

AmpleLogic EMS

A Pharmaceutical Environmental Monitoring System (EMS) providing real-time monitoring, data tracking, and customizable alerts to ensure compliance and product safety.

<https://amplelogic.com/gamp-solutions/environmental-monitoring-system/>

Overview

AmpleLogic EMS (Environmental Monitoring System) is a robust, GAMP-compliant software solution designed specifically for regulated industries like Pharmaceuticals, Biotech, and Life Sciences to ensure product safety and regulatory adherence.

Product Overview & Key Benefits

The system automates the entire environmental monitoring workflow, including microbial checks, and eliminates the need for manual, paper-based processes, which helps to reduce manual errors and save time. It is built on AmpleLogic's low-code/no-code Application Platform as a Service (aPaaS), which allows for customization and integration with existing systems. Key benefits include enhanced productivity, improved data integrity and accuracy, cost savings, and audit readiness.

Main Features and Capabilities

Real-time Monitoring and Alerts: Provides real-time environmental monitoring with an auto alert system that instantly notifies users of deviations or when predefined limits are exceeded.

Automated Microbial Checks: Facilitates excellent monitoring of the environment for microbial checks, ensuring adherence to the Microbiological Sampling Plan.

Data Tracking & Analysis: Tracks comprehensive data of monitoring activities and offers extensive analysis, enhancing microbiological management and adherence to sampling plans.

Compliance & Audit Readiness: Ensures strict compliance with global regulatory standards like US FDA 21 CFR Part 11 and EU Annexure 11.

Intuitive Interface & Reporting: Features an intuitive interface for easy navigation and operation, along with real-time report generation for quick decision-making and compliance documentation.

Target Users and Use Cases

AmpleLogic EMS is primarily targeted at Quality Assurance (QA), Quality Control (QC), and manufacturing teams in highly regulated sectors such as Pharmaceuticals, Life Sciences, and Biotechnology. Primary use cases include maintaining a compliant environmental monitoring program, tracking contamination sources, managing sampling frequency and locations per SOPs, and ensuring quality assurance in cleanroom environments.

Key Features

- Real-time Environmental Monitoring
- Automated Microbial Checks
- Auto Alert System for Deviations
- Comprehensive Data Tracking & Analysis
- Real-time Report Generation
- Scalability
- Compliance with FDA 21 CFR Part 11 and EU Annexure 11

Pricing

Model: enterprise

Pricing is not publicly disclosed. Contact the vendor directly for a custom quote and proposal.

Target Company Size: medium, enterprise

Integrations

Existing Systems (Seamless Integration), LIMS, eQMS, DMS, MES/eBMR, LMS

Compliance & Certifications

FDA 21 CFR Part 11, EU Annexure 11, GAMP 5, GMP, ISO 9001