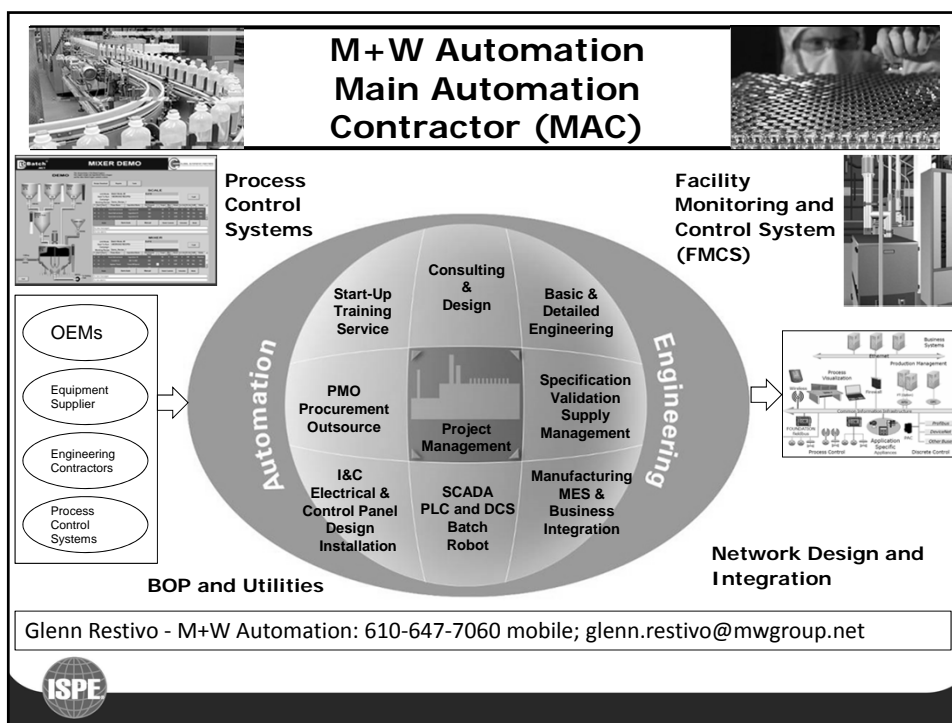




## M+W U.S. Profile (complete engineering of process plants from design to implementation)



- Established 1989
- Headquarters in Albany, New York
- 2011 Revenue approximately \$1 Billion
- 17 Offices in North America, Mexico & the Caribbean
- 1,800 employees (300 automation and information engineers)
- Integrated facility design, engineering, procurement, construction, automation and ongoing facility services
- **M+W Automation Capabilities (full range of services for Life Science Industry):**
  - Concepts, Specifications (URS), Basic / detailed engineering
  - Single point of responsibility for automation and information projects, materials & equipment, full system integration
  - Automation, MES, Historian, I&C and FMCS Expertise
  - Project Management, GAMP5, SDLC methodologies



## Equipment Monitoring System (EMS) Project Overview

*"Implementing an Operations Information Infrastructure"*

**Ken Kovacs, CMC**

**Quality Business Systems Manager**

**Fujirebio Diagnostics, Inc.**

**Member: ISPE and GAMP MES Special Interest Group**



May 16, 2013

**FUJIREBIO**  
Diagnostics, Inc.



## Agenda

---

- Fujirebio Diagnostics, Inc. – *Who we are...*
- Project Objectives & System Overview
- User Navigation & System Functionality
- Benefits & Future Expansion Capabilities
- Project Success Principals



## Fujirebio Diagnostics, Inc.

---

- For over 20 years, Fujirebio Diagnostics, Inc. is the trusted source of innovative solutions in clinical diagnostics.
- Fujirebio Diagnostics' products form the base of a product line that has been long recognized as the *worldwide standard of excellence in cancer biomarkers*.
- Our core technology is based on our proprietary monoclonal antibodies originally developed to detect a variety of tumor markers.
- To learn more about Fujirebio Diagnostics' products available in the United States please visit our website at <http://www.fdi.com>
- We are located in Malvern, PA
  - Proven manufacturing process, GMP Compliant, ISO 9001 and ISO 13485 certified quality system

***The world's most extensive array of biomarkers  
for disease states with a focus on oncology.***



## Oncology Product Portfolio

### Gold Standard Bio Markers

- CA 125 II™ - Ovarian Cancer
- CA 19-9™ - Pancreatic Cancer
- CA 15-3® - Breast Cancer
- CA 72-4® - Gastrointestinal Cancer
- CYFRA 21-1™ - Lung Cancer
- MESOMARK™ - Mesothelioma
- HE4 Ovarian Cancer
- PSA & Free PSA
- AFP
- CEA
- CanAg™ NSE – Lung Cancer
- CanAg™ SCC – Gyn Cancer
- CanAg™ CA242 – Gastrointestinal Cancer
- CanAg™ S100 – Malignant Melanoma

*"Everyday 1000's of people, all over the world, live a better life because of the things we do here. There is no better way to make a living, than by helping others."*

Grady Barnes Ph. D., Chief Scientific Officer, Fujirebio Diagnostics, Inc.



