UCI Division of Continuing Education

MEDICAL PRODUCT DEVELOPMENT

CERTIFICATE PROGRAM • ONLINE

Emerging technologies, ever-changing regulations, and increased competition create many challenges for the medical product industry. UCI Division of Continuing Education's program, developed with government and industry advisors, fulfills a recognized need for comprehensive professional learning in the successful design, development and delivery of medical devices, pharmaceuticals, and other biomedical products. The curriculum addresses the breadth of the development process, including a thorough understanding of compliance, engineering for improved performance, how to mitigate commercial and financial risks, and building marketing success.

WHO SHOULD ENROLL

- Regulatory professionals, such as those in regulatory affairs or quality assurance
- Engineers, such as those involved in biomedical product design and development
- Manufacturing professionals
- Clinical managers and other healthcare professionals
- Life science managers, such as research scientists and product managers

PROGRAM BENEFITS

- Gain the knowledge needed to design and create medical devices and pharmaceuticals
- 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 medical device design and manufacturing by avoiding common quality and regulatory pitfalls
- UCI Division of Continuing Education is a Regulatory Affairs Professional Society (RAPS) Professional Development provider
- Earn credits to qualify for RAC recertification
- Learn from instructors seasoned in practical industry experience who share their knowledge effectively

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)	$3,740
Candidacy Fees	$125
Textbook Fees	$560
Total Estimated Cost	**$4,425**

OCRA Orange County Regulatory Affairs Discussion Group

www.ocra-dg.org
Members Save 10%

RAPS PROFESSIONAL DEVELOPMENT PROVIDER

UCI DCE is a Regulatory Affairs Professionals Society (RAPS) Professional Development provider. UCI DCE is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs UCI DCE has agreed to follow RAPS' established operational and educational criteria.

TRANSFER CREDIT

Graduates from UCI Division of Continuing Education's Medical Product 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**
- **University of Nebraska-Lincoln Online Master in Engineering Management (MEM)**
- **University of Wisconsin-Platteville Online Master of Science in Engineering**
- **Keck Graduate Institute (KGI) Of Applied Life Science's: Part-Time Master of Bioscience (MBS) Program**

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

TO ENROLL

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

FOR MORE INFORMATION:

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MEDICAL PRODUCT DEVELOPMENT CERTIFICATE PROGRAM

COURSE#	REQUIRED COURSES	UNITS
BME X408	Medical Product Life Cycle Management*	3
EECS X445.2	Regulatory Requirements for Medical Devices*†	3
MGMT X442.6	Medical Product Quality Systems	3
COURSE#	**ELECTIVE COURSES (Minimum 6 units)**	**UNITS**
	REGULATORY AFFAIRS	
MGMT X445	Medical Product Marketing	3
MED X413.4	Application of Good Clinical Practices	3
BME X414	Biomedical Business and Legal Management Essentials	3
	QUALITY AND COMPLIANCE	
EECS X445.22	Medical Product Manufacturing	3
BME X407	Process Validation for Medical Product Development	3
BME X406	Medical Device Risk Management	3
BIO SCI X450	Fundamentals of Clinical Trials	3
MED X413.41	Good Laboratory Practices	1.5
	ENGINEERING AND SCIENCE	
BME X405	Applied Anatomy and Physiology for Clinical Studies	4
EECS X445.23	Medical Device Design and Evaluation	3

*Courses BME X408, EECS X445.2 and EECS X445.26 have been pre-approved by RAPS as eligible for up to 15 credits towards a participant's RAC recertification upon full completion.

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