DESIGN QUALITY SERVICES
DRIVEN TO SUPPORT INNOVATORS

DESIGN VALIDATION

COURSE OVERVIEW

Design Validation is the process of establishing objective evidence that a medical device meets user needs and intended uses in the actual or simulated use environment. It answers the critical question: “Did we build the right product?” This course was developed by practitioners, for practitioners, to ensure devices meet real-world user needs while supporting global regulatory submissions.

COURSE CURRICULUM

- Introduction to Design Validation
- Key Distinctions in Validation
- Types of Design Validation
- User Needs Development
- Design Inputs (DI)
- Design Outputs (DO) & Essential Outputs
- Risk Management Overview
- Technical Writing & Presenting Data
- Usability Engineering & Human Factors
- Simulated Use Studies
- Clinical Trials & Investigations
- Sample Size Selection & Study Design

COURSE AT A GLANCE

Price: $1,500
Lessons: 222
Video Content: 2 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 Design Validation procedure
- Key templates: Analytical/Bench Testing Protocol/Report, Simulated Use Protocol, Clinical Investigation Plan, Design V&V Protocol/Report, Labeling Validation Protocol/Report, Usability Evaluation Plan Protocol/Report, Software Validation Protocol/Report, and Use Specification
- Practice device exercises with DQS answers and a list of additional resources

LEARNING OBJECTIVES

- Build a foundation in Design Validation and highlight key differences with Design Verification and Process Validation
- Understand the multiple types of Design Validation and apply a layered approach based on device risk and complexity
- Develop well-crafted User Needs and translate them into measurable, verifiable Design Inputs
- Link Risk Management outputs to Design Outputs to identify Essential Design Outputs (EDO)
- Apply Design Validation types: Analytical/Bench, Simulated Use, Usability Engineering/Human Factors, Labeling, Software, and Clinical Investigations
- Conduct sample size selection using sound statistical and engineering judgment
- Plan and execute Simulated Use studies that demonstrate device performance under realistic conditions
- Understand clinical trial requirements and when clinical investigations are necessary for Design Validation
- Apply technical writing best practices to create clear, defensible validation documentation
- Complete practice device exercises using the provided templates for immediate job application