DESIGN QUALITY SERVICES
DRIVEN TO SUPPORT INNOVATORS

DESIGN AND DEVELOPMENT

COURSE OVERVIEW

The phased-based Design and Development process is crucial to business success. Managing the chaos of device development is essential in bringing innovative devices to market. This course was developed by practitioners, for practitioners, to ensure devices are safe, effective, and compliant before release while building better device businesses.

COURSE CURRICULUM

- Introduction to Design & Development
- Design Planning & Project Scope
- User Needs & Stakeholder Needs
- Design Inputs (DI)
- Design Review (DR) & Maturity Assessment
- Risk Management & FMEA Overview
- Usability Engineering Overview
- Design Outputs (DO) & Essential Outputs
- Design Verification
- Design Validation
- Design Transfer
- Design Changes & Change Control
- Technical Writing & Presenting Data
- Design Documentation & Medical Device File

COURSE AT A GLANCE

Price: $1,000
Lessons: 244
Video Content: 1.5 hours
Quizzes: 14
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 and Development procedure
- DDP, DHF, Design Review, Design V & V Protocol/Report, and Traceability Matrix templates and work instructions
- Design Transfer and Design Maturity Assessment checklists
- Practice device exercises and a list of additional resources

LEARNING OBJECTIVES

- Understand regulatory requirements that mandate Design and Development processes and when these apply
- Create Design and Development Plans establishing project scope, team responsibilities, and risk management strategies
- Gather and document User Needs and translate them into measurable, verifiable Design Inputs
- Plan and conduct effective Design Reviews and integrate Risk Management principles throughout design
- Create comprehensive Design Outputs, identify Essential Design Outputs, and establish complete traceability
- Plan and conduct Design Verification to confirm outputs meet inputs
- Conduct Design Validation to ensure the device meets User Needs in actual or simulated use conditions
- Successfully transfer designs from development to production using systematic procedures
- Implement effective change control processes throughout the device lifecycle
- Create and maintain comprehensive Medical Device Files (MDF) that demonstrate compliance