multisoft
Systems

Veeva Vault CDMS Training

COURSE CONTENT

GET IN TOUCH

Multisoft Systems
B - 125, Sector - 2, Noida

(+91) 9810-306-956

info@multisoftsystems.com

www.multisoftsystems.com

About Multisoft

Train yourself with the best and develop valuable in-demand skills with Multisoft Systems. A leading certification training provider, Multisoft collaborates with top technologies to bring world-class one-on-one and certification trainings. With the goal to empower professionals and business 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; project Based Training, comprehensive learning solution with lifetime e-learning access, after training support and globally recognized training certificates.

About Course

Veeva Vault CDMS Training by Multisoft Systems is a comprehensive program designed to help professionals develop expertise in modern clinical data management using the Veeva Vault Clinical Data Management Suite. The course provides in-depth knowledge of the platform's capabilities for managing clinical trial data, improving data quality, streamlining study execution, and ensuring regulatory compliance throughout the clinical research lifecycle.

Module 1: Introduction to Veeva Vault CDMS

- ✓ Overview of Clinical Data Management Systems (CDMS)
- ✓ Introduction to Veeva Vault CDMS
- ✓ Features and capabilities of Vault CDMS
- ✓ Cloud-based architecture and benefits
- ✓ Role of CDMS in clinical trials
- ✓ Understanding EDC, CDB, and RTSM integration
- ✓ Regulatory compliance and industry standards
- ✓ Navigation of the Vault CDMS interface
- ✓ User roles and permissions

Module 2: Clinical Trial Fundamentals

- ✓ Basics of clinical research and trials
- ✓ Phases of clinical trials
- ✓ Study protocols and study lifecycle
- ✓ CRF (Case Report Form) concepts
- ✓ Data collection methodologies
- ✓ Clinical terminology and standards
- ✓ Introduction to CDISC standards
- ✓ GCP (Good Clinical Practice) guidelines
- ✓ Data privacy and security concepts

Module 3: Vault CDMS Architecture

- ✓ Vault Platform overview
- ✓ Components of Vault CDMS
- ✓ Study startup workflow
- ✓ Data flow architecture
- ✓ Integration with other Veeva Vault applications
- ✓ User access management

- ✓ Audit trails and compliance tracking
- ✓ System environments and configurations
- ✓ Cloud infrastructure concepts

Module 4: Study Design and Setup

- ✓ Creating new studies in Vault CDMS
- ✓ Configuring study parameters
- ✓ Building study structures
- ✓ Site and subject configurations
- ✓ Form and visit creation
- ✓ Study milestones and timelines
- ✓ Managing study metadata
- ✓ Protocol-driven study design
- ✓ Study version management

Module 5: Form and CRF Design

- ✓ Designing electronic Case Report Forms (eCRFs)
- ✓ Form layout and structure
- ✓ Field creation and configuration
- ✓ Data types and validations
- ✓ Dynamic forms and conditional logic
- ✓ Repeating forms and visits
- ✓ Edit checks and derivations
- ✓ Form versioning and approvals
- ✓ Best practices for CRF design

Module 6: Edit Checks and Validation Rules

- ✓ Introduction to edit checks
- ✓ Types of edit checks
- ✓ Query generation mechanisms

- ✓ Creating validation rules
- ✓ Cross-form validations
- ✓ Range and consistency checks
- ✓ Custom logic implementation
- ✓ Auto-query generation
- ✓ Query lifecycle management

Module 7: Data Entry and Data Capture

- ✓ Subject data entry workflows
- ✓ Source data verification concepts
- ✓ Manual and automated data entry
- ✓ Managing subject visits
- ✓ Handling missing and incomplete data
- ✓ Data corrections and audit trails
- ✓ Bulk data upload concepts
- ✓ Data locking and freeze procedures
- ✓ Investigator and site workflows

Module 8: Query Management

- ✓ Query lifecycle overview
- ✓ Creating and managing queries
- ✓ Site communication workflows
- ✓ Query resolution processes
- ✓ Auto-generated vs manual queries
- ✓ Query reports and dashboards
- ✓ Escalation and tracking
- ✓ Data clarification forms
- ✓ Best practices for query management

