



Environmental Monitoring Checklist

Objectives/Expected Results: Ensure a controlled lab environment compliant with CGMP regulations throughout various stages of drug development.

Purpose of the Task: To monitor, record, and manage the environmental conditions in a GMP lab, ensuring product quality and safety.

Instructions: Mark each section with a check (✓) once compliance is verified or action is completed. If an item is not applicable, please mark it as not applicable (N/A).

SECTION	ASPECT	CHECKPOINTS	ACTION REQUIRED	FREQUENCY	COMPLETE ✓
Facility Design and Controls	Environmental Control	Ensure lab design supports proper environmental control. Verify HVAC systems are designed to prevent contamination.	Inspect and validate design and systems.	As needed	<input type="checkbox"/>
Temperature and Humidity Monitoring	Temperature Control	Temperature-controlled environments, such as storage rooms and incubators, are maintained within specified ranges.	Monitor and adjust temperature settings.	Continuous	<input type="checkbox"/>
	Humidity Control	Humidity levels controlled and monitored in critical areas.	Monitor and adjust humidity settings.	Continuous	<input type="checkbox"/>
Lux (Light Intensity) Monitoring	Light Intensity	Light intensity monitored and controlled in areas critical for experiments or material stability.	Monitor and adjust light settings.	As needed	<input type="checkbox"/>
Differential Pressure Monitoring	Cleanroom Pressure	Appropriate differential pressures maintained in cleanrooms.	Monitor and maintain pressure levels.	Continuous	<input type="checkbox"/>



CO2 and Air Quality Monitoring	CO2 Levels	CO2 levels monitored to ensure adequate ventilation.	Monitor and manage CO2 levels.	Continuous	<input type="checkbox"/>
	Airflow Control	Proper airflow and ventilation maintained to minimize contamination risk.	Monitor and manage airflow systems.	Continuous	<input type="checkbox"/>
Environmental Monitoring Equipment and Calibration	Equipment Calibration	Monitoring equipment is regularly calibrated for accuracy.	Calibrate and maintain equipment.	Per calibration schedule	<input type="checkbox"/>
	Data Logging and Alerts	A system for real-time data logging and alerts for out-of-spec conditions is in place.	Implement and maintain data logging system.	Continuous	<input type="checkbox"/>
Process Controls	SOPs Implementation	SOPs for environmental monitoring are implemented and followed.	Train staff and document SOP adherence.	As SOPs are updated	<input type="checkbox"/>
Documentation	Record Keeping	Detailed records of all monitoring activities are kept. SOPs are reviewed and updated regularly.	Maintain and review documentation.	Continuous	<input type="checkbox"/>
Testing and Sampling	Microbial and Particulate Testing	Conduct regular microbial and particulate testing using appropriate methods and locations.	Perform and document testing.	Per testing schedule	<input type="checkbox"/>
Data Review and Trend Analysis	Trend Analysis	Environmental monitoring data analyzed for trends.	Analyze data and implement actions as necessary.	Continuous	<input type="checkbox"/>
Regulatory Compliance and Documentation	Regulatory Adherence	Compliance with relevant regulatory requirements is maintained.	Review regulations and ensure compliance.	Continuous	<input type="checkbox"/>
	Compliance Records	Accurate records of environmental parameters are maintained for	Update and maintain records.	Continuous	<input type="checkbox"/>



Quality Assurance	QA Program	reporting purposes. A quality assurance program that includes environmental monitoring is established.	Assess and audit QA program.	Per QA schedule	<input type="checkbox"/>
Reporting and Remediation	Deviation Handling	Procedures for addressing environmental parameter deviations are in place.	Document and address deviations.	As deviations occur	<input type="checkbox"/>
	Reporting	A system for reporting environmental monitoring data to regulatory authorities is maintained.	Prepare and submit reports as required.	As required by regulations	<input type="checkbox"/>

For more information on Ellab Monitoring or to learn more about how Ellab can help you:

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