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Systems

Veeva Vault Validation Management

COURSE CONTENT

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About Multisoft

Train yourself with the best and develop valuable in-demand skills with Multisoft Systems. A leading certification training provider, Multisoft collaborates with leading technologies to bring world-class one-on-one and certification training. Intending to empower professionals and businesses across the globe, we offer more than 1500 training courses, which are delivered by Multisoft's global subject matter experts. We offer tailored corporate training, a comprehensive learning solution with lifetime e-learning access, after-training support and globally recognized training certificates.

About Course

Veeva Vault Validation Management Training equips professionals with the practical knowledge required to manage computerized system validation within regulated life sciences organizations. The course covers validation planning, requirements management, test execution, traceability, deviation management, change control, reporting, compliance, and validation best practices. Through practical implementation and industry-focused scenarios, participants gain the skills needed to support efficient, compliant, and inspection-ready validation processes.

Module 1: Introduction to Veeva Vault Validation Management

- ✓ Overview of Validation Management
- ✓ Computer System Validation (CSV)
- ✓ GxP Fundamentals
- ✓ GAMP 5 Overview
- ✓ Validation Lifecycle
- ✓ Regulatory Expectations
- ✓ Vault Platform Overview

Module 2: Validation Management Configuration

- ✓ Validation Projects
- ✓ Validation Objects
- ✓ Document Types
- ✓ Lifecycle Configuration
- ✓ Security Roles
- ✓ User Permissions
- ✓ Configuration Best Practices

Module 3: Validation Requirements and Risk Assessment

- ✓ Business Requirements
- ✓ Functional Requirements
- ✓ Requirement Traceability
- ✓ Risk Assessment Methodology

- ✓ Criticality Assessment
- ✓ Risk Mitigation
- ✓ Validation Planning

Module 4: Validation Protocol Authoring and Execution

- ✓ IQ Protocols
- ✓ OQ Protocols
- ✓ PQ Protocols
- ✓ Test Script Management
- ✓ Test Execution
- ✓ Evidence Collection
- ✓ Execution Status Tracking

Module 5: Deviation and Issue Management

- ✓ Validation Deviations
- ✓ Defect Management
- ✓ Root Cause Analysis
- ✓ Corrective Actions
- ✓ Preventive Actions (CAPA)
- ✓ Issue Resolution Workflow
- ✓ Approval Process

Module 6: Validation Documentation and Traceability

- ✓ Validation Plans

- ✓ Validation Reports
- ✓ Traceability Matrix
- ✓ Requirement Mapping
- ✓ Test Coverage
- ✓ Document Version Control
- ✓ Audit Readiness

Module 7: Change Control and Periodic Review

- ✓ Change Requests
- ✓ Impact Assessment
- ✓ Revalidation Strategy
- ✓ Change Approval Workflow
- ✓ Periodic Review
- ✓ Continuous Compliance
- ✓ Validation Maintenance

Module 8: Reporting and Compliance Management

- ✓ Validation Dashboards
- ✓ Standard Reports
- ✓ Compliance Reporting
- ✓ Validation Metrics
- ✓ KPI Monitoring
- ✓ Audit Reports
- ✓ Regulatory Documentation

Module 9: Integration with Veeva Vault Quality Applications

- ✓ Vault Quality Suite Overview
- ✓ Integration with QualityDocs
- ✓ Integration with QMS
- ✓ Training Integration
- ✓ Change Control Integration
- ✓ Document Management
- ✓ End-to-End Validation Process

Module 10: Validation Best Practices

- ✓ Risk-Based Validation
- ✓ GAMP 5 Best Practices
- ✓ FDA 21 CFR Part 11 Considerations
- ✓ Annex 11 Compliance
- ✓ Documentation Standards
- ✓ Inspection Readiness
- ✓ Industry Use Cases

Module 11: End-to-End Validation Management Project

- ✓ Validation Project Planning
- ✓ Requirements Definition
- ✓ Risk Assessment
- ✓ Protocol Creation
- ✓ Test Execution

- ✓ Deviation Handling
- ✓ Traceability Verification
- ✓ Compliance Reporting
- ✓ Final Validation Review
- ✓ Capstone Project