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Systems

Pharmaceutical DCS Automation

COURSE CONTENT

GET IN TOUCH

Multisoft Systems
B - 125, Sector - 2, Noida

(+91) 9810-306-956

info@multosoftsystems.com

www.multosoftsystems.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 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

The Pharmaceutical DCS Automation Training focuses on the application of distributed control systems across regulated pharmaceutical manufacturing operations. It combines core DCS engineering concepts with batch automation, process instrumentation, control strategies, HMI configuration, alarm management, data handling, validation, and regulatory considerations.

The training provides participants with an understanding of how automation systems support reliable and traceable pharmaceutical production while maintaining controlled process conditions and appropriate electronic records. Pharmaceutical-oriented scenarios covering batch processes, CIP/SIP operations, utilities, recipes, audit trails, system validation, and lifecycle activities help connect DCS engineering practices with real manufacturing requirements.

Module 1: Introduction to Pharmaceutical Process Automation

- ✓ Overview of pharmaceutical manufacturing
- ✓ Role of automation in pharmaceutical production
- ✓ Automation hierarchy in manufacturing facilities
- ✓ PLC, DCS, SCADA, MES, and historian overview
- ✓ DCS applications in pharmaceutical plants
- ✓ Process automation lifecycle
- ✓ Critical and non-critical automation systems
- ✓ Automation requirements in regulated environments
- ✓ Overview of GMP-oriented automation practices

Module 2: DCS Fundamentals and System Architecture

- ✓ Distributed Control System fundamentals
- ✓ DCS functional architecture
- ✓ Engineering stations
- ✓ Operator stations
- ✓ Process controllers
- ✓ I/O subsystems
- ✓ Application and system servers
- ✓ Historian servers
- ✓ Redundant system architecture
- ✓ Control and supervisory networks
- ✓ Server-client architecture
- ✓ System availability and reliability concepts

- ✓ DCS integration with plant-level systems

Module 3: Pharmaceutical Manufacturing Processes and Automation Requirements

- ✓ Overview of pharmaceutical production workflows
- ✓ API manufacturing automation
- ✓ Formulation processes
- ✓ Granulation process control
- ✓ Blending and mixing operations
- ✓ Tablet manufacturing
- ✓ Coating processes
- ✓ Liquid manufacturing
- ✓ Sterile manufacturing considerations
- ✓ Clean-in-Place (CIP) automation
- ✓ Sterilize-in-Place (SIP) automation
- ✓ Water system automation
- ✓ Purified Water (PW) systems
- ✓ Water for Injection (WFI) systems
- ✓ HVAC and cleanroom monitoring considerations
- ✓ Process parameters and Critical Process Parameters (CPPs)

Module 4: Instrumentation and Field Devices

- ✓ Fundamentals of process instrumentation
- ✓ Temperature measurement

- ✓ Pressure and differential pressure measurement
- ✓ Flow measurement
- ✓ Level measurement
- ✓ Conductivity measurement
- ✓ pH measurement
- ✓ Analytical instrumentation
- ✓ Control valves and actuators
- ✓ On/off valves
- ✓ Variable Frequency Drives (VFDs)
- ✓ Motors and pumps
- ✓ Digital and analog signals
- ✓ 4–20 mA signals
- ✓ HART communication concepts
- ✓ Instrument ranges and scaling
- ✓ Instrument status and diagnostics
- ✓ Instrument calibration considerations

Module 5: DCS Hardware, Controllers, I/O, and Communication

- ✓ DCS controller architecture
- ✓ Controller processing concepts
- ✓ Controller redundancy
- ✓ Power supply redundancy
- ✓ Analog Input (AI)
- ✓ Analog Output (AO)

- ✓ Digital Input (DI)
- ✓ Digital Output (DO)
- ✓ Remote I/O concepts
- ✓ I/O channel configuration
- ✓ Signal conditioning
- ✓ Marshalling concepts
- ✓ Network architecture
- ✓ Industrial Ethernet
- ✓ Modbus communication
- ✓ OPC communication concepts
- ✓ Fieldbus overview
- ✓ Device communication and diagnostics
- ✓ Network redundancy concepts