Module 9: Medical Coding Integration

- ✓ Introduction to medical coding
- ✓ MedDRA coding concepts
- ✓ WHO Drug coding
- ✓ Adverse event coding workflows
- ✓ Concomitant medication coding
- ✓ Auto-coding functionality
- ✓ Coding review and approval
- ✓ Coding dictionaries management
- ✓ Reconciliation workflows

Module 10: Study Conduct and Monitoring

- ✓ Subject enrolment management
- ✓ Visit tracking and monitoring
- ✓ Data review workflows
- ✓ Risk-based monitoring concepts
- ✓ Site management activities
- ✓ Clinical operations integration
- ✓ Monitoring dashboards
- ✓ Protocol deviation tracking
- ✓ Study progress reporting

Module 11: Data Review and Cleaning

- ✓ Data review methodologies
- ✓ Data discrepancy management
- ✓ Review workflows
- ✓ Medical review processes
- ✓ Reconciliation procedures
- ✓ External data reconciliation

- ✓ SAE reconciliation
- ✓ Data quality metrics
- ✓ Data cleaning best practices

Module 12: Reporting and Dashboards

- ✓ Standard reports in Vault CDMS
- ✓ Custom report creation
- ✓ Dashboard configuration
- ✓ Study metrics and KPIs
- ✓ Exporting clinical data
- ✓ Visualization tools
- ✓ Real-time reporting
- ✓ Audit and compliance reports
- ✓ Management reporting

Module 13: Integration and External Systems

- ✓ Integration with RTSM systems
- ✓ ePRO and eCOA integrations
- ✓ Lab data integrations
- ✓ Safety system integrations
- ✓ API concepts and connectivity
- ✓ Data import/export mechanisms
- ✓ Integration troubleshooting
- ✓ Third-party system connectivity
- ✓ End-to-end data flow management

Module 14: Regulatory Compliance and Validation

- ✓ FDA 21 CFR Part 11 compliance
- ✓ GxP validation concepts
- ✓ Computer system validation (CSV)

- ✓ Audit readiness
- ✓ Electronic signatures
- ✓ Inspection preparation
- ✓ SOP alignment
- ✓ Compliance documentation
- ✓ Risk management principles

Module 15: User Administration and Security

- ✓ User creation and management
- ✓ Role-based access control
- ✓ Permission management
- ✓ Security policies
- ✓ Password and authentication controls
- ✓ User activity tracking
- ✓ Audit trail review
- ✓ Data privacy controls
- ✓ Security best practices

Module 16: Database Lock and Study Closeout

- ✓ Database freeze and lock procedures
- ✓ Final data review
- ✓ Study closeout workflows
- ✓ Archiving clinical data
- ✓ Regulatory submission readiness
- ✓ Final reconciliation processes
- ✓ Data retention policies
- ✓ Lessons learned documentation
- ✓ Study completion activities

Module 17: Hands-on Practical Sessions

- ✓ Creating a sample study
- ✓ Designing eCRFs
- ✓ Building edit checks
- ✓ Query generation and resolution
- ✓ Subject data management
- ✓ Data review exercises
- ✓ Reporting and dashboard creation
- ✓ Study lock simulation
- ✓ End-to-end project workflow practice

Module 18: Real-Time Industry Use Cases

- ✓ Oncology study management
- ✓ Vaccine trial workflows
- ✓ Multi-site clinical trial scenarios
- ✓ Decentralized clinical trials
- ✓ Global study data management
- ✓ Regulatory inspection case studies
- ✓ Common implementation challenges
- ✓ Industry best practices
- ✓ Career opportunities in CDMS

Capstone Project

- ✓ Configure a complete clinical study in Vault CDMS
- ✓ Design forms and edit checks
- ✓ Perform subject data entry & generate and resolve queries
- ✓ Conduct data review and cleaning
- ✓ Create reports and dashboards
- ✓ Execute database lock activities & Final project presentation