manage medical device intellectual property rights
- Learn how to implement successful design and manufacture medical products by avoiding common quality and regulatory pitfalls
- Earn professional development credits to maintain your RAC credential with RAPS-Regulatory Affairs Professional Society
- Learn from seasoned instructors with practical industry experience

CERTIFICATE ELIGIBILITY AND REQUIREMENTS

A certificate is awarded upon completion of 15 credit units (9 required and 6 elective credit units), with a grade of "C" or better in each course. **NOTE:** 6 credit units may be counted toward the Clinical Trials: Medical Device and Drug Development or the Regulatory Affairs and Compliance program when courses are shared. All requirements must be completed within 5 years after the student enrolls in his/her first course. Students not pursuing a certificate are welcome to take as many individual courses as they wish.

PROGRAM FEES

The total cost of the certificate program varies depending on the electives chosen. Actual fees may differ from the estimate below. Fees are subject to change without prior notice.

Course Fees (9 required and 6 elective units)	$3,675
Candidacy Fees	$125
Textbook Fees	$600
Total Estimated Cost	**$4,400**

OCRA Orange County Regulatory Affairs Discussion Group **www.ocra-dg.org** **Members Save 10%**

TO ENROLL

Visit ce.uci.edu/mdd for full course descriptions, instructor biographies, and to enroll.

TRANSFER CREDIT

Graduates from UCI Division of Continuing Education's Medical Device Development program are eligible to transfer credits to:

- **Northeastern University, Master of Science in Regulatory Affairs for Drugs, Biologics, and Medical Devices OR Master of Science in Project Management**
- **Rutgers School of Health Professions, Master of Science in Clinical Research Management**

NOTE: Any student wishing to transfer credits must obtain a "B" or better in each course.

FOR MORE INFORMATION:

EngineeringSciences@ce.uci.edu

MEDICAL DEVICE DEVELOPMENT CERTIFICATE PROGRAM

COURSE#	REQUIRED COURSES	UNITS
EECS X445.2	Regulatory Requirements for Medical Devices†	3
BME X408	Medical Device Life Cycle Management*	3
MGMT X442.6	Medical Device Quality Systems	3
COURSE#	**ELECTIVE COURSES (Minimum 6 units)**	**UNITS**
MGMT X445	Medical Device Marketing	3
EECS X445.22	Medical Device Manufacturing	3
BME X406	Medical Device Risk Management	3

† Candidates may take both courses and count one as an elective.

ADVISORY COMMITTEE

Matthew Jenusaitis, Chief of Staff, UC San Diego, Health System

Dan Modi, Director, Quality & Regulatory Certification, Alcon Research, Ltd.

Albert Rego, Scientific Consultant to the Life Science Industry

Sumit Sen, Chemist (Technology-Based Expert), U.S. Food and Drug Administration

Travis Smith, Managing Director, Square-1 Engineering; President, DeviceAlliance

Del Stagg, Ph.D., Regulatory Consultant, Founder of the Orange County Regulatory Affairs Society (OCRA)

John Via, D. Eng., P.E., Consultant, Pharmaceutical & Medical Device Manufacturing

Carl Wyrwa, President, CW Software Solutions, Inc.