



## 21 CFR Part 11 Compliant Training Management System



Designed specifically for the life sciences industry, the eTraininfo Training Management System automates your training processes for improved compliance and productivity. eTraininfo is fully compliant with 21 CFR Part 11 requirements and hence can be used for paperless tracking and management of training records. The system is fully configurable and can be implemented quickly and easily. An available validation package accelerates system validation and deployment.

eTraininfo is brought to you by CIMCON Software, a trusted leader in providing 21 CFR Part 11 compliant solutions to FDA-regulated industries. CIMCON's compliance software and services have been implemented by over 500 companies in North America, Europe and Asia to improve business operations and compliance. CIMCON compliance solutions have been adopted as a corporate standard and implemented globally by many of the world's largest FDA-regulated companies.

### Enterprise Training Management

**eTraininfo Validation Package:** A comprehensive and detailed validation package written by validation experts is available for quick and easy implementation.

**21 CFR Part 11 Compliance:** Allows paperless training processes and operations.

### Validation Services

CIMCON Software can provide you with validation services that include risk assessment, SOP preparation, protocol execution, and training.

## Features

### Training Records Management

- ✓ Automatic determination of training requirements
- ✓ Schedule training based on needs assessment
- ✓ Register persons that need training
- ✓ Maintain training records
- ✓ Assess training requirements following a document version change
- ✓ Assess refresher training requirements
- ✓ Wide range of built-in Reports
- ✓ Configure email notifications



### Wide Range of Built-In Reports

- ✓ Training Requirements by Employee or Department
- ✓ Training Records by Employee
- ✓ Overdue Training
- ✓ Document Change Training Requirements
- ✓ Refresher Training Requirements
- ✓ Training Schedule
- ✓ Training Registrations



### 21 CFR Part 11 Compliance

- ✓ Audit trail records the Date, Time, User ID, Full User Name, and Action for all training activity.
- ✓ Comprehensive and detailed assignment of security rights, privileges and system roles.
- ✓ Configure actions that require electronic signatures that include the userid and printed name of the signer, date and time, and the meaning associated with the signature.
- ✓ Enforce minimum length and composition of passwords.
- ✓ Password Aging forces a new password after a configurable period.
- ✓ Account lockouts after a configurable number of retries.
- ✓ Automatic Session Timeouts.



## Benefits

- **Paperless management of training records for improved compliance and productivity.**
- **Wide Range of Reports instantly highlight training requirements and change impact.**
- **Reduce costs with documented self-training.**
- **Role-based dashboards for decision making.**
- **Easy to configure, use and maintain.**
- **Reduced validation effort using available validation package.**



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