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THE ROLE OF INDUSTRIAL AUTOMATION IN QUALIFIED BUILDING AUTOMATION SOLUTIONS

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Rockwell Automation

Introduction

Building Automation Systems (BAS) operate in almost every commercial enterprise across the world. The primary purpose of this type of system is to provide a comfortable working environment. Since the comfort range for most people will accommodate fluctuations in their surrounding there was little need for building automation systems to provide anything other than a basic level of control. Therefore these control systems allowed a rather wide variance of environmental factors like temperature, pressure and relative humidity. However, in some manufacturing facilities the environmental fluctuations that were well tolerated by people were not well tolerated by the products being produced. These fluctuations caused increases in scrap, rework and affected other aspects of production and product quality.

In industries such as pharmaceutical and biotechnology the effects of environmental changes have become better understood. As such, it has been recognized that these fluctuations should not only be controlled more closely but also monitored, tracked and recorded. They are also subject to compliance regulations. This forced some manufactures to look to traditional BAS suppliers for solutions that would meet the requirements of tighter environmental controls and regulatory compliance. The BAS solutions provided were usually comprised of system components such as programmed unitary controllers, a network of varying protocols and associated commercial instrumentation that were not originally designed to address the monitoring, tracking and reporting requirements of a validated system. In addition some of these solutions were from vendors with little or no system validation expertise. These problems often lead to custom solutions that integrate various system components via proprietary protocols that often carried expensive service agreements.

Now it is becoming widely understood that the same "industrial standard" equipment that manages the manufacturing process can also manage the facility's environment. In this case we refer to the same Process Automation Controllers (PACs), industrial networks and instrumentation that you would find in automated manufacturing systems. By merging process automation, building automation and environmental monitoring together into a single system it creates a paradigm shift. This will ease validation efforts, improve product quality, reduce total cost and improve time to market.

Problem Statement

Facilities that operate within the bounds of today's regulated environment are typically supported by various disparate control systems. Traditional Building Automation Systems have not historically embraced the widely accepted GAMP model, let alone the basics of the 21 CFR part 11 standards, and therefore required significant investment and customization to meet those requirements. The issue becomes how can these facilities reduce the cost of customization, eliminate the need for multiple system validation, effectively reduce on-going maintenance cost and still meet regulatory requirements.

Traditional Automation Solutions

When faced with the need for regulatory compliant environment control, there were two traditional options: customized commercial systems or unintelligent stand alone systems. While the custom systems could usually be made to fulfill the requirements, it was unlikely that the unintelligent system could provide the required level of traceability needed to fulfill regulatory requirements. Unitary controllers typically had to be integrated into a network which was different from the instrumentation and operating devices. This drove the need for some kind of protocol conversion for data transfer to a data historian. In some cases, this was a proprietary archiving mechanism that did not provide easy access to the level of event tracking and

reporting needed to meet regulatory requirements. In other cases ODBC and OPC services were used to provide the needed connectivity with additional engineering effort. However, in these cases the data integrity could then be in question due to the transaction between disparate information sources.

Unified Automation Solution

What if the challenge of validation was mitigated through a unified approach to engineering and standard documentation while preserving a robust platform? Today some process automation system's can easily provide the required functionality of a qualified building automation system.

Rockwell Automation has invested in the development of HVAC functionality that is now native to a range of Process Automation Controllers (PACs) part of their "Integrated Architecture" solution. This architecture makes use of common information, common open networking, and common products to provide a unified solution for the manufacturing enterprise. The key is not the ability to combine the building and process automation systems, but rather the added functionality of the process automation infrastructure.

The same functionality that is applied to meeting the process validation can be used to meet the validation requirements for the building automation system. All of a sudden problems like event historization, data security and reporting become much easier due to the availability of a system designed to meet regulatory requirements. For example, the Plant Historian can now provide auditable secure data. Electronic Batch Reporting (EBR) can include environmental data that is properly time sequenced with conditions occurring during production for reliable accurate reports.

In addition, common validation documentation will cover both building automation and process automation equipment. For instance, a full GAMP document set for a piece of equipment for a CIP skid will include URS, FRS, O Q, IQ and DRS documentation sets. All of these documents will be tested for operational concurrence at the time of validation. These documents will state the functional operation and status mode for any given step during that operation. Documentation will follow the format, which includes the qualified environmental conditions.

Potential Benefits

Easier Validation

- Common validation tools and system architecture
- Single source validation services
- 21 CFR part 11 conformant data handling capabilities
- Simplification of audits
- Fast and easy access to data with electronic records
- Product environment and critical equipment data easily integrated in your batch record

Improved Quality

- Reduced variations on drug quality and efficacy from environmental factors
- Reduced time to market

Reduced Costs

- Pre-engineered control modules
- Single plant-wide maintenance strategy
- Reduced training and maintenance burden
- Common and fewer on-site spare parts
- Flexible services & support
- Standard ISA S88 control module methodology
- Pre-developed faceplates and templates
- Lower total cost of ownership

Implementation

Rockwell Automation's implementation and consulting engineering organization provides a broad scope of capabilities needed to design, engineer and implement targeted solutions. This organization consists of domain experts focused on the needs of Qualified Building Automation Solutions.

Rockwell Automation has developed an "out of the box" configurable solution that can be easily installed, commissioned and validated. This can be achieved using Rockwell Automation's own validation team, a partner organization or an independent third party.

Based upon the provision of the facility AF&ID documents and intended URS, these engineers can configure systems based upon our standard control platforms and visualization systems. The solution will control the building's environmental factors. The operational application software that resides in the PAC is configured using standard tools and HVAC specific function block libraries. Secure data is recorded for all validated points. Operator screens are created that reflect the plant and allow operators to view the overall system, individual components, set points, process variables and alarm events. Once the system is installed and commissioned, or a documentation set provided by others.

Summary

The role of industrial automation in validated environments has become a significant factor for many manufacturers in regulated industries. These manufacturers are starting to benefit from a unified building automation system (BAS). This BAS reduces validation cost, lowers spare parts inventory, and allows common maintenance strategies, and also utilizes standard control technology while improving product quality.

www.rockwellautomation.com

Power, Control and Information Solutions Headquarters

Americas: Rockwell Automation, 1201 South Second Street, Milwaukee, WI 53204 USA, Tel: (1) 414.382.2000, Fax: (1) 414.382.4444
Europe/Middle East/Africa: Rockwell Automation, Vorstlaan/Boulevard du Souverain 36, 1170 Brussels, Belgium, Tel: (32) 2 663 0600, Fax: (32) 2 663 0640
Asia Pacific: Rockwell Automation, Level 14, Core F, Cyberport 3, 100 Cyberport Road, Hong Kong, Tel: (852) 2887 4788, Fax: (852) 2508 1846

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