Environmental Monitoring Checklist

for Life Sciences

Environmental Monitoring Checklist

Introduction

In life science industry, the number one priority is to ensure product and patient safety, while adhering to compliance standards. Environmental monitoring plays an important role in managing and overseeing the spaces where specific conditions are needed to maintain the quality of pharmaceutical products and other samples.

Regulatory bodies, like the FDA or WHO, have strict sterility and cleanliness standards for critical spaces, such as laboratories, freezers, or cleanrooms. And because of these standards, continuous monitoring and tracking of key parameters (CO2, temperature, humidity…) are needed to ensure they remain within the needed levels.

Purpose

We've put together this checklist to help you streamline the process of continuous environmental monitoring. This document has been designed and formulated following the requirements essential for maintaining a controlled lab environment, compliant with CGMP regulations throughout various stages of product development.

Instructions

For each aspect, we present a checkpoint question. Simply provide a verification by marking the appropriate response with a checkmark or indicating "Yes," "No," or "N/A" as applicable.

Environmental Monitoring Checklist

SECTION/ ASPECT	CHECKPOINTS	ACTION REQUIRED	COMPLETED
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.	
Temperature and Humidity Monitoring			
Temperature Control	Temperature-controlled environments, such as storage rooms and incubators, are maintained within specific ranges.	Monitor and adjust temperature settings.	
Humidity Control	Humidity levels controlled and monitored in critical areas.	Monitor and adjust humidity settings.	
Lux (Light Intensity) Monitoring			
Light Intensity	Light intensity monitored and controlled in areas.	Monitor and adjust light settings.	
Differential Pressure Monitoring			
Cleanroom Pressure	Appropriate differential pressures maintained in cleanrooms.	Monitor and maintain pressure levels.	
CO2 and Air Quality Monitoring			
CO2 Levels	CO2 levels monitored to ensure adequate ventilation.	Monitor and manage CO2 levels.	
Airflow Control	Proper airflow and ventilation maintained to minimize contamination risk.	Monitor and manage airflow systems.	

Environmental Monitoring Checklist

SECTION/ ASPECT	CHECKPOINTS	ACTION REQUIRED	COMPLETED
Process Controls			
SOPs Implementation	SOPs for environmental monitoring are implemented and followed.	Train staff and document SOP adherence.	
Environmental Monitoring Equipment and Calibration			
Equipment Calibration	Monitoring equipment is regularly calibrated for accuracy.	Calibrate and maintain equipment.	
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.	
Documentation			
Record Keeping	Detailed records of all monitoring activities are kept. SOPs are reviewed and updated regularly.	Maintain and review documentation.	
Testing and Sampling			
Microbial and Particulate Testing	Conduct regular microbial and particulate testing using appropriate methods and locations.	Perform and document testing.	
Data Review and Trend Analysis			
Trend Analysis	Environmental monitoring data analyzed for trends.	Analyze data and implement actions as necessary.	

Environmental Monitoring Checklist

SECTION/ ASPECT	CHECKPOINTS	ACTION REQUIRED	COMPLETED
Quality Assurance			
QA Program	A quality assurance program that includes environmental monitoring is established.	Assess and audit QA program.	
Regulatory Compliance and Documentation			
Regulatory Adherence	Compliance with relevant regulatory requirements is maintained.	Calibrate and maintain equipment.	
Compliance Records	Accurate records of environmental parameters are maintained for reporting purposes.	Update and maintain records.	
Reporting and Remediation			
Deviation Handling	Procedures for addressing environmental parameter deviations are in place.	Document and address deviations.	
Reporting	A system for reporting environmental monitoring data to regulatory authorities is maintained.	Prepare and submit reports as required.	

By using this checklist, you are ensuring critical parameters are consistently controlled, protecting your products, staff, and patients while meeting compliance standards.

Environmental monitoring isn't just about meeting standards, it's about creating safe, stable spaces, protecting product quality, and minimizing contamination risks. With Ellab's environmental monitoring solution, your assets will be protected: always be inspection-ready while ensuring a timely and quick response to any anomalies with our TrackView Pro solution for continuous monitoring.

Read more about our environmental monitoring solutions and find out how Ellab can help you with asset preservation.

Follow Us

/ellab
/c/EllabValidationMonitoringSolutions

Ellab Benelux
Tel. +31 74 205 12 34
E: benelux@ellab.com

Ellab DACH
Tel. +49 4286 92662 0
E: germany@ellab.com

Ellab Philippines
Tel. +632 621 9174
E: ph@ellab.com

Ellab Denmark
Tel. +45 4452 0500
E: contact@ellab.com

Ellab UK
Tel. +44 151 355 1314
E: uk@ellab.com

Ellab US
Tel. +1 303 425 3370
E: usa@ellab.com

Ellab Dubai
Tel. +971 502049520
E: dubai@ellab.com

Ellab Ireland
Tel. +353 801 3770
E: ireland@ellab.com

Ellab France
Tel. +33 344 2302 57
E: france@ellab.com

Ellab Italy
Tel. +39 02349 1751
E: italy@ellab.com

Ellab A/S
Trollesmindealle 25
3400 Hillerød
Denmark

ellab.com