Combined domain expertise, industry knowledge, and world-class offerings create an unparalleled solution in the Life Sciences industry.
**BAS / BMS / HVAC:** Building Automation System
- **Description:** Controlling & monitoring of HVAC, lighting, security, etc. systems.
- **Compliance:** Not required – Commercially Commissioned

**QBAS:** Qualified Building Automation System
- **Description:** Closed loop *control & monitoring* of Temperature, Pressure, Humidity, Door Status and maybe Particulate – the “ENTIRE” HVAC System – typically 20 to 30 hardwired points per AHU”. Monitoring, Reporting, Historian
- **Compliance:** Validation / 21 CFR part 11 requirements.

**EMS:** Environmental Monitoring System
- **Description:** Monitoring Temperature, Pressure, Humidity, Door Status and maybe Particulate – “Direct Impact” parameters - typically 5 to 10 points per room”. Monitoring, Reporting, Historian
- **Compliance:** Validation / 21 CFR part 11 requirements.

**PAS / PlantPAx:** Process Automation System
- **Description:** Process Control, Monitoring, Reporting, Historian
- **Compliance:** Validation / 21 CFR part 11 ready
Impact of Manufacturing Environment

What Environmental Conditions Impact Product Quality?

- Federal Regulation 21 CFR 211.68 states:
  - ‘...if a computer (or controller) can affect product quality, it must be “Validated”.
  - ISPE Baseline Guide on Commissioning & Qualification states:
    - ‘...if something can directly affect product quality, it is classified as “Direct Impact”, and therefore, it should be commissioned, qualified, and have enhanced documentation.’

- Direct Impact On Product Quality
  - Qualified / Validated

- Indirect Impact On Product Quality
  - Validatable

- No Impact On Product Quality
  - Commercially Commissioned
The Impact of Validation in the Manufacturing Environment

User Requirements:

- Identify, capture and manage critical environmental data - “Direct Impact”
- Effectively meet regulatory requirements for: documentation, data collection, security, storage and reporting.
- Increase overall operational excellence

Validate the air handler control system or just Temperature, Pressure, Humidity, Particulate – direct impact parameters?
Traditional Approach - QBAS

Non-Validated Environment

Commercial Controls

- HVAC,
- Chillers,
- Boilers,
- Lighting,
- Security,
- etc

BAS

Validate the AHU Control System, Monitoring & Alarming of
- Temperature
- Pressure
- Humidity
- Particulate

Validated Environment

Commercial Controls

QBAS
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Migrate from commercial proprietary “black box” controllers to Process Controls in the Validated Environment - QBAS
Risk Based Approach

Non-Validated Environment
Commercial Controls

Commercial Control:
- HVAC,
- lighting,
- security,
- etc

Validatable Environment
Process Controls

AHU Control – “read only” Temperature, Pressure, Humidity, Particulate from EMS

Validate Direct Impact Parameters –
Temperature, Pressure, Humidity, Particulate, Door Status
### Common System to Learn, Validate, Operate and Maintain

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<th>Commercial Building Automation Systems</th>
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<td>Common Audit Trail</td>
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</tbody>
</table>
Common Platform Meeting Regulatory Requirements

Common:
- System Infrastructure
- Data Management
- Report Structure
- Validation Methods
- Data Time Stamping
- Alarm Management
- Operator Interface
- Maintenance Strategy
- Parts Inventory

Enables Functionality
- Batch
- Historian
- Scheduling - ERP Integration

21 CFR 11

- Utility Control
  - BAS
  - EMS
  - Compressors
  - Boilers
  - Chillers

- Process
- Packaging
- Shipping & Receiving
Potential Life Cycle Savings

10-15% Potential Savings
- Open Programming / 3rd Party Interfaces
- Longevity
- Documentation
- Open Training
- Open Support / Services / In House Maintenance
- Flexibility, IO, Common Platform, Spare Parts
- Reliability, System Availability
- Initial service cost + reduced annual service cost

Lower Total Cost of Ownership
Air Handler Controllers – Constant or Variable Volume

- Standard Control platforms
  - ControlLogix
  - CompactLogix
- Object-oriented, ISA S88 based code
- Configurable code:
  - HVAC parameters set via spreadsheet
  - No additional device operation ladder programming required
- Expandable - advanced control algorithms specific to your process & facilities
- Compatible with Unitary and Central Plant systems

Re-usable Control Modules
Re-usable Equipment Modules
Re-usable Graphic Templates
Re-usable Validation Documents
Automation Application Design is Moving From To

