FMS 5.0 FACILITY MONITORING SOFTWARE FOR LIFE SCIENCE APPLICATIONS

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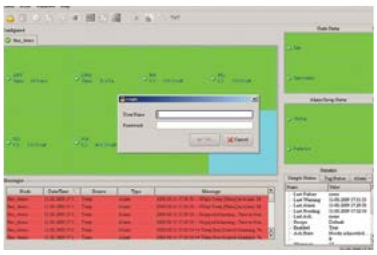
ENSURE REGULATORY COMPLIANCE WITH FMS 5.0

REGULATORY COMPLIANCE

FMS 5.0 is compliant environmental monitoring system software for the Pharmaceutical, Medical Device and Life Science industries. All software development activities at TSI follow the ISPE GAMP® lifecycle model. FMS 5.0 is assigned current GAMP® as a configurable software. It is specifically intended for use where compliance to EU GMP Annex 1 and the aseptic processing FDA cGMP is required.

FMS 5.0 enables compliance to the FDA 21 CFR Part 11 ruling. Full audit trail, password aging and lockout after failed logins, ensures secure, tamper proof data archiving and reporting. System security is easily configurable. User groups allow users and managers appropriate levels of system access.



21 CFR Part II: Unique user name and password

The Leading Facility Monitoring Software

TSI FMS system is an advanced, reliable, and user-friendly monitoring software suite that features a truly open architecture, supporting multiple instrument inputs from any manufacturer. Typical inputs include:

+ Airborne particle counters
+ Temperature and humidity sensors
+ Differential pressure gauges
+ Liquid particle counters
+ ESD
+ Airborne molecular contamination and more

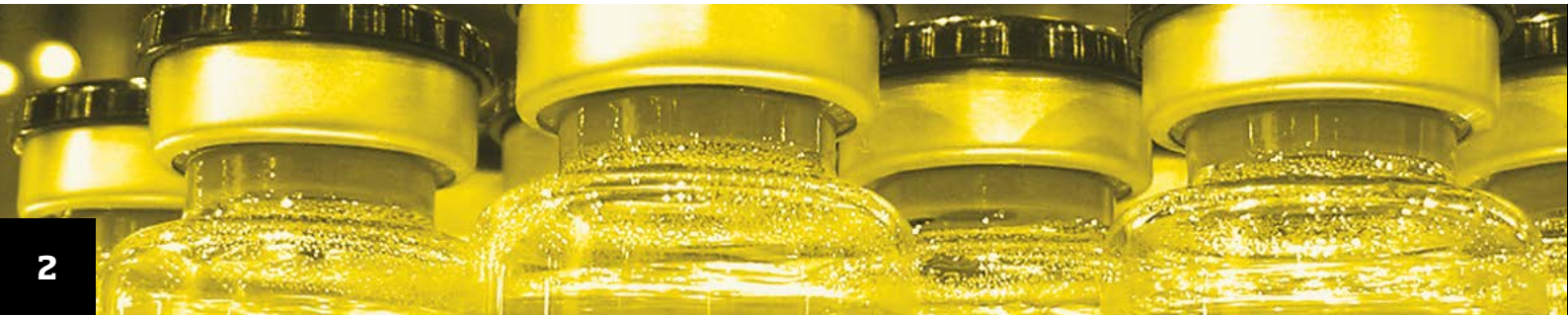
Features and Benefits

+ Open architecture
+ Meets all regulatory guidelines for GMP pharmaceutical production
+ Built-in system redundancy
+ Intuitive operation
+ Unique Buddy automatic hot standby option
+ Display and auto reporting
+ Easy data export
+ Group, acknowledgement, and auto alarms
+ Fully GAMP® compliant
+ Enables 21 CFR Part 11 compliance
+ Back up via mirror database
+ Multi-level maps
+ Notifications via email, SMS and telephone
+ User defined reporting
+ SPC control charts

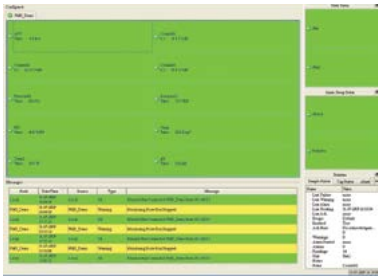
Validation

Full project based validation lifecycle documentation based on the latest ISPE GAMP® guidelines is available and tailored to meet your requirements.

+ User Requirement Specification (URS)
+ Configuration Statement (CS)
+ Installation Qualification (IQ)
+ Functional Specification (FS)
+ Factory Acceptance Test (FAT)
+ Operational Qualification (OQ)



Ease of Use

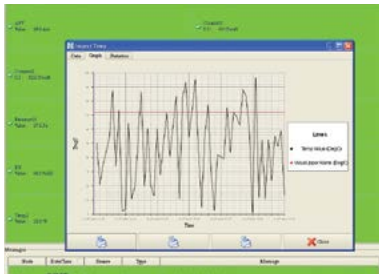


An intuitive, user configurable interface means immediate visibility of real-time data. Single mouse click access to historical data and report generation leads to reduced operator training, immediate data access and improved process control.

Mapping

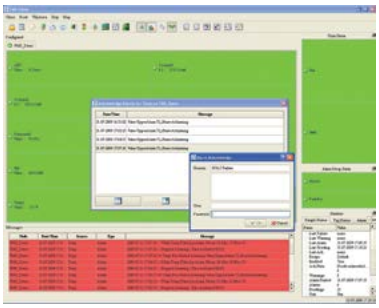
Multi-level maps display the last recorded value for each instrument and show real-time icons in Red for Alarm, Yellow for Warning, Green for Okay and Blue for Instrument Failure. Simply click on the instrument icon for instant, detailed information.

Graphing & Reporting



FMS comes with its own report generation tool. This allows users to create customized reports to meet your needs. Where more advanced reporting is required, third party tools can be easily deployed to use with FMS 5.0 databases. All collected data can be turned into useful process information via powerful FMS 5.0 reporting and graphing tools. Critical reports can be generated each day, and auto reports can be created based on recorded events.

Communication



FMS 5.0 supports multiple system outputs like beacons, sounders, SMS text, email, auto-dialers and reporting are supported. Operators and managers are immediately informed of an event. This information aids in root cause investigations, process validation and improved product quality.

NEED A BUDDY?

FMS offers a unique Buddy (Automatic Hot Standby) system option for built-in system redundancy. This completely integrated back-up system resides on an alternate computer. If anything happens to the primary FMS 5.0 system, the Buddy automatically takes over, continuing to collect secure data. No manual intervention is required in the event of a computer failure, meaning no system down time, no lost validated data, and peace of mind.

FACILITY MONITORING SYSTEM OVERVIEW