

Certificate

## Regulatory Affairs

This program enables you to master regulatory affairs by developing global strategies, managing risk, and ensuring compliance for medical devices, drugs, and biological products, preparing you for success in the regulatory field and the RAC certification. The Regulatory Affairs program consists of seven required courses.

**Total Units:** 14

**Completion Time:** 9-12 months (full-time)

**Modality:** Online with live-online and self-paced course formats.

**Special Programs:** Not currently approved for F-1 Compliance or WIOA/TAA Funding.



*Courses may have prerequisites; review the course page before enrolling. A checkmark indicates the course is typically offered during that term. \**

### Required Courses

14 Units | Choose 7 Courses

COURSE NAME & NUMBER	UNITS	FALL	WINTER	SPRING	SUMMER
Quality Management Systems for Medical Devices: ISO 13485 and FDA Requirements   MEDD.X407	2.5	✓		✓	
Foundations in Medical Devices: Developing Premarket U.S. Regulatory Strategies and Working in a Regulated Environment   REGL.X410	2.0		✓		✓
Global Medical Device Submissions and Strategy REGL.X401	1.5	✓		✓	✓
Design Control for Medical Devices MEDD.X400	2.0	✓		✓	✓
Good Manufacturing Practices REGL.X400	3.0		✓		✓
Communicating and Negotiating with the FDA REGL.X402	1.5	✓	✓	✓	
Regulatory Submissions: Devices and Diagnostics REGL.X405	2.5		✓		✓
Post-Market Regulatory Obligations for Medical Devices MEDD.X406	1.5		✓		✓
European Medical Device Regulation: Clinical Evaluation and Post-Market Surveillance   REGL.X408	3.0	✓		✓	

### Completion Review

Once all certificate requirements have been met and your final grades are posted, please access your Student Portal to enroll in the "[Certificate Completion Fee](#)" to begin the review process. Please allow 4-6 weeks to receive your certificate.

### Professional Development

UCSC Silicon Valley Professional Education is a Regulatory Affairs Professional Society (RAPS) RAC Recertification Approved Provider. Visit our [Regulatory Affairs program page](#) to view courses that meet RAC recertification requirements to maintain the credential.