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.

University of California, Irvine  ce.uci.edu/mpd
COURSE # | REQUIRED COURSES | UNITS
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EECS X445.2 | Regulatory Requirements for Medical Devices* † | 3
BME X408 | Medical Product Life Cycle Management* | 3
MGMT X442.6 | Medical Product Quality Systems | 3

COURSE # | ELECTIVE COURSES (Minimum 6 units) | UNITS
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MGMT X445 | Medical Product Marketing | 3
MED X413.4 | Application of Good Clinical Practices | 3
BME X414 | Biomedical Business and Legal Management Essentials | 3

REGULATORY AFFAIRS
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

QUALITY AND COMPLIANCE
ENGINEERING AND SCIENCE

*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.