

# METASYS<sup>®</sup> FOR VALIDATED ENVIRONMENTS

## challenge

Capture and manage critical facility data more effectively to meet FDA Electronic Records and Signature requirements (Title 21 CFR Part 11, 58, 210, 211, 820). Plus, provide precise control of temperature, humidity, ventilation, pressurization and security.

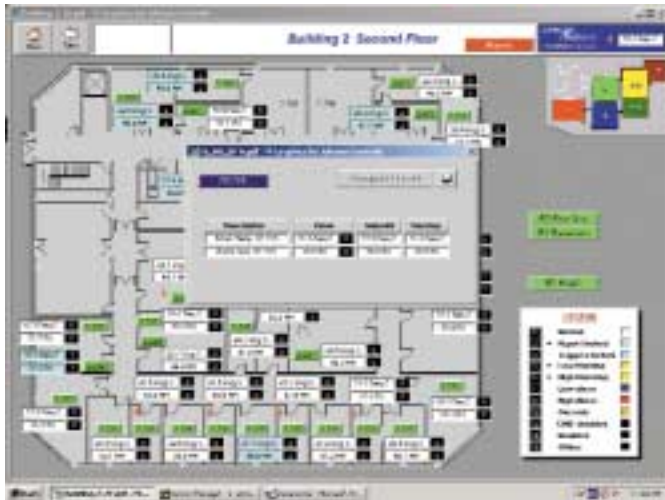


# solution

Responding to the need for Part 11 compliance in critical environments, Johnson Controls tailored a Metasys<sup>®</sup> system specifically for the Life Sciences market — Metasys for Validated Environments (MVE). Built to perform using the full capabilities of our new M5 Metasys workstation, Metasys for Validated Environments offers you unparalleled state-of-the-art building automation for all your facility environments.

Working with a large manufacturer of bulk active pharmaceutical ingredients, Johnson Controls successfully designed, installed and commissioned a Metasys for Validated Environments (MVE) system for a new manufacturing suite. The project was a critical element in a fast-track construction project. Along with building automation, the system can control, report, integrate and manage day-to-day compliance.

# METASYS® FOR VALIDATED ENVIRONMENTS



## Turning Data Into Information

Our MVE solution helps you capture and manage critical data more effectively. From Pareto charts to comprehensive statistical analysis, MVE works hand-in-hand with your scientists, lab technicians, facilities operators and other key associates to effectively manage the day-to-day information required to carry out Life Sciences operations. Such key features as precision control, management reporting, systems security, alarm reporting, time-stamped audit trails, and traceable electronic records make the jobs of your key resources easier, allowing them to concentrate on their main functions – discovering and delivering products in the most efficient manner possible.

## Scalable Yet Structured Control

Metasys for Validated Environments helps you achieve and maintain regulatory compliance. It increases your efficiency when retrieving, viewing and reporting environmental parameters – and it provides for system security and restricted access for authorized users only. Our MVE solution is flexible to meet the needs of almost any facility. At the same time, it provides the strict control you need to operate a world-class validated facility.

## Seamless Integration

Through the Metasys Compatible program, Johnson Controls has developed the world's largest library of software drivers to integrate third-party devices and subsystems. From air handlers and chillers to programmable logic controllers, to particle

counters and building automation systems (BAS) from other vendors, integrated devices seamlessly become part of the MVE system and are granted the same data security and electronic traceability features.

Metasys for Validated Environments is an environmental control system for Life Sciences facilities subject to FDA Regulations (Title 21 CFR Part 11, 58, 210, 211, 820).

Metasys for Validated Environments Hardware solutions designed to meet Life Science requirements

- Precision Digital Environmental Control
- Scalable Configurations
- Turnkey Installations

Software Solutions specific to Title 21 CFR Part 11 Electronic Records and Signatures

- System Security
- Secure Data Management and Reporting
- Electronic Records and Signatures
- Time-stamped Audit Trails
- Extensive Sub-system Integration Libraries
- Web-based Reporting
  - Mean Kinetic Temperature
  - Trend Analysis
  - Alarm Analysis
- Intuitive Data Visualization Tools

