Environmental Monitoring for USP 797 and USP 800

A practical approach to monitoring sterile compounding areas and hazardous drug environments

Executive summary

A pharmacy monitoring program should help teams recognize changes in critical conditions, respond promptly, and retain evidence of what happened. Continuous environmental monitoring supports this work by connecting room and equipment measurements with alarms, historical trends, and documented review.

For facilities working under USP <797> and USP <800>, the monitoring design must reflect the actual compounding activities, room boundaries, storage needs, and approved response procedures. A system is most useful when each monitored point has a defined purpose and each alarm has an accountable owner.

This white paper explains how to plan that program, use monitoring records in daily operations, and maintain measurement reliability over time. It addresses physical conditions such as temperature, relative humidity, and differential pressure. Microbiological sampling, hazardous drug surface testing, and independent cleanroom certification serve different purposes within the broader facility program.

Who should use this paper

Pharmacy leaders, facilities and engineering teams, quality personnel, and IT stakeholders can use this paper when evaluating a new monitoring system or reviewing an existing installation. The central recommendation is to define the monitoring requirements and response workflow before selecting or configuring technology.

Monitoring technology supports a facility's compliance program. Compliance also depends on facility design, engineering controls, personnel practices, procedures, certification, and the requirements of the applicable regulatory jurisdiction. [1–4]

Define the monitoring scope

Start with the facility's operating model. Identify where sterile preparations are compounded, where hazardous drugs are handled, and where materials and finished preparations are stored. These activities determine which conditions need to be monitored and how the records will be used.

Understand how the chapters work together

USP <797> addresses sterile compounding. Facilities compounding sterile hazardous drugs must also meet USP <800>. The revised <797> chapter became official on November 1, 2023. USP <800> became official on December 1, 2019, and compendially applicable to the extent that <795> and <797> apply on November 1, 2023. Facilities should confirm the requirements adopted by their regulators. [1–4]

For hazardous drug operations, the facility's hazardous drug list and any permitted drug-specific assessment of risk inform the containment strategy. Monitoring points should follow the approved design and handling practices. The NIOSH hazardous drug list provides a reference for this assessment. [4,5]

Connect each point to an operating decision

Monitoring area	Typical measurements	Operational purpose
Compounding rooms	Temperature, relative humidity, differential pressure	Identify changes in approved room conditions and pressure relationships.
Hazardous drug containment	Differential pressure and specified ventilation signals	Track containment conditions and notify the responsible team of excursions.
Storage equipment and areas	Refrigerator, freezer, and ambient temperature; selected door or power status	Support storage oversight and investigation of temperature excursions.
Monitoring infrastructure	Communication and device status	Identify interruptions that could affect measurement visibility or data availability.

For each point, document its location, measurement range, required accuracy, recording interval, limits, and responsible department. Include the reason for monitoring it. This gives pharmacy, engineering, and quality a shared basis for approving the configuration.

Monitor conditions in context

Temperature and relative humidity

Temperature and humidity measurements help teams understand whether rooms are operating within approved conditions. Continuous records provide context between manual checks and help identify recurring patterns. The facility should establish limits and review procedures using the official chapter, its room design, and its operating requirements.

Storage monitoring should address each refrigerator, freezer, or ambient area included in the program. Probe placement should represent the intended storage conditions. Where mapping is appropriate, use the results to inform placement and evaluate locations that may behave differently during routine use.

Differential pressure and containment

Pressure monitoring measures the relationship between spaces. The boundary being measured, the direction of airflow intended by the design, and the sensor's sign convention should be clear in the point description and alarm configuration.

USP <800> requires the containment secondary engineering control, or C-SEC, to maintain negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent areas at all times. The appropriate air exchange must also be maintained when the room is not in use. Pressure trends support oversight of these conditions, while ventilation performance requires separate engineering evidence. [4]

Airflow and other integrated signals

Airflow, fan status, damper status, or building-system signals may be included when the project provides suitable instruments and interfaces. Specify the source, units, scaling, and ownership of each signal. A fan-running indication alone does not demonstrate that the room meets its required air exchange rate.

Recognize what physical sensors cannot establish

Temperature, humidity, and pressure sensors do not determine microbial contamination or hazardous drug residue. Viable air and surface sampling, particle testing, and cleanroom certification require their own methods and records. USP <800> recommends hazardous drug wipe sampling; its FAQs clarify that this sampling is recommended rather than required by the chapter. [4]

Use physical monitoring trends alongside certification and sampling results. Each provides a different type of evidence about the facility and its controls.

Build alarms and records into daily work

An alarm is useful when it reaches someone who can act and the response is documented. Configure the system around the facility's approved procedures, including coverage during evenings, weekends, holidays, and staff changes.

Set limits and escalation deliberately

Pharmacy, facilities, and quality should approve warning thresholds, alarm limits, delays, recipients, and escalation paths. Warnings can provide early notice of a developing condition. Any delay should have a documented rationale and remain consistent with the facility's requirements.

