

An Independent & EMS - Validated Environmental Monitoring System Solution

The Background

Irish Power and Process (IPP) is a leading supplier of validated Environmental Monitoring Systems (EMS), an independent back up to site Building Management Systems (BMS) systems in the Pharmaceutical, Medical Device and Laboratory industries.

BMS Systems play a vital role in the running of a manufacturing process where the monitoring and control of atmospheric changes is crucial to consistency of production, sterility of end product and comfort of operators in the working environment.

The validation of a BMS system is both a costly and timely exercise which many companies would rather avoid. The solution is the installation of an independent system that is easily validated and provides auditable records with full traceability of operation critical variables.

The Key Product

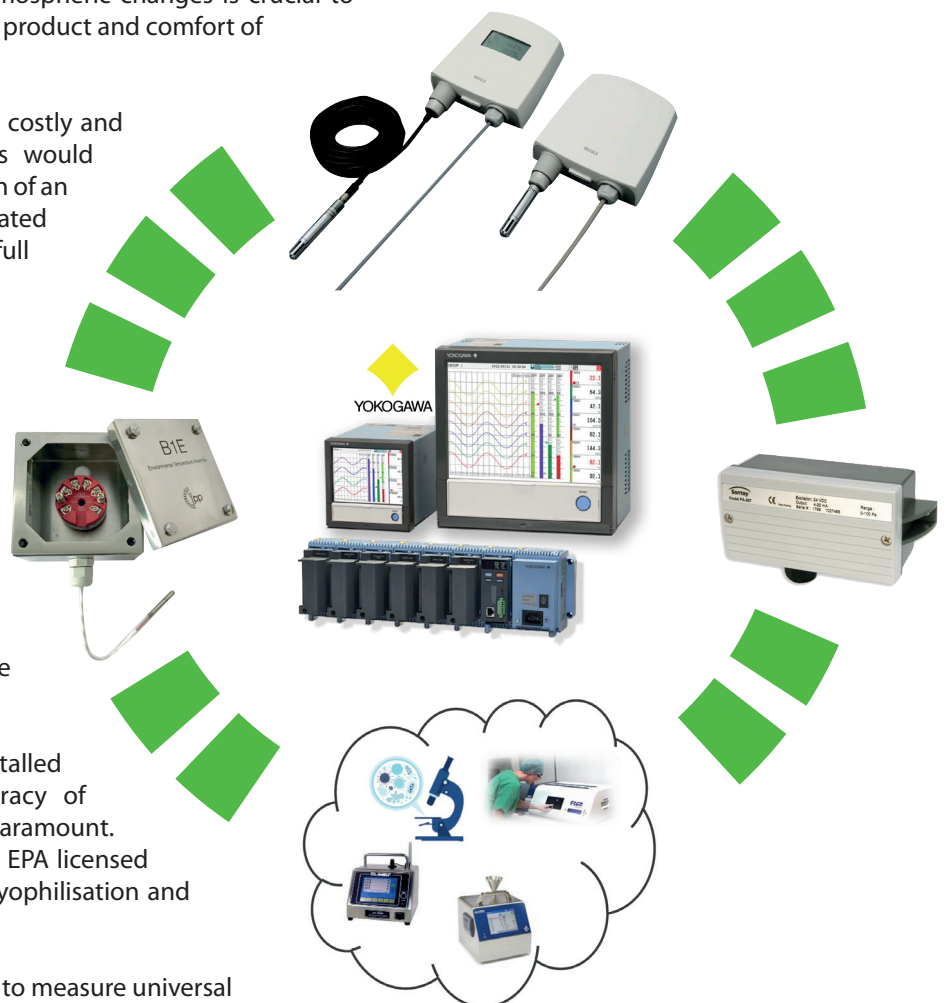
When critical process conditions need to be measured securely then the Yokogawa SmartDac+ GX/GM Paperless Recorders offer the perfect solution.

This Data Acquisition system has been successfully installed by IPP in large numbers throughout Ireland in heavily regulated Pharmaceutical and Medical Device companies, audited by both the FDA and HPRA.

These validated systems are typically installed in GMP critical processes where accuracy of measurement and security of data is paramount. Such applications include validated EMS, EPA licensed Environmental monitoring, sterilisation, lyophilisation and WFI processes.

This product owes its success to its ability to measure universal inputs accurately, securely and meeting 21CFR compliance.

Its Ethernet functionality allows data to be networked so that data can be accessed from a local PC or Server. It also offers the ability to communicate or integrate where necessary with PLC's, SCADA, LIMS and Data Historians.





With the ever-increasing demands for access to industrial data and the ability to merge data into broader data management systems, taking a more holistic approach to EMS monitoring is becoming crucial.

Mirrhia EMS software provides web-based data acquisition from multiple sources including Temperature, Humidity,

Pressure, CO2 but also direct measurement from Particle Counters and Air Sampling systems.

The historical approach to standalone monitoring of particle counting can be replaced with a system capable of giving the user all of their EMS related data under one secure and compliant interface.

