

SECURING PHARMACEUTICAL REGULATORY COMPLIANCE

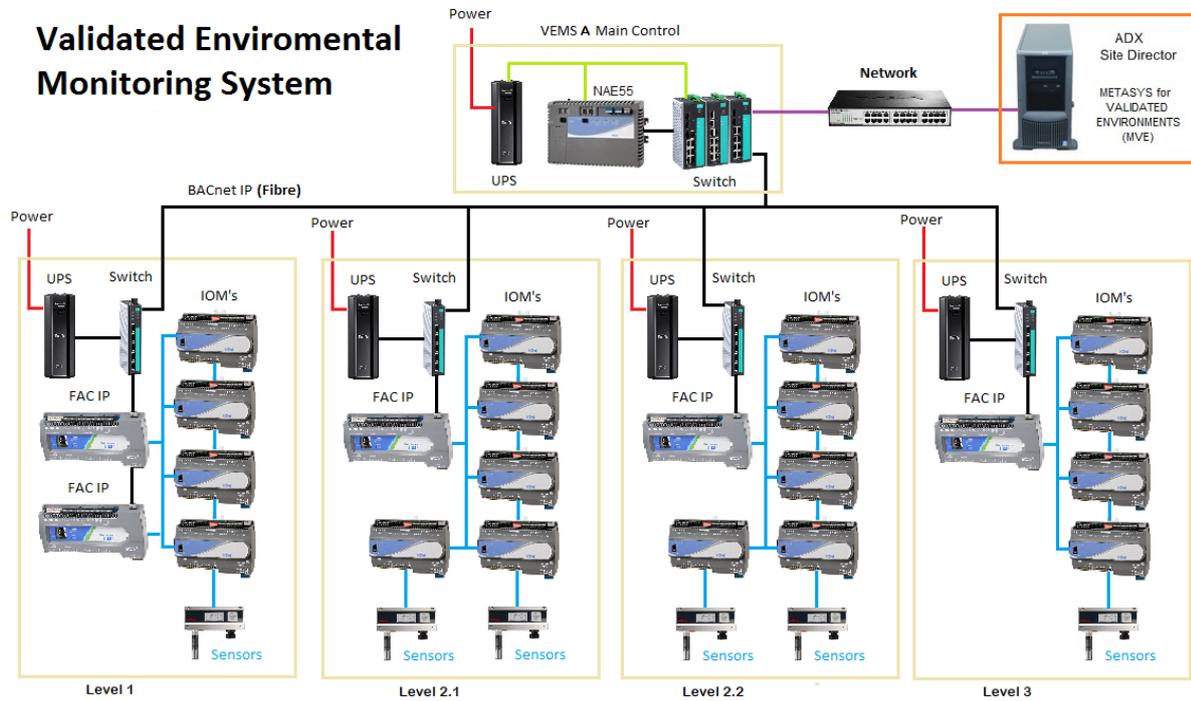
Recording, monitoring and maintaining environmental conditions is one of the critical challenges facing pharmaceutical production facilities today. Validation of this environmental data is crucial to Food and Drug Administration (FDA) Title 21, Code of Federal Regulations Part 11 as well as Annex 11 of the European Union Good Manufacturing Practice (EU GMP) regulations (European Medicines Agency [EMA] 1998) compliance.

The pharmaceutical industry faces numerous concerns related to validated environmental monitoring systems (VEMS), especially when it comes to the need for automatic redundancies, the high costs of validation and limitations related to systems efficiency and repeatability. When it comes to pharmaceutical production and storage facilities, a VEMS that not only abides by industry-related regulations, but also adopts the GAMP@5 risk-based approach is fast becoming key to overcoming these challenges.

ITD Group incorporates the Johnson Controls Metasys® for Validated Environments (MVE) software and new Johnson Controls IP-based controllers, to create self-contained, validated and fully managed IP networks which enhance the stability, efficiency and accuracy of pharmaceutical environmental monitoring systems.

In addition to the implementation of Metasys®, our use of validated IP controllers and validated IP networks – which adopt a GAMP@5 risk-based approach to Compliant GxP Computerised Systems – allows for the creation of safer, more secure, more efficient and lower cost systems.

BREAKING BARRIERS TO PHARMACEUTICAL ENVIRONMENTAL REGULATORY COMPLIANCE



The benefits of using VEMS software together with a validated IP network to manage pharmaceutical environmental control systems include:

IMPROVED EFFICIENCY AND COST

The use of a GAMP@5 risk-based approach allows high and low-risk areas in a system to be identified and subsequent compliance testing to be tailored to the system being validated – reducing unnecessary testing points.

INCREASED ACCURACY AND RELIABILITY

Validated IP networks facilitate the installation of optional mirrored environmental monitoring systems which are both validated and constantly communicate with each other to confirm accuracy and repeatability. This duplication facilitates greater system reliability by allowing one system to verify the other. This ensures 100% up-time of conditions recording.

GREATER FUNCTIONALITY, FLEXIBILITY, ROBUSTNESS

Remote monitoring of a VEMS provides an extra layer of expert support and facilitates more efficient, predictive monitoring. The use of BACnet open source communications protocol aids flexible communications between the various elements of the facility including power, services and other utilities. In addition, the use of Spanning Tree Protocol helps to reduce risk by providing alternative routes for data to flow if failures or physical damage occurs to the control network.

ENHANCED COMMUNICATION SPEED AND SYSTEM SAFETY

Connecting via an IP network allows for faster transmission of data and improved access to devices connected to a VEMS. System overall stability, control and speed is enhanced with the use of a dedicated BACnet IP network which is independent of corporate infrastructure. Complex passwords and usernames enhance system and user security, enhancing user authentication and preventing unauthorised access.



Using the Johnson Controls Metasys® for Validated Environments (MVE) together with innovative validated open source IP networks and technologies, ITD Group recently delivered the first-of-its-kind networked validated building management system in the South Africa, Africa, Middle East region.