DESIGN QUALITY SERVICES
DRIVEN TO SUPPORT INNOVATORS

PROCESS VALIDATION (PV)

COURSE OVERVIEW

Process Validation is a systematic approach used to ensure that a manufacturing process consistently produces products that meet predetermined quality standards and requirements. This course was developed by practitioners, for practitioners, to demystify process validation, connect it to risk management, and provide practical tools for conducting efficient and compliant validations.

COURSE CURRICULUM

- Introduction to Process Validation
- PV Terminology & Regulations
- IQ, OQ, and PQ Basics
- Retrospective & Re-Validation
- Validation Master Plan (VMP)
- Process Validation Planning
- Risk Management & Statistical Tools
- Critical Quality Attributes (CQA)
- Sample Size Selection
- Design of Experiments (DoE)
- Capability Studies & Gage R&R
- Control Plans & Charts
- IQ/OQ/PQ Execution
- Maintaining the Validated State

COURSE AT A GLANCE

Price: $1,500
Lessons: 180
Video Content: 1.5 hours
Quizzes: 21
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 Process Validation procedure
- Key templates: IQ, OQ, PQ Protocol/Report, Validation Master Plan, Gage R&R, PV Project Plan
- CNC Mill example exercises with DQS answers and a list of additional resources

LEARNING OBJECTIVES

- Understand global regulations (FDA, ISO) and the four types of process validations: prospective, concurrent, retrospective, and re-validation
- Develop a clear connection between Risk Management and Process Validation using Critical Quality Attributes (CQA)
- Apply a systematic rubric for establishing appropriate PV sample sizes based on risk and statistical requirements
- Execute Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) protocols
- Apply key engineering tools, including Design of Experiments (DoE), ANOVA, and capability studies
- Conduct Gage Repeatability and Reproducibility (GR&R) and Measurement Systems Analysis (MSA) studies
- Implement worst-case selection strategies for efficient device or component family validations
- Develop comprehensive Validation Master Plans (VMP) and validation protocols
- Create Control Plans and Control Charts to maintain the validated state
- Apply practical PV templates and tools for immediate job application