

CLEANROOM COMPLIANCE GUIDE

How InstruVU supports environmental monitoring, excursion visibility, and audit readiness across ISO-classified cleanrooms

Cleanroom operators are expected to maintain controlled conditions, document compliance, and respond rapidly to excursions that could compromise product quality, patient safety, or process integrity. InstruVU provides a centralized monitoring layer that transforms sensor and event data into actionable compliance evidence.

Designed for:
ISO 8 | ISO 7 | ISO 6 | ISO 5

Use cases:
Pharma | Biotech | Life sciences | High-spec manufacturing

Monitoring functions that strengthen cleanroom compliance

The table below reflects common cleanroom control expectations and the role InstruVU can play in continuous monitoring, evidence capture, and response management.

Sensor / event input	Control objective	How InstruVU helps	Highest-value ISO zones
Differential pressure sensors	Verify pressure cascade and airflow direction between rooms, airlocks, and support spaces.	Continuously trends room-to-room pressure relationships, flags drift or reversal, timestamps excursions, and preserves records for investigation and CAPA support.	ISO 5–8
Temperature sensors	Maintain stable thermal conditions aligned with SOPs, product needs, and operator comfort requirements.	Logs temperature at configured intervals, applies thresholds and alerts, and produces auditable history for reviews, batch correlation, and deviation analysis.	ISO 5–8
Particle count sensors	Demonstrate control of airborne particulate levels in operation and at rest, according to cleanroom classification strategy.	Consolidates live particle trends, identifies count spikes, supports alarm routing, and helps document sustained control or event-driven review by area.	ISO 5–7

Sensor / event input	Control objective	How InstruVU helps	Highest-value ISO zones
Door open / close sensors	Reduce contamination risk from uncontrolled access, prolonged openings, or poor personnel/material flow discipline.	Records every state change, highlights excessive door-open duration, correlates access events with pressure or particle excursions, and supports root-cause reconstruction.	ISO 5–8

ISO-class monitoring emphasis by cleanroom level

Control strategies differ by classification, process criticality, and local quality procedures. InstruVU helps standardize visibility while allowing alarm and review logic to be scaled by room criticality.

ISO level	Typical compliance focus	InstruVU application
ISO 8	General environmental stability, pressure relationships, and documented basic cleanroom control.	Ideal for baseline monitoring of temperature, pressure, and door discipline in support and staging areas.
ISO 7	Routine particulate control, stronger trending expectations, and faster response to room condition drift.	Supports particle trend visibility, tighter alerting, and coordinated investigation across HVAC and behavioral events.
ISO 6	Heightened contamination control, more restrictive operating windows, and stronger excursion scrutiny.	Enables narrower thresholds, event correlation, and disciplined audit trails for critical production environments.
ISO 5	Highest sensitivity to contamination events, with strict control of pressure, airflow integrity, occupancy behavior, and particles.	Best used as part of a high-frequency, alarm-driven strategy that links particle, pressure, and door events into one evidence stream.

Compliance-oriented outcomes

What quality teams need

- Continuous, time-stamped evidence rather than manual spot checks alone
- Immediate awareness of conditions that may trigger deviation review
- Defensible records for investigations, audits, and management review
- A practical way to compare environmental events across rooms and shifts

What InstruVU delivers

- Unified dashboards for pressure, temperature, particles, and door-state signals
- Threshold-based alarms and exception visibility for faster intervention
- Historical trending to support root-cause analysis and CAPA documentation
- Scalable monitoring architecture across multiple ISO zones and facility areas

Recommended positioning for regulated environments

InstruVU should be positioned as a monitoring, alarming, and evidence-enablement platform that strengthens cleanroom oversight. It supports quality systems by improving visibility into environmental conditions that matter for classification control and contamination prevention.

It should not be represented as replacing facility qualification, airflow studies, formal cleanroom classification, microbiological monitoring, or the user's quality management system. Rather, it enhances the operator's ability to detect, document, review, and respond to conditions that may affect compliance status.

Suggested marketing language

“InstruVU helps cleanroom operators maintain continuous awareness of differential pressure, temperature, airborne particle trends, and door-state events—supporting faster intervention, stronger documentation, and better readiness for internal and external audit review across ISO-classified spaces.”

Important note: This guide is written in a regulatory-aligned, authoritative style for marketing and sales enablement. It is not issued by a government agency, notified body, or standards organization, and it does not replace ISO 14644, GMP requirements, site SOPs, or validation obligations.