LabVIEW SOFTWARE

With LabVIEW Software, you can easily create applications that are compliant with FDA regulation 21 CFR Part 11. LabVIEW is a graphical development environment with built-in functionality for data acquisition, instrument control, measurement analysis, and data presentation. LabVIEW provides the flexibility of a powerful programming language without the complexity of traditional development environments. The LabVIEW also contains add-on modules for development environment that offers data management tools, such as easy-to-use I/O configuration for high-channel-count applications, automatic data logging, full alarm management, event logging, and real-time and historical trending. Also, with easy networking, a networked real-time database for distributed logging, built-in security, and OPC connectivity, you can use the add-on module to get your application up and running easily and quickly.

21CFR PART 11 COMPLIANCE

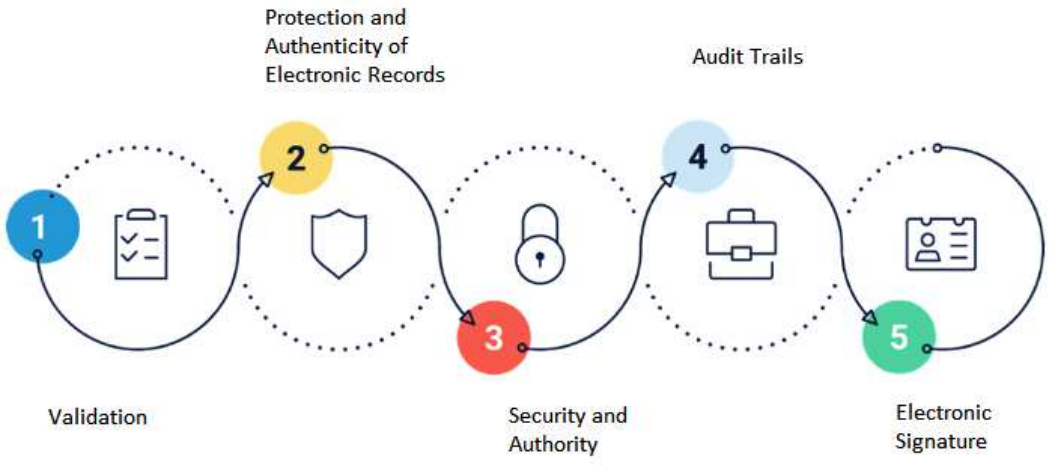
LabVIEW Software is not for 21 CFR Part 11-compliant applications but design tools you can use to create 21 CFR Part 11-compliant applications. This document discusses how you use the software to create an application that is compliant with the 21 CFR Part 11 regulation followed by a detailed description on how to meet this requirement using the LabVIEW Software.

Compliance Brief

The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation's food supply, cosmetics, and products.

This tool is designed to help clinical researchers, Pharma industries to ensure that studies using computer systems to gather data electronically are in compliance with federal regulations.

Lubi Electronics provide software solution for 21CFR Part 11 Compliance in pharma and food industries where we supply PC based HMI and 21CFR part11 software.



Data flow of operational Process Analysis

Software Features:

- User Management System, Password Policy & Access Privileges

- Electronics Records & Electronic Signature

- Audit Trail

- Backup & Restore

- Reports

USER MANAGEMENT SYSTEM, PASSWORD POLICY & ACCESS PRIVILEGES

- Unlimited user creation.
- Password-protected individual user accounts.
- Activate/Deactivate user facility.
- Block/Unblock User Facility.
- 5 User Level Group
  i.e. Operator, Supervisor, Manager, Calibration, Maintenance and Admin
- Compulsory Password Change on First Login.
- User Password Expiry.
- Electronically Require Users to Change their password at regular intervals.
- Automatically limit number of failed login attempts.
- Auto log-off computer/SCADA systems when idle for short periods of time.
- From this user access privileges feature you can manage that what user can access in the software.
- The privileges like delete, copy, cut, paste, rename. etc. shall not be allowed to an authorized user

ELECTRONIC RECORD AND SIGNATURE

- Any combination of text, graphics, data, audio, pictorial or other information representation in digital form that is created, Modified, maintained, archived, retrieved or distributed by a computer system.
- Electronic data and report should be human readable and suitable for inspection and review.
- Ensure the content Performed by with date and time stamp, Print by with date and time, reviewed by with date and time stamp, system analysis parameter related information generated data shall not be edited or altered.
- System must generate accurate and complete copies of records in both printed hardcopy and electronic format.

AUDIT TRAIL

- Protected from unauthorized deletion or alteration.
- Automatically generated.
- Secured & time-stamped.
- Audit trails are to be retained as long as Electronic data is required to be retained.
- Electronic record must be available for inspection, review, and copying the records in both human-readable and electronic form.

BACKUP & RESTORE

- Automatically backup generation on settable time.
- Backup Generation available for local machine as well as server.
- Easy data restore facility.

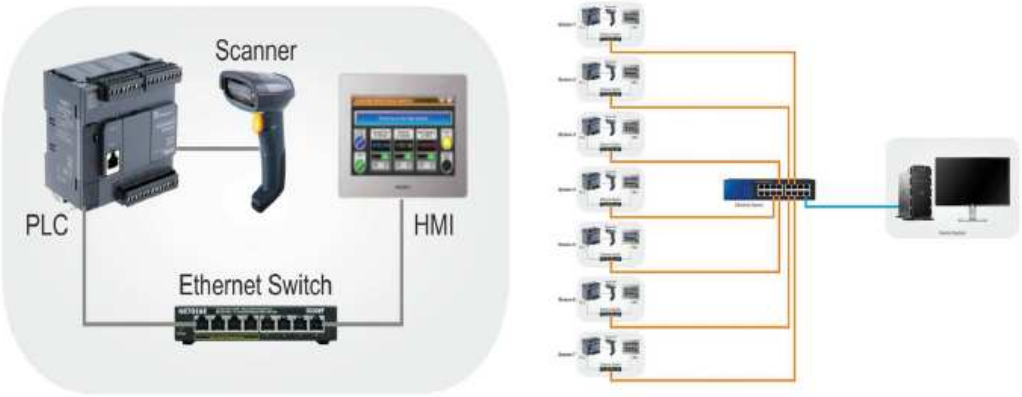
REPORTS

- Audit Trail Report
- Batch Report
- Batch Summary Report
- Alarm Report
- Date Wise Filter
- Batch Wise Filter
- User Wise Filter
- Report generation in PDF
- Direct Print to Physical Printer.

Project: Automobile Part Assembly Line

Digitization, cloud based monitoring system and assembly line real time capturing of manufacturing Data been always become necessity for the Automobile industry which adopts to acquire the savvy information of automobile parts manufacturing assembly line to analyse overall equipment efficiency of the operational cycle with providing traceability of part in individual station.

Labview software developed by LUBI caters Data acquisition of Automobile part assembly line for ease with optimization at various stations scanned and centralized monitoring to perform defects of part manufactured during assembly line as well as protection and authenticity of data records for security and audit trails with electronic signatures.



Software Features:

- Batch Code/Child Barcode for Individual Station
- Line Efficiency
- Live Data Monitoring
- Tool Calibration
- Tool Life
- Traceability
- Online SPC
- Production Data
- Summary Report
- Alert
- User Management