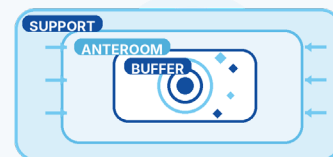


USP <797> ENVIRONMENTAL INTELLIGENCE

USP <797> Compliance Has a Blind Spot: Time.

Make the air visible between scheduled samples.



THE EVIDENCE GAP

Required certification and culture-based sampling are essential - but episodic. Short-duration events can occur between collection points.

USP <797> requires independently certified compounding areas and facility-specific microbiological air and surface monitoring. SensusAir sits between those checkpoints, screening continuously for environmental occurrence patterns so teams can focus on the right zone, time window and response.

SENSUSAIR: AN ALWAYS-ON INTELLIGENCE LAYER FOR CONTROLLED ENVIRONMENTS

01 SENSE

High-frequency environmental screening around critical compounding zones.

- Biological occurrence signatures associated with bacteria and fungi
- Particulate, VOC, temperature and relative humidity context
- Zone baselines across buffer, ante, SCA and support spaces
- Continuous history to reconstruct short-duration deviations

02 INTERPRET

Living Intelligence™ turns raw signals into usable operational context.

- AI/ML anomaly detection, pattern recognition and personalized baselines
- Time + zone mapping to isolate when and where drift began
- Source-oriented patterns: human/procedural, reservoir or airflow/outdoor
- Daily and weekly digests that highlight occurrence windows and trends

03 ACT + DOCUMENT

Move from a signal to targeted, auditable corrective action.

- Configurable alerts plus daily and weekly environmental digests
- Focused investigation with Pharmacy, Facilities, EVS and Quality
- Intervention tracking and Air Ledger™ evidence of response + recovery
- Before/after comparison to support CAPA follow-through and team learning



CONTINUOUS SCREENING + REQUIRED CONFIRMATORY METHODS + DOCUMENTED CORRECTIVE ACTION

HIGH-VALUE MONITORING ZONES

BUFFER ROOMS • ANTEROOMS • SEGREGATED COMPOUNDING AREAS • PASS-THROUGHS • HAZARDOUS DRUG AREAS • STORAGE / STAGING • ADJACENT SUPPORT SPACES

SensusAir is supplemental environmental screening and decision support. It does not enumerate CFU, replace required USP <797>/<800> sampling or certification, certify ISO classification, or substitute for pharmacy, microbiology or engineering judgment.

From Excursion to Evidence-Driven Prevention.

When a laboratory result identifies an excursion, SensusAir provides the missing history: what changed, where it began, how long it persisted and whether corrective action restored the baseline.

WHERE SENSUSAIR CREATES OPERATIONAL VALUE

DESIGNATED PERSON / PHARMACY LEADERSHIP Gain earlier visibility into environmental drift; coordinate investigation, escalation, SOP response and longitudinal review.	FACILITIES / HVAC / CERTIFICATION Focus on a specific room and time window; correlate with HEPA, pressure, airflow, maintenance, temperature and RH records.
QUALITY / REGULATORY / PATIENT SAFETY Strengthen root-cause analysis, CAPA, trend review and survey readiness with time-stamped environmental evidence.	EVS / CLEANING PROGRAM Compare occurrence patterns before and after cleaning or sporicidal intervention; target recleaning and verify recovery.
INFECTION PREVENTION / MICROBIOLOGY Add contextual evidence to culture results; prioritize confirmatory sampling and source investigation when conditions change.	COMPOUNDING STAFF / COMPETENCY Identify windows associated with traffic, garbing, material transfer or workflow; support focused coaching and retraining.
OPERATIONS / SUPPLY CONTINUITY Protect compounding capacity by shortening disruption, discard, rework, emergency outsourcing and therapy delay.	SYSTEM / EXECUTIVE LEADERSHIP Standardize playbooks across sites, compare performance, prioritize capital and demonstrate accountable governance.

LIKELY OUTCOMES: FROM PERIODIC EVIDENCE TO CONTINUOUS AWARENESS

EARLIER AWARENESS Recognize episodic changes between scheduled tests.	FASTER ROOT CAUSE Direct teams to the most relevant room, shift and event.	FOCUSED CONFIRMATION Use required sampling where evidence is strongest.
TARGETED CORRECTION Focus cleaning, behavior, airflow or maintenance response.	VERIFIED RECOVERY Compare pre-/post-intervention trends and preserve the record.	COMPOUNDING CONTINUITY Reduce broad shutdowns, avoidable discard and premium outsourcing.

THE ROI IS IN TIME, CAPACITY + AVOIDED DISRUPTION

Build the business case with local values - not generic claims.

ANNUAL VALUE =

- avoided downtime (hours × local cost/hour)
- avoided discard, rework and repeat sampling / certification
- pharmacy + facilities + quality labor recovered
- avoided premium outsource / expedite spend and therapy disruption

Payback months = platform investment ÷ average monthly benefit

REGULATORY + ENGINEERING FRAMEWORK

USP <797> (official Nov. 1, 2023) requires independently certified areas and facility-specific microbiological air/surface monitoring. USP <800> overlays hazardous-drug controls. ASHRAE/ASHE Standard 170 and ASHRAE's 2024 white paper address filtration, ACH, pressure, airflow, temperature and RH. Adoption and enforcement vary by jurisdiction. New technology must be validated and may not bypass chapter requirements.

TRADITIONAL EVIDENCE MODEL

Scheduled certification / culture sampling → incubation + lab review → retrospective investigation → correction → repeat testing

SENSUSAIR-AUGMENTED MODEL

Continuous screening → targeted alert → focused confirmatory sampling → coordinated correction → verified trend recovery → QA learning

Regulatory references: USP General Chapter <797> and USP <797> FAQs (Dec. 11, 2023); USP <800> FAQs (Jan. 21, 2026); ANSI/ASHRAE/ASHE Standard 170-2021 and Addendum t (2025); ASHRAE, HVAC Design of Compounding Pharmacies (2024).