A unique Monitoring Solution



**GMP
CRITICAL DATA**



**PREDICTIVE
MAINTENANCE**



**CONTAMINATION
MANAGEMENT**



QUALIFIED

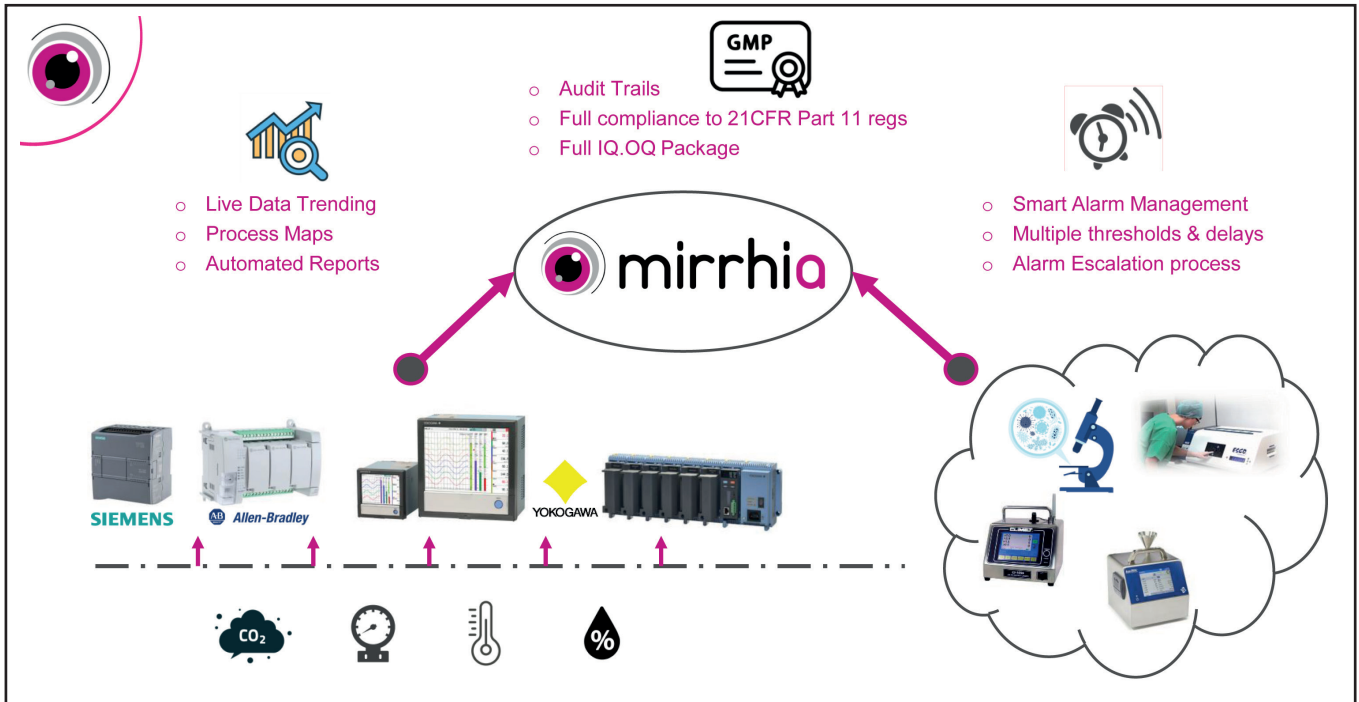


**HIGH
COMPATIBILITY**



**GLOBAL
MONITORING**

Monitor your equipment and environment and generate your Electronic Batch Record automatically thanks to Mirrhia



Key Features

- Multiple EMS process variables including Temperature, Humidity & Differential Pressure
- Inline with data integrity guidelines the system generates binary encrypted data files with data trending, alarm history and full audit trail.
- Maths Functionality - to generate other key process variables such as Mean Kinetic Temperature (MKT).
- Web view – Allowing remote viewing of live data from recorder.
- Ethernet serial communication for interfacing with other site systems.

The Solution

In addition to providing the Yokogawa paperless recorders and Mirrhia EMS software system, IPP can also offer a complete turnkey EMS system to the customer, providing the knowledge of the instrumentation required and the experience of the regulations governing the monitoring of Environmental data.

The complete package that Irish Power and Process (IPP) offer includes:

1 SYSTEM INSTALL: Complete install of EMS hardware (recorder) into stainless or mild steel panels with full wiring of independent sensors back to hardware. All channels wired back to terminals and each input individually isolated. Networking of hardware to local server to allow automatic transfer of data to server and web-view access.

2 CONFIGURATION: Complete configuration of hardware to ensure measurements ranged and grouped correctly. Install of Data viewing software on relevant local PC's for operators to view EMS data in detail if and when necessary.

3 CALIBRATION: Full system or loop calibration of the EMS sensors/probes to the paperless recorder and supply of accredited calibration certs on completion.

4 VALIDATION: Supply of full IQ/OQ documentation for hardware and associated software with availability of a qualified Validation Engineer to provide full validation execution service.

5 TRAINING: Full on-site training for operators on EMS hardware and software and supply of training certificates on successful completion.