Enterprise Series

IntegPro

Digital Compliance™ Technology

Data Integrity Management System

IntegPro™ is a purpose-built solution designed from the ground up to help regulated firms manage and track their company's data integrity compliance status. Based on FDA's guidance on data integrity, the software allows heads of quality, departmental heads and system owners to know their data integrity compliance status at a glance, understand the compliance gaps, and help take remedial action. The system contains built-in audit questions that can be modified if needed and applied at a global, departmental or system level. Each question is cross-referenced with FDA guidance, predicate rules and a firm's internal policies to aid users in completing audits. Completed audits can be reviewed and approved by department managers and then quality assurance to implement a standardized workflow process, with email notifications on system status changes.

Full compliance with 21 CFR Part 11 means that IntegPro can be implemented as an efficient paperless system with electronic signatures avoiding the need for time-consuming handling and storage of paper records. As a fully web-based, zero client system with no installation required on desktops and an available validation package, IntegPro can be implemented quickly and easily in your organization.

The software is designed to be used by departments or as part of a corporate initiative for data integrity compliance.

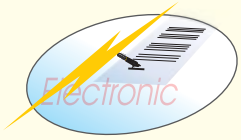
About CIMCON Software

CIMCON Software is a pioneering market leader in providing 21 CFR Part 11 compliant solutions to the FDA-regulated industry. CIMCON products are proven and mature solutions that benefit from over twenty (20) years of industry experience and a large global client base in 30 countries. CIMCON products save customers save time and money by replacing tedious, error-prone and manual processes with automated, electronic and compliant systems. With a deep focus on customer satisfaction and available 24 x 7 support, CIMCON delivers peace of mind no matter where in the world you may be located.

Features

Data Integrity Audit Management

- ☑ Create departments and an inventory of systems to manage the data integrity audit process
- ☑ Assign department managers and system owners
- ☑ Use built-in audit questions or configure your own
- ☑ Questions can be assigned at a global, department or system level
- ☑ Cross-reference audit questions with FDA guidance, predicate rules and your own company's policies to assist system owners in completing audits



Workflow and Reporting

- ☑ Once completed, audit questionnaires can be reviewed and approved by department managers and quality assurance
- ☑ Email notifications on system status changes
- ☑ Data integrity status reporting by system or department
- ☑ Dashboards for ongoing monitoring

21 CFR Part 11 Compliance

- ☑ Audit trail records all system entries with date, timestamp, User ID, type of entry, old value and new value as applicable
- ☑ Configure changes or actions that require electronic signatures
- ☑ Role-based assignment of security and user access controls within the application
- ☑ Integrate with Active Directory or create local users
- ☑ Password Aging forces a new password after a configurable period
- ☑ Account lockouts after a configurable number of retries
- ☑ Automatic Session time-outs

Benefits

- Quick and easy implementation of a data integrity process using a purpose-built, out-of-the-box system
- Centralized storage, monitoring and reporting
- Highly flexible and configurable to the needs of your organization
- Knowledge based system allows you to cross reference audit questions with FDA guidance, predicate rules and your own policies and procedures to aid users in completing audits
- Role based system assigns clear responsibilities for data integrity compliance
- 21 CFR Part 11 Compliance allows paperless implementation
- Zero Client Web Based solution
- Reduce costs, implement a paperless and efficient data integrity process for enhanced compliance

CIMCON Software
234 Littleton Road, Westford, MA 01886, USA
Tel: +1 (978) 464 9180
E-mail: info@cimcon.com
Web: www.part11solutions.com

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