

Pharmaceutical Facility Monitoring System (FMS) Solution

I. Executive Summary

The **HR-FMS** by Suzhou Honri Purification Technology is an integrated compliance solution designed specifically for the pharmaceutical industry. It adheres to international authoritative standards, including **EU GMP Annex 1 (2022)**, **US FDA 21 CFR Part 11**, and **ISO 14644-1:2015**. The system provides 24/7 continuous monitoring of airborne particles, microorganisms, and environmental parameters to ensure data integrity and full lifecycle traceability.

II. Core Compliance Principles

- Continuous Control:** Replaces manual inspections with automated 24h data collection to eliminate the risk of unrecorded deviations.
- Data Integrity:** Fully compliant with **21 CFR Part 11** for electronic records and signatures, ensuring audit trails are non-tamperable.
- Scientific Sampling:** Adheres to ISO 14644-1 ($N=\sqrt{A}$) for point calculation and ensures isokinetic sampling in Grade A zones to maintain laminar flow.

III. Hardware Specifications

| Parameter | Model | Key Specifications | Compliance |
|-----------------------|----------------|--|--------------------------------------|
| Airborne Particles | CLJ-R310/R310P | 28.3L/min; Monitors 0.3/0.5/5.0 μ m particles. | EU GMP Annex 1 & ISO 14644-1. |
| Active Air Sampling | FSC-R10 | Collection efficiency \geq 98%; Remote real-time sampling. | Meets <1 cfu limit for Grade A. |
| Differential Pressure | DP-30R/DP-25 | Range: 0- \pm 125 Pa; Response time <3s. | Prevents backflow and contamination. |
| Air Velocity | WS-30R/WS-25 | Accuracy: \pm 0.1 m/s; Monitors 0.36-0.54 m/s flow. | ISO 14644-4 airflow design. |
| Temp & Humidity | TH-30R/TH-25 | Temp: \pm 0.3°C; Humidity: \pm 3%RH. | Meets international IAQ standards. |

IV. Software Capabilities

- Audit Trail:** Features three-level permission management (Admin, Engineer, Operator) for total accountability per 21 CFR Part 11.
- Smart Alarms:** Multi-level thresholds with alerts via on-site sirens, SMS, and the Movicom mobile APP.

- **Compliance Reporting:** One-click generation of encrypted PDF reports compliant with ISO 14644-1 and EU GMP Annex 1.