Review brief pressure changes associated with normal door use separately from sustained excursions. Use the room design and approved procedures to determine the appropriate response. Test notification delivery and escalation under the operating conditions the facility expects to encounter.

Review trends as well as alarm events

Historical measurements can show gradual drift or recurring changes before a limit is reached. Establish who reviews the data, how frequently the review occurs, and how the review is recorded. Automated reporting can support this routine, but the facility still needs an accountable reviewer.

When investigating an excursion, retain the measured values, start and end times, duration, relevant alarm events, acknowledgements, and response information. Compare the event with door activity, maintenance, or ventilation changes where those records are available. The facility determines product impact and any exposure-risk implications.

Plan for retrieval and continuity

Define record retention, access permissions, report approval, backup, and archival requirements for the selected deployment. Confirm that records needed for investigations or inspections can be retrieved in a usable format. Time stamps, point names, and measurement units should make the record understandable without reconstructing the system configuration.

Communication supervision and local buffering, where supported by the selected components, can help manage interruptions. Document what remains available during a network or power failure, how personnel are notified, and how data recovery is verified. Include these scenarios in system testing.

Illustrative pressure excursion

If a containment room moves outside its approved pressure band, the designated recipient follows the response SOP. Facilities investigates the room and ventilation condition, while pharmacy assesses the operational impact. The event is closed with the response, recovery evidence, and any required corrective action recorded. This is a workflow example, not a substitute for facility-specific procedures.

Maintain a reliable monitoring program

System performance depends on decisions made before installation and on maintenance after release. A clear division of responsibilities helps keep configuration, measurement accuracy, and response procedures aligned as the facility changes.

Establish requirements and acceptance evidence

The user requirements specification should define monitored locations, sensor performance, alarms, records, access, and continuity needs. Agree on the documentation package and acceptance criteria before installation. Depending on the project, evidence may include configuration records, calibration certificates, alarm and communication tests, and installation and operational qualification protocols.

Qualification should demonstrate that the purchased system is installed and operates as intended against the approved protocol. Define any performance qualification or additional commissioning, qualification, and validation work in the contracted scope. Keep cleanroom certification and airflow balancing evidence alongside the monitoring records.

Keep measurements and configuration current

Maintain a sensor inventory and a documented calibration or accuracy-verification schedule. USP <797> FAQs clarify that humidity sensors, pressure monitors, and thermostats are examples of monitoring equipment covered by the chapter's calibration or verification provision. Use the official requirements and manufacturer recommendations to establish the schedule. [2]

Changes to room use, HVAC operation, equipment locations, alarm recipients, software, or network architecture may affect monitoring. Evaluate changes through the facility's change-control process and determine what testing, calibration, qualification, or certification needs to be repeated.

How Rees Scientific supports the program

Rees Scientific provides monitoring technology and lifecycle services that can support sterile compounding and hazardous drug environments. Depending on the selected system and scope, capabilities include continuous measurement of configured conditions, warning and alarm management, time-stamped history, trends, controlled access, audit trails, and reports.

Project support may include system design, configuration, calibration, training, qualification, preventive maintenance, and technical service. Hardware, software version, deployment model, integrations, and contracted services determine the functions and documentation delivered. Confirm these details in the proposal and statement of work.

For an existing system, begin by reviewing monitored locations, recurring alarms, calibration status, response coverage, and record retrieval. For a new installation, begin with the facility requirements and intended workflow. Rees Scientific can help evaluate the monitoring scope and available system options. Visit reesscientific.com to discuss your facility's needs.

References and scope of use

The references below provide regulatory background. Use the current official USP text for requirements and interpretation. USP FAQs provide technical support and do not replace the official chapters. References reviewed September 29, 2026.

1. USP General Chapter <797> Pharmaceutical Compounding Sterile Preparations

https://www.usp.org/compounding/general-chapter-797

2. USP <797> Frequently Asked Questions updated December 11, 2023

https://pages.usp.org/rs/711-SXF-172/images/USP_HQS_797_FAQs_December2023_V6__002.pdf

3. USP Compounding Frequently Asked Questions

https://www.usp.org/compounding/frequently-asked-questions

4. USP <800> Frequently Asked Questions updated January 21, 2026

https://pages.usp.org/rs/711-SXF-172/images/USP_HQS_800_FAQs_January2026.pdf

5. NIOSH List of Hazardous Drugs in Healthcare Settings 2024 Publication 2025 103

https://www.cdc.gov/niosh/docs/2025-103/default.html

Scope of use

This white paper describes how environmental monitoring can support selected operational and documentation activities. It is not a complete interpretation of USP <797> or USP <800> and does not certify a facility or product as compliant. It does not provide legal, regulatory, pharmacy, industrial hygiene, or engineering advice.

The healthcare entity remains responsible for interpreting the official chapters and applicable rules, approving procedures and limits, maintaining facilities and engineering controls, responding to excursions, and making product-impact and exposure-risk decisions. Independent certification and sampling remain the responsibility of the facility and its qualified providers.

Available Rees capabilities depend on the selected configuration and contracted scope.