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. 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 Regulatory Strategies 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		✓		✓
Regulatory Strategy and FDA Negotiation in the Age of AI REGL.X402	1.5	✓	✓	✓	
FDA Submissions Using AI Tools: Ensuring Regulatory Success REGL.X405	2.5		✓		✓
Post-Market Regulatory Obligations for Medical Devices MEDD.X406	1.5		✓		✓
European Medical Device Regulation (EU MDR) 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.