Module 6: DCS Engineering and Project Configuration

- ✓ Understanding the DCS engineering environment
- ✓ Creating an automation project
- ✓ Plant hierarchy configuration
- ✓ Area and unit organization
- ✓ Equipment hierarchy
- ✓ Tag naming philosophy
- ✓ Database configuration
- ✓ Process tag creation
- ✓ I/O assignment
- ✓ Engineering units
- ✓ Range and scaling configuration

- ✓ Signal status configuration
- ✓ Control module concepts
- ✓ Reusable control objects
- ✓ Engineering templates
- ✓ Configuration standards
- ✓ Project backup and version management

Module 7: Control Strategies and Regulatory Control

- ✓ Process control fundamentals
- ✓ Open-loop and closed-loop control
- ✓ Feedback control
- ✓ PID control principles
- ✓ Proportional action
- ✓ Integral action
- ✓ Derivative action
- ✓ PID parameter configuration
- ✓ Controller operating modes
- ✓ Manual and automatic operation
- ✓ Cascade control
- ✓ Ratio control
- ✓ Split-range control
- ✓ Feedforward concepts
- ✓ Override and selector control
- ✓ Loop tuning fundamentals
- ✓ Pharmaceutical process control examples

Module 8: Sequence, Interlock, and Equipment Control

- ✓ Sequential control concepts
- ✓ Equipment control philosophy
- ✓ Equipment modules
- ✓ Motor control logic
- ✓ Pump control
- ✓ Valve control
- ✓ Permissive logic
- ✓ Interlock logic
- ✓ Trip conditions
- ✓ Start/stop sequences
- ✓ State-based control
- ✓ Equipment operating modes
- ✓ Auto/manual control
- ✓ Failure handling
- ✓ Sequence transitions
- ✓ Safe-state concepts
- ✓ Process equipment coordination
- ✓ Troubleshooting sequence logic

Module 9: Batch Process Automation and ISA-88

- ✓ Introduction to batch manufacturing
- ✓ Pharmaceutical batch processes
- ✓ ISA-88 fundamentals
- ✓ Physical model

- ✓ Process model
- ✓ Procedural control model
- ✓ Process cells
- ✓ Units
- ✓ Equipment modules
- ✓ Control modules
- ✓ Procedures
- ✓ Unit procedures
- ✓ Operations
- ✓ Phases
- ✓ Recipe concepts
- ✓ Master recipes
- ✓ Control recipes
- ✓ Recipe parameters
- ✓ Equipment allocation
- ✓ Phase execution
- ✓ Batch sequencing
- ✓ Hold, restart, stop, and abort concepts
- ✓ Exception handling
- ✓ Batch status monitoring
- ✓ Electronic batch information concepts

Module 10: HMI, Process Graphics, Trends, and Operator Interface

- ✓ HMI fundamentals

- ✓ Pharmaceutical operator interface requirements
- ✓ Process graphic hierarchy
- ✓ Overview displays
- ✓ Unit-level displays
- ✓ Equipment faceplates
- ✓ Controller faceplates
- ✓ Navigation concepts
- ✓ Process values and status indications
- ✓ Equipment status visualization
- ✓ Command configuration
- ✓ Operator interaction
- ✓ Dynamic graphic objects
- ✓ Color and status philosophy
- ✓ Trend displays
- ✓ Real-time trends
- ✓ Historical trends
- ✓ Operator usability considerations
- ✓ Situational awareness concepts

Module 11: Alarm Management and Event Handling

- ✓ Alarm system fundamentals
- ✓ Alarm versus event
- ✓ Alarm philosophy
- ✓ Alarm priorities
- ✓ Alarm limits
- ✓ Process alarms

- ✓ Equipment alarms
- ✓ System alarms
- ✓ Alarm acknowledgment
- ✓ Alarm shelving concepts
- ✓ Alarm suppression concepts
- ✓ Alarm flooding
- ✓ Nuisance alarm considerations
- ✓ Alarm rationalization overview
- ✓ Alarm history
- ✓ Sequence of Events (SOE)
- ✓ Event logging
- ✓ Operator action tracking
- ✓ Alarm management lifecycle

