HR-FMS Cleanroom Online Monitoring System Solution (ISO 14644)

7×24H Automated Environmental Compliance & Risk Management

1. SOLUTION OVERVIEW

The **HR-FMS Cleanroom Online Monitoring System** by Honri Purification provides a comprehensive, 24/7 automated solution for monitoring critical environmental parameters. Developed in strict accordance with the **ISO 14644** series (including ISO 14644-1 for classification and ISO 14644-4 for airflow design), the system tracks suspended particles, viable organisms, temperature, humidity, differential pressure, and air velocity.

2. CORE COMPLIANCE PRINCIPLES

2.1 Scientific Classification & Sampling Design (ISO 14644-1)

- **Sampling Location Calculation**: The minimum number of sampling locations (N_L) is determined by the standard ISO 14644-1 formula:

NL = √A

> **Parameters:**
>
> - **NL**: Minimum number of sampling locations (rounded up to the next whole number).
> - **A**: Area of the cleanroom in m².

- **Positioning Requirements**: Sampling probes are positioned at a uniform height of 0.8–1.2 m; locations must be ≥ 30 cm from walls and ≥ 1 m from HEPA filters to ensure representative data.

2.2 Airflow Integrity Control (ISO 14644-4)

- **Unidirectional Flow Monitoring**: Ensures ISO Class 5 (Grade A) zones maintain a stable air velocity between **0.36–0.54 m/s**.
- **Isokinetic Sampling**: Grade A zones are equipped with isokinetic sampling heads to ensure intake velocity matches the laminar airflow, preventing air turbulence and ensuring count accuracy.

2.3 Data Integrity & Traceability (21 CFR Part 11)

- **Audit Trail**: Full compliance with electronic record and signature requirements. Ensures the entire data lifecycle—from collection to export—is tamper-proof and traceable (ALCOA+).

3. CORE HARDWARE CONFIGURATION

Parameter	Recommended Model	Key Specifications	Compliance
Airborne Particles	CLJ-R310	28.3 LPM flow rate; monitors ≥ 0.5/5.0 µm particles	ISO 14644 / ISO 21501
Viable Particles	FSC-R10	Collection efficiency ≥ 98%; automated remote sampling	ISO 14644-1 / GMP
Temp & Humidity	TH-30R / TH-25	Temp Accuracy: ± 0.3°C; Humidity: 0–100% RH	ISO 14644 Stability
Differential Pressure	DP-30R / DP-25	Range: 0–± 125 Pa up to 5000 Pa	Pressure Gradient ≥ 15 Pa
Air Velocity	WS-30R / WS-25	High-precision hot-wire; monitors 0.36–0.54 m/s	ISO 14644-4

4. SOFTWARE SYSTEM CAPABILITIES

- **Static & Dynamic Modes**: Supports both "At-rest" classification and "In-operation" routine monitoring.
- **3-Level User Rights**: Strict access control for Administrators, Engineers, and Operators with full action logging.
- **Intelligent Alarms**: Real-time notifications via local sirens, SMS, and mobile APPs based on ISO 14644 limits.
- **Automated Reporting**: Generates encrypted PDF reports compliant with regulatory audits at the click of a button.
- **Seamless Integration**: Supports RS485 (MODBUS), TCP/IP, and WiFi for easy connection to LIMS or MES systems.

5. STRATEGIC VALUE

1. **Guaranteed Compliance**: Fully aligned with international ISO 14644 and GMP regulatory frameworks.
2. **Operational Efficiency**: 7×24H automated monitoring replaces manual labor and eliminates human error.
3. **Proactive Risk Control**: Immediate detection of environmental drifts prevents product contamination and downtime.
4. **Turnkey Implementation**: Comprehensive service including layout design, Validation (IQ/OQ/PQ), and calibration.

Manufactured by:
Honri Airclean Technology (Suzhou) Co., Ltd.