
“Achieving
21 CFR Part 11
Compliance”
anmeda
RetroN21

## Why RetroN21

Every equipment or machine that is involved in the manufacturing of pharmaceutical products is required to be operationally compliant to meet the CFR Part 11 guidelines for electronic data processing.

Older machines that do not have the in-built capability to meet the CFR Part 11 guidelines are to be upgraded to enable these machines to be compliant to CFR Part 11 guidelines such as by user management, audit trails, implementing necessary controls, system validations, electronic signatures, access controls and production data management. This will help you achieve complete regulatory compliance for your production process.

## Product Overview

As part of 21 CFR Part 11 guidelines for production equipment, every equipment which is directly or indirectly engaged in the production of a finished product must fulfill the basic requirements of the Part 11 guidelines such as user management & access control, electronic data integrity & management and audit trails of user actions. RetroN21 takes an innovative approach to achieve the above requirements by utilizing the existing PLC/HMI of the machine and making them CFR compliant.

RetroN21 works by enhancing the capabilities of the existing PLC and HMI based system by leveraging the in-built features of the existing system in logging the required information. The equipment is connected to a centralized system that acquires the process data, monitors the equipment and governs the compliance process in the equipment.



## Product Features

1. 21 CFR Part 11 offers compliant user management with a multi-level, hierarchy-based, machine-based and restricted role-based user logins
2. Integrated audit trail reporting with all modules including user management
3. Integrated alarm and event management acknowledgment with e-signatures
4. Centralized report management with soft approval: automatic report work-flow for paper-less report generation, verification and approval process
5. Electronic data management and archival: The centralized system network including the line server and the central server works together to read the data continuously from the PLC/HMI and transfers it to the central server
6. Built-in data management and archival feature as:
    a. Integrated data security as per 21 CFR Part 11 guidelines
    b. Built-in manual or scheduled backup feature
    c. Option for centralized data storage for analytics
7. Open standard support for any third-party system integration



## Product Highlights

1. Faster implementation of an equipment-wise upgrade for CFR compliance
2. Retaining the original operational process of the equipment from the HMI by not disturbing the original operation of the equipment
3. Substantial reduction in overall implementation time, as there is no need to replace every HMI with an IPC
4. Flexibility to adapt, configure and extend capabilities as required
5. Provide Data Storage and expansion capability which is configurable based on requirements
6. Can be integrated with third-party application integrations such as ERP, eBRM, BMS, energy management, etc.





## Key Benefits:

1. Enables you to adhere to regulatory compliance guidelines, achieve operational excellence and effectiveness
2. Provides wide functionality to adapt, configure and extend capabilities
3. Provides great UI which is functional and user-friendly
4. Integrated audit trail reporting with all modules including user management
5. Provides faster implementation of results
6. Flexible and scalable application architecture enabling integration from a single plant to multiple plants
7. Provides a centralized platform for machine analytics
8. Provides data storage and expansion capability which is configurable based on customer requirements
9. Open standards support for third-party application integration such as ERP, BMS, utility management, water plant, etc.

## About Anmeda and its capabilities

We are focused on providing innovative software solutions for industrial automation predominantly in pharma based verticals. With a blend of technology and industrial automation domain experience, Anmeda Systems bring result-oriented solutions to help companies achieve a competitive advantage, manage business goals and at the same time meet regulatory compliances.

Anmeda Systems are equipped with the latest technologies, diverse knowledge and expertise in the field of industrial automation while having hands-on experience in various standard PLCs and automation devices available in the market.
The company has provided a solution on each of the different automation platforms and helped organizations leverage existing infrastructure and move towards an integrated agile manufacturing system.

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