

## 21 CFR Part 11 Compliant X2 Series HMI for Pharmaceutical Industry



The **21CFR Part 11** guidelines were defined in 1997 by Food and Drug Administration. These regulations mainly deal with the Electronic Records and Electronic Signature. This was a major step towards defining the equivalence of these records to the legacy Paper based records and handwritten signatures. Along with this guidelines, introduction of Information Technology (IT) in compliance was a milestone.

This regulation defines how paperless record systems compliant with the current good manufacturing practice under which they will be considered equivalent to conventional paper records & handwritten signatures.

This document issued as information for **21 CFR Part 11** Compliance functionality available in **X2 Series Beijer HMI**.

The system construction by the user must be based on the following points to comply HMI Platform with the **FDA 21 CFR Part 11 regulations**.

✓ **User Management Functionalities:**

- Password protected individual Unique user account.
- Password Complexity.
- Minimum 8 Character password length.
- Configurable Number of Wrong Attempt
- User Block/Unblock Facility
- Password Validity.
- Multiple User Level as per the User Rights

✓ **Audit Trail:**

- Tamperproof and Non-Editable Audit Trail Data Format.
- The time stamp of the change of the parameter value and user making the change
- The audit trail records following details-
  - User Creation
  - User Login/ Logout
  - Wrong attempts of login
  - User Block / Unblock by Administrator
  - Old value and new value of parameter change
  - The time stamp of each event

✓ **System Data and Data Backup:**

HMI offers basic connectivity for data exchange with Central SCADA / MES / ERP by following means-

- Through OPC UA
- Through Data file transfer
- Through USB / SD Card Backup

✓ **Electronic Data Record and Data storage:**

- Review of the reports on the HMI Screen for Production, Alarms and Audit Trail.
- Storage limit can be interlocked in terms of the number of batches produced or % of the memory consumed.

✓ **Report Generation and Printing:**

- Batch data is stored in secured database format and **Batch Report** can be generated using this data.
- Report Printing: The report printing has been offered in multiple ways-
  - Online printing of Alarms, Events and Logged data through Serial Printer
  - Printing of General report through USB and Network Printing