The Paradigm Shift:

- Understanding the process as a grouping of modules
- Thinking in terms of function instead of hardware and software
- **STOP** designing and constructing custom solutions
- **START** using modules to assemble and configure your solutions
Process BAS Software - Architecture Diagram

- Unit / Scheduler Module
- AHU Equipment Modules
- Exhaust Fan Equipment Modules
- Supply Fan Equipment Modules
- PID Control Module
  - Heating/cooling/reactivation
- Process Xmtr Control Module
  - Analog In
- Press. Sw. E-Stop Freeze Alarm Control Module
  - Digital In
- Fan Control Module
  - Vfd or starter
- Damper Control Module
  - Valve or Analog Out
Flexibility and Module Independence Speeds Meeting Customer Requirements

- Modular ISA88 design allows swapping of modules in and out to meet differing user requirements by individual customers.

- Highly configurable modules enable simple configuration changes versus complex code changes.
ISA88 Flexibility Speeds Development

- Divide applications into logical groups
- Use a set of common terminology
- Swap modules to meet individual customer / AHU requirements
- Configurable modules reduces complex code changes

Unit
- ‘Owns’ the equipment EMs
- Manages supervisory functions:
  - Monitoring communications
  - Alarm records
  - Transferring system data

Equipment Module
- ‘Owns’ the equipment CMs
- Allows alarm propagation/management

Control Module
- Inputs: AI, DI
- Outputs: AO, DO
- Control: PID, PIDC
PlantPAx, the next step - GEMS (Global Engineering Modularity Standards)

- Industry specific framework of control and equipment modules (i.e. Life Sciences)
- For use by Rockwell Solutions delivery.
- Built on programming standards and the Rockwell Automation Foundations of Modular Programming.
- Identical interface to Process Modules
- Provides End Users a consistent industry specific starting point with the flexibility to add your Intellectual Property.
- Being used today by multiple industries since 2005.
Industry Specific Modules – to support Life Science

- GAMP 5
  - Promotes a risk-based approach to validation (QRM – Quality Risk Management)
  - Promotes the leveraging of supplier activities (i.e. code, documentation and testing)
  - Pre-Validated Module Set
  - End users benefit from reuse
  - Within a project
  - From project to project

- Engineering provided for each module:
  - Functional Specification (SMFS) Component
  - Design Specification (SMDS) Component
  - Code Object (AOI)
  - HMI Faceplate(s)
  - Test Specification (SMTS) Component
  - Certified Test Results
  - Programmers Reference Manual

- Life-Cycle Managed
  - GEMS Application Template
  - Library of building blocks
  - Leverage GEMS standards
  - Life-cycle managed library of modules which represent devices for process industry
  - Significantly reduced engineering time, with documented pre-engineered, pre-built, pre-tested modules

- GAMP 5
  - Promotes a risk-based approach to validation (QRM – Quality Risk Management)
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  - Within a project
  - From project to project
Value Add for Life Sciences

Equipment Phase
- Commands
- Set points
- Status
- Acquire
- Mode
- Alarms

Phase Manager
- GAMP Compliant
- Documentation
- FS, SMFS, SDS, SMDS

GEMS Industry Specific CM
- Commands
- Set points
- Status
- Alarms

GEMS D.1 Release

HMI Interface
- E-Signature
- Enhanced Security
- Audit Log/Traceability

Tested to LS Quality Plan
Pre-Tested Modules
Life Science Functionality

- **E-Signature**
  - Commands
  - Configurable

- **Audit Trail**
  - Record Operator Actions
  - Cmds, SP Changes

Configurable to allow choice of:
- No Confirmation,
- Confirm w/o E-Sig
- E-Sig (Performer Only) or
- E-Sig (plus Approver)
For Device Commands
OEM Skid Coordination

- Skid Network Connectivity
  - Network Design Specification (addressing and isolation)
  - Data and Alarm Collection
  - Security Integration
- Interfacing to an OEM Skid
  - Skid request for WFI
  - Status and Interlocking between skids.
  - Supervisory SCADA for monitoring of Skids
- Integrating Skids
  - Sequencing of Equipment Operation (Formulation CIP Skid)
  - Create Interface layer for sequencing of Unit Operations.
  - Use Phase Manager as Interface from Batch Server to Vendor Supplied Code.
  - Batch Server is used as the engine to Start/Stop, Download Parameters and Upload Reports for Unit Operations.
- Full Integration
  - OEM only supplies the equipment, Rockwell does all the automation design and code.
  - Fully integrated systems for long term lower cost of ownership. Common operator, maintenance and validation interfaces and documentation.
OEM Integration Advantage