Module 12: Historian, Reporting, Audit Trails, and Electronic Records

- ✓ Process historian fundamentals
- ✓ Historical data collection
- ✓ Tag historization
- ✓ Sampling and storage concepts
- ✓ Trend analysis
- ✓ Process data retrieval
- ✓ Production reporting concepts
- ✓ Batch data reporting
- ✓ Event history

- ✓ Alarm history
- ✓ Operator action records
- ✓ Audit trail concepts
- ✓ Electronic records
- ✓ Time synchronization
- ✓ Data retention considerations
- ✓ Data archival
- ✓ Data retrieval requirements
- ✓ Integration with reporting and higher-level systems

Module 13: GMP, GxP, 21 CFR Part 11, and Data Integrity

- ✓ Introduction to pharmaceutical regulations
- ✓ GMP fundamentals
- ✓ GxP concepts for automated systems
- ✓ Regulatory expectations for computerized systems
- ✓ Introduction to 21 CFR Part 11
- ✓ Electronic records considerations
- ✓ Electronic signature concepts
- ✓ User authentication
- ✓ Access control
- ✓ Role-based authorization
- ✓ Audit trail requirements
- ✓ System-generated records
- ✓ Data integrity fundamentals
- ✓ ALCOA principles
- ✓ ALCOA+ concepts

- ✓ Accurate time stamping
- ✓ Record retention
- ✓ Controlled system changes
- ✓ Traceability considerations
- ✓ Automation system compliance considerations

Module 14: DCS Validation, Testing, and Pharmaceutical Documentation

- ✓ Computerized system validation concepts
- ✓ DCS validation lifecycle
- ✓ Validation planning
- ✓ User Requirement Specification (URS)
- ✓ Functional Requirement Specification (FRS)
- ✓ Functional Design Specification (FDS)
- ✓ Hardware Design Specification
- ✓ Software Design Specification
- ✓ Control philosophy documentation
- ✓ I/O list
- ✓ Instrument list
- ✓ Cause-and-effect documentation
- ✓ Functional testing
- ✓ Factory Acceptance Test (FAT)
- ✓ Site Acceptance Test (SAT)
- ✓ Installation Qualification (IQ)
- ✓ Operational Qualification (OQ)

- ✓ Performance Qualification considerations
- ✓ Requirement traceability
- ✓ Test protocols
- ✓ Test evidence
- ✓ Deviation management
- ✓ Validation reports
- ✓ Change control
- ✓ Configuration documentation

Module 15: DCS Cybersecurity, User Management, Backup, and Maintenance

- ✓ Cybersecurity considerations for DCS environments
- ✓ User account administration
- ✓ User roles and privileges
- ✓ Password policy concepts
- ✓ Access control
- ✓ Network segmentation concepts
- ✓ Firewall considerations
- ✓ Remote access considerations
- ✓ Antivirus and endpoint security considerations
- ✓ System hardening fundamentals
- ✓ Backup strategy
- ✓ Controller and application backups
- ✓ Database backup
- ✓ Restore procedures

- ✓ Disaster recovery concepts
- ✓ System health monitoring
- ✓ Controller diagnostics
- ✓ Network diagnostics
- ✓ Preventive maintenance
- ✓ Patch and update considerations
- ✓ Change management in validated environments

Module 16: Pharmaceutical DCS Project Implementation and Practical Case Studies

- ✓ Understanding pharmaceutical automation requirements
- ✓ Preparing an automation control philosophy
- ✓ Developing tag and I/O databases
- ✓ Configuring process measurements
- ✓ Creating control loops
- ✓ Developing equipment control logic
- ✓ Creating permissives and interlocks
- ✓ Developing process sequences
- ✓ Configuring batch-oriented operations
- ✓ Building HMI graphics
- ✓ Configuring alarms
- ✓ Creating historical trends
- ✓ User access configuration
- ✓ Testing automation functionality
- ✓ FAT scenario preparation

- ✓ SAT considerations
- ✓ Validation documentation overview
- ✓ Troubleshooting common DCS issues
- ✓ Pharmaceutical batch process case study
- ✓ CIP/SIP automation case study
- ✓ PW/WFI system automation case study
- ✓ End-to-end pharmaceutical DCS project workflow