# Detailed Features List For

# Web Based 21 CFR Part 11

# Software

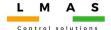**LMAS WEB 1.0 : 21 CFR COMPLAINCE SOFTWARE FEATURES LIST**

## Introduction

This application is a Base Ready Application which can communicate with Data Loggers, PLC's, HMI's with TCP/IP or FTP Protocol for Logging Temperature, Humidity or any other Environmental Parameters. This Base Ready Product is for Manufacturers of Stability Chambers, Data Loggers, Scanners, Controllers, Cold Room Manufacturers etc. It's a Browser Based Application with Client-Server Architecture. Application gets installed on a Centralized Server along with the Background Services required for pulling Data from Machines Connected in various Network Nodes in multiple Departments. Data Pulled from multiple Machines can be viewed from any Client Node using Server's IP Address. In Multi Department Mode, Access Rights to users can be given Department Wise. This application is future scalable for hosting on Cloud.
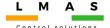
## Salient Features

- ✓ Multiple Equipment Configuration
- ✓ Password Protection with Alpha Numeric Password with min 8 characters
- ✓ Password Ageing
- ✓ Username and Password Encryption
- ✓ Wrong Password attempt account locking
- ✓ User Access Levels
- ✓ Department Access Levels
- ✓ User Audit Trails at Each Event
- ✓ Settable Parameters such as Temperature SV, LL and UL, Humidity SV, LL and UL along with Log Intervals
- ✓ Settable PID Parameters
- ✓ Equipment RTC Sync Facility
- ✓ SMS and Email Alert for Alarms
- ✓ Real Time Summary and Real Time Display
- ✓ Input / Output Status Display
- ✓ System Diagnostics for Services and Equipment Status
- ✓ Review Data Log
- ✓ Approve Data Log
- ✓ Digital Acknowledgement of Alarms with Audit Trails
- ✓ Audit Trails for User, Equipment, SMS and Email
- ✓ Auto and Manual Backup

**LMAS WEB 1.0 : 21 CFR COMPLAINCE SOFTWARE FEATURES LIST**

- ✓ Data Archive with Archive Analysis
- ✓ History Log Analysis
- ✓ Dashboard with Live Equipment Status
- ✓ White Labelled Solution without our Name and Details
- ✓ Will Support Continuous Data Logging from Background Service
- ✓ Application is compatible as per 21 CFR Part 11 Guidelines

## 21 CFR Part 11 Guidelines for Pharma Industry

- ✓ Alpha Numeric Password with min 8 char.

- ✓ Password ageing.

- ✓ Username and Password Encryption.

- ✓ Wrong Password attempt account locking.

- ✓ User login with same username from different location will not be allowed.

- ✓ User Access level.

- ✓ Audit trail at each event with comments from user.

- ✓ Digitally acknowledgement of Alarms with audit trails.

- ✓ Digital Approval of Data with 2 level facilities along with Batch Approval facility.

  - ✓ Review Data Log.

  - ✓ Approved Data Log.

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## System Architecture Diagram