Specialization

Global Regulatory Compliance

This specialization develops practical skills in interpreting global medical device regulations, implementing compliant quality management systems, and conducting effective regulatory audits. The Global Regulatory Compliance specialization consists of three required courses.

Total Units: 7

Learning Outcomes

- Interpret and apply requirements of the Quality Management System Regulation (QSMR) and ISO 13485:2016.
- Develop an EU MDR compliance strategy for documenting clinical evaluations, technical documentation, and post-market surveillance.
- Plan, conduct, and document risk-based, process-driven quality systems audits.

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

Core Courses

7 Units | 3 Courses

COURSE NAME & NUMBER	UNITS	FALL	WINTER	SPRING	SUMMER
Quality Management Systems for Medical Devices: ISO 13485 and FDA QMSR | MEDD.X407	2.5	✓		✓	
European Medical Device Regulation (EU MDR) REGL.X408	3.0	✓		✓	
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 "Specialization in Global Regulatory Compliance Completion Fee" to begin the review process. Please allow 5-8 weeks to receive your certificate.