Veeva QMS (Quality Management System) Training

COURSE CONTENT

About Multisoft

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About Course

Veeva QMS (Quality Management System) Training by Multisoft Systems is designed to help professionals build strong, practical expertise in managing regulated quality processes using Veeva Vault QMS. The program focuses on how modern life sciences organizations standardize, document and control quality activities to meet GxP expectations and internal compliance standards.

Module 1: Introduction to Veeva QMS

- ✓ What is Veeva QMS and why it's used?
- ✓ Quality Management concepts and regulatory context
- ✓ Key features and capabilities
- ✓ Typical lifecycle of quality processes
- ✓ System benefits and business drivers

Module 2: Veeva QMS Architecture and Navigation

- ✓ Cloud-based platform overview
- ✓ Veeva Vault foundation (common data structure)
- ✓ UI layout, menus, dashboards, and search
- ✓ User roles and permissions fundamentals
- ✓ Navigation best practices
- ✓ Terminology and taxonomy

Module 3: Core Quality Processes in Veeva QMS

- ✓ Overview of supported quality processes:

  - o CAPA (Corrective and Preventive Action)

  - o Change Control

  - o Deviations

  - o Audit Management

  - o Complaints Management

  - o Training Management

  - o Document Control

- ✓ How these modules interact?

Module 4: CAPA Management

- ✓ CAPA lifecycle overview
- ✓ Initiation and documentation of CAPA
- ✓ Cause investigation and risk assessment
- ✓ Action planning and tracking
- ✓ CAPA review and closure
- ✓ Notifications and follow-ups
- ✓ CAPA performance metrics

Module 5: Change Control Processes

- ✓ Purpose of change control
- ✓ Initiation and documentation
- ✓ Impact assessment and risk evaluation
- ✓ Approval workflows
- ✓ Implementation planning
- ✓ Verification and effectiveness checks

Module 6: Deviations and Nonconformance

- ✓ Types of deviations (product, process, supplier)
- ✓ Creating and managing deviation records
- ✓ Root cause analysis tools
- ✓ Decision outcomes and corrective actions
- ✓ Trending and reporting

Module 7: Audit Management

- ✓ Planning and scheduling audits
- ✓ Audit checklist configuration
- ✓ Conducting audit activities
- ✓ Findings and observations

- ✓ Audit reports and metrics
- ✓ Follow-up on audit outcomes

Module 8: Complaints Handling

- ✓ Complaint intake and logging
- ✓ Investigation and classification
- ✓ Escalation and cross-functional review
- ✓ Communication and resolution tracking
- ✓ Regulatory reporting requirements

Module 9: Document Control and Management

- ✓ Document lifecycle and status (draft, approved, retired)
- ✓ Version control and historical tracking
- ✓ Document review and approval workflows
- ✓ Linking documents to processes
- ✓ Access control and permissions
- ✓ Audit trails for compliance

Module 10: Training Management

- ✓ Training requirement setup
- ✓ Assigning training to individuals and roles
- ✓ Scheduling and tracking completions
- ✓ Retraining and certification rules
- ✓ Integration with document changes
- ✓ Reporting on training compliance

Module 11: Reporting and Dashboards

- ✓ Standard dashboards and KPI views
- ✓ Creating custom reports and charts

✓ Filters and drill-downs

✓ Quality metrics for leadership and regulators

✓ Exporting and sharing insights

Module 12: Security, Roles & Access Control

✓ Overview of security model in Veeva QMS

✓ User administration and role design

✓ Permission sets and functional access

✓ Confidentiality and segregation of duties

✓ Audit logging and compliance

Module 13: Integration with Other Systems

✓ Veeva Vault ecosystem (Documents, PromoMats, eTMF)

✓ Integration with ERP and MES systems

✓ Data exchange concepts (API/flat file)

✓ Best practices for secure integration