

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 μm 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- ± 125 Pa; Response time < 3 s.	Prevents backflow and contamination.
Air Velocity	WS-30R/WS-25	Accuracy: ± 0.1 m/s; Monitors 0.36-0.54 m/s flow.	ISO 14644-4 airflow design.
Temp & Humidity	TH-30R/TH-25	Temp: $\pm 0.3^\circ\text{C}$; Humidity: $\pm 3\%$ RH.	Meets international IAQ standards.

IV. Software Capabilities

- [cite_start]**Audit Trail:** Features three-level permission management (Admin, Engineer, Operator) for total accountability per 21 CFR Part 11[cite: 33].
- [cite_start]**Smart Alarms:** Multi-level thresholds with alerts via on-site sirens, SMS, and the Movicom mobile APP[cite: 7, 35].
- [cite_start]**Compliance Reporting:** One-click generation of encrypted PDF reports compliant with ISO 14644-1 and EU GMP Annex 1[cite: 34, 46].