



USABILITY ENGINEERING (UE) AND HUMAN FACTORS (HF)

COURSE OVERVIEW

Usability Engineering and Human Factors Engineering apply scientific knowledge of human behavior, capabilities, and limitations to medical device design, ensuring safe, effective, and satisfying use throughout the product lifecycle. This course was developed by practitioners, for practitioners, to optimize usability and minimize use errors in medical devices.

COURSE CURRICULUM

- Introductions & Foundations
- Key Definitions: Use Error, User Interface
- Use Specification Development
- Use-Related Risk Analysis (URRA)
- Perception-Cognition-Action (PCA) Model
- ANSI/AAMI HE75 Design Principles
- Formative Evaluation Methods
- Human Factors Validation Testing
- Sample Size & Learning Decay
- Documentation & UE File
- Post-Market & Lifecycle Management
- Regulatory Expectations (FDA & EU MDR)
- Technical Writing for UE Documentation
- Special Considerations: Home Use, Combination Products, Software UI

<p>COURSE AT A GLANCE</p> <p>Price: \$1,500</p> <p>Lessons: 129</p> <p>Video Content: 1.0 hours</p> <p>Quizzes: 10</p> <p>Final Exam: 1</p> <p>Time Limit: 60 days</p> <p>Certificate: Yes, upon passing</p> <p>Format: Self-paced</p>	<p>LIVE EXPERT SESSIONS</p> <p>Each student receives two live virtual sessions with a DQS expert:</p> <p>Before Class: 30-minute orientation session</p> <p>After Class: 60-minute Q&A and implementation support</p> <p><i>90 minutes of personalized expert guidance included!</i></p>
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DOWNLOADABLE FILES

- Complete course slides and sample Usability Engineering procedure
- Key templates: Use Specification, URRA, Usability Engineering File (UEF), UOUP Assessment, and Usability Evaluation Plan/Report
- Sample device exercises with DQS answers and a list of additional resources

LEARNING OBJECTIVES

- Understand regulatory context, terminology, and relationship between IEC 62366-1, ISO 14971, FDA guidance, and ANSI/AAMI HE75
- Create and maintain Use Specifications, Use-Related Risk Analyses (URRA), and Usability Engineering Files (UEF)
- Apply the Perception-Cognition-Action (PCA) model to identify Use Errors and implement effective risk controls
- Apply ANSI/AAMI HE75 design principles to optimize User Interface elements
- Conduct formative evaluations including cognitive walkthroughs, heuristic evaluations, and user interviews
- Plan and execute Human Factors Validation Testing with appropriate sample sizes and user populations
- Identify critical tasks from Safety Risk Management and link HF Validation to RCM verification
- Apply technical writing best practices to create clear, defensible usability engineering documentation
- Address special considerations for home use devices, combination products, and software user interfaces
- Complete practice device exercises using provided templates for immediate job application