Certificate

Medical Device Quality and Design

This program helps you gain expertise in medical device quality design and regulatory compliance, covering key areas like risk management, human factors, and quality systems, and guides you in developing compliant documentation and risk management plans. The Medical Device Quality and Design program consists of six to eight core courses.

Total Units: 14
Completion Time: 9-12 months (full-time)
Modality: Online with live-online and self-paced 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. **

Core Courses

14 Units | Choose 6 to 8 Courses

COURSE NAME & NUMBER	UNITS	FALL	WINTER	SPRING	SUMMER
Quality Management Systems for Medical Devices: ISO 13485 and FDA Requirements | MEDD.X407	3.0	✓		✓	
Design Control for Medical Devices MEDD.X400	2.0	✓		✓	
Risk Management for Regulated Industries MEDD.X409	3.0	✓		✓	
Medical Device Process Validation MEDD.X411	2.0		✓		✓
Software Validation for Medical Devices MEDD.X410	2.0		✓		✓
Human Factors and Usability in Medical Device Development MEDD.X401	2.0	✓		✓	
Mobile Health, SaMD, and AI/ML Devices MEDD.X404	1.0		✓		✓
European Medical Device Regulation (EU MDR) | REGL.X408	3.0	✓		✓	
Regulation of in vitro Diagnostics in Europe and the US MEDD.X408	2.5		✓		✓
Effective Auditing: Interviewing, Influence & Audit Psychology MEDD.X412	1.5		✓		✓

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.

Note: You will need an understanding of statistics for this program.