Managed Ethernet Switch for Enterprise Network (EN) – Business Communications

- Domain Controllers (existing)
  - For the Enterprise
  - FT View SE and/or FT Historian
  - Terminal Server Clients
  - FT View SE
  - FT Historian
  - Terminal Server Clients
  - IP Printer

Managed Ethernet Switch for Control System Network (CSN) – HMI/Ctrl Communications

- Domain Controllers
  - For the Control System
  - Managed Ethernet Switch for Control System Network (CSN)
  - FT View SE and/or FT Historian
  - Terminal Server Clients
  - FT View SE
  - Thick Clients
  - FT Historian
  - FT Historian Clients
  - Terminal Servers
  - Engineering Workstation

Managed Ethernet Switch for Control System Network (CSN) – HMI/Ctrl Communications

- Control Network (FFB, DNet, ENet)
  - Data and HMI Server
  - Pan Coater
  - OEM Process Skid

- Data and HMI Server
- OEM Utility Skid
- QBMS
- Building Automation System

Firewall
QBAS - Typical System Configuration

HMI
- FT View SE and/or
- FT Historian
- Terminal Server Clients

Packaged Air Handlers
- Single Zone
- Fan Coil
- AHU Control
- Make-up Air
- VAV Box

Central Plant
- Boilers
- Chillers
- Pumping, Compressors,
- Cooling Towers
- 3rd Party Interfaces
- 3rd Party Protocol
- BACNet Devices

Batch Historian
- Scheduler
- Central Plant
- Oracle / SQL
Third Party Protocol Interfaces

- BACNet
- N2 - (JCI)
- ArcNet – (JCI)
- FES-Frick - chillers
- Profibus
- Lonworks
- Trane - chillers
- McQuay - chillers
- York - chillers
- Modbus
- HART
- Foundation Fieldbus
- OPC
Typical Redundant Controller Configuration

Redundancy:
- Operator Stations (HMI)
- HMI Servers
- Data Servers
- Historians
- Redundant Controllers - ControlLogix
- Networks
- I/O - Rack, Flex or Point I/O: temp, press, humidity, particulate
- Networked AC Drive and Motor Overload interface for diagnostic and data collection.
Typical Project Overview

- Operator Work Stations
- Air Handler Units
  - ControlLogix / CompactLogix
  - Distributed I/O
  - Intelligent Motor Control
  - Variable Speed Drive
  - Field Instrument Devices
- Make Up air
- Recirculation Fans
- Exhaust Fans
- Central Plant Control
- Air Flow Stations
EMS – Environmental Monitoring System
Project Methodology

LONG TERM SUPPORT
- Parts Management
- Preventive Maintenance
- Training

KICK-OFF
- Functional Specification
- Sequence Of Operation
- Define Project Timeline
- Define Project Team
- Schedule Deliverables

PLAN / DESIGN
- System Architecture
- Preliminary Design Review
- Define Design Templates
- OEM Coordination Procedures

REVIEW / LAUNCH
- Detailed Project Requirements
- Safety Procedure Review
- Final Design Review / Approval

EXECUTE
- Code Development
- Global OEM Coordination
- Project Scope Management
- Project Resource Management
- FAT
- Commissioning Schedule Review

ACCEPTANCE
- SAT / Customer Witness Test
- System Handover

COMMISSION
- Pre-Startup Site-Test
- Application Startup
- System Integration

TECHNOLOGY TRANSFER
- Customized Training
- Embedded Engineer
Rockwell Automation Expertise

- **Project Manager**
  - Scope Management
  - Project Resources
  - Risk Management
  - Development of Project Plan & Schedule
  - Schedule Resources

- **Technical Lead**
  - Subject Matter Expert
  - Lead Development
  - Operational Training
  - Start up & Testing
  - Documentation

- **Validation Lead**
  - Documentation development & control

- **Commercial Support**
  - Sales
  - Technology Training
  - Technical Support

- **Installation**
  - Site Project Management
  - Schedule
  - Network
  - Installation/Calibration
Why Rockwell Automation for QBAS, BAS & EMS?

- Modular Software – Add on instructions
- Subject Matter Expertise
- Global Capability & Local Support
- Internal Maintainability

Reduce Total Cost of Ownership
Qualified Building Automation Solution

Questions???