



SAFETY RISK MANAGEMENT (SRM)

COURSE OVERVIEW

Medical device Safety Risk Management (SRM) per ISO 14971 is a systematic process for identifying hazards, estimating and evaluating associated risks, controlling those risks to acceptable levels, and monitoring effectiveness throughout the device lifecycle. This course was developed by practitioners, for practitioners, to teach the intricacies of ISO 14971, supporting global product submissions, and building better device businesses.

COURSE CURRICULUM

- Introduction & Foundations
- Key Definitions: Hazard, Harm, Risk
- The Three H's: Hazard to Harm Chain
- Risk Management Plan (RMP)
- Risk Matrix & Acceptability Criteria
- Risk Analysis (RA) & Occurrence
- Risk Control Hierarchy & RCM Verification
- Benefit-Risk Analysis
- Overall Residual Risk (ORR)
- Risk Management Review (RMR)
- Post-Market Surveillance & PMS Feedback
- Usability Engineering & Human Factors
- Technical Writing for Risk Management
- Related Standards: IEC/TR 80002-1, TIR34971, SW96

COURSE AT A GLANCE

Price: \$1,500
Lessons: 181
Video Content: 1.5 hours
Quizzes: 12
Final Exam: 1
Time Limit: 60 days
Certificate: Yes, upon passing
Format: Self-paced

LIVE EXPERT SESSIONS

Each student receives two live virtual sessions with a DQS expert:

Before Class: 30-minute orientation session
After Class: 60-minute Q&A and implementation support
90 minutes of personalized expert guidance included!

DOWNLOADABLE FILES

- Complete course slides and sample SRM procedure
- Key templates: Risk Management Plan, Risk Analysis, Risk Management Review, and Overall Residual Risk
- RMF audit readiness checklist
- Sample device case study activities and list of additional resources

LEARNING OBJECTIVES

- Understand the regulatory context, core terminology, and relationship between ISO 14971 and other medical device standards
- Create and maintain Risk Management Plans, Risk Analyses, Overall Residual Risk evaluations, and Risk Management Reviews
- Apply the risk control hierarchy, verify implementation and effectiveness, and document evidence with full traceability
- Evaluate residual risks against medical benefits and establish PMS systems that feed back into risk management
- Apply technical writing best practices to create specific, traceable, and defensible risk management documentation
- Identify critical tasks from risk analysis Severity (SHarm) ratings and link human factors validation to RCM verification
- Anticipate auditor expectations, avoid common deficiencies, and demonstrate systematic risk management
- Apply related standards (IEC/TR 80002-1, AAMI TIR34971, IEC 80001-1, ANSI/AAMI SW96) for software, AI/ML, networked devices, and security risk management
- Use the P1 × P2 methodology to estimate the probability of harm occurrence
- Conduct Benefit-Risk Analysis using the FDA framework and appropriate data sources