## Project Objective / System Overview



***"To replace an existing paper-based GMP record system and manual process for logging equipment temperature readings and related process data and information"***

- ✓ Allow personnel to *monitor equipment* from their Workstations
- ✓ Maintain all temperature readings in *electronic records*
- ✓ Generate electronic GMP reports for *"review by exception"*
- ✓ Provide authorized personnel *electronic signature* capabilities to approve reports
- ✓ *Notify authorized personnel* in event of adverse temp trends
- ✓ *Reduce* current paper-based logging effort (now over 900 hours)
- ✓ Implement an *Operations Information Infrastructure* to *simplify* the installation of future "electronic initiative" projects

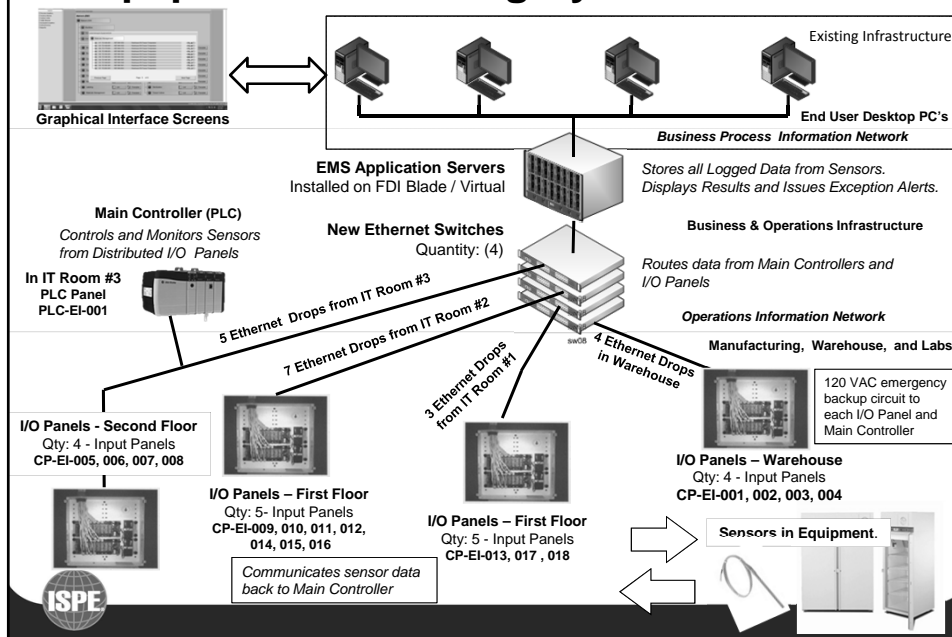


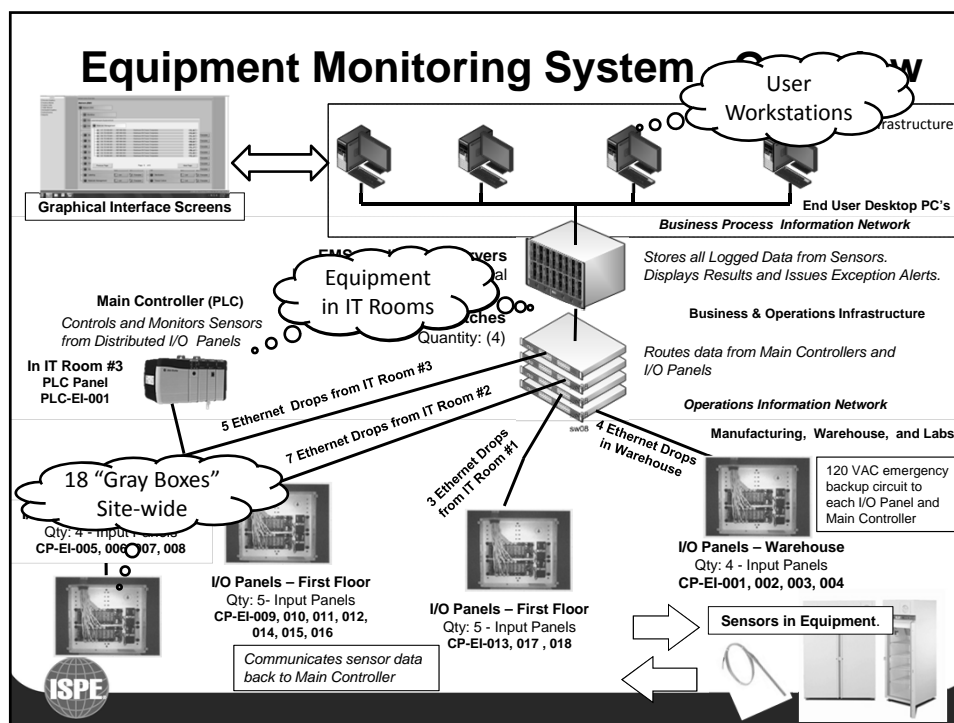
## Considerations

- A dedicated Equipment Monitoring System was proposed and quotes obtained.
  - A focused application
  - Limited flexibility
- A PLC / HMI / MOM Server-based solution was then discussed, specified, and quotes obtained.
  - Included a new operations-level infrastructure
    - To provide a basis for implementing new applications
  - EMS solution specified as first application
  - About 50% higher cost than dedicated EMS, but overall *less expensive and more efficient* than implementing a series of future standalone systems.
- **Decision made: This was our Solution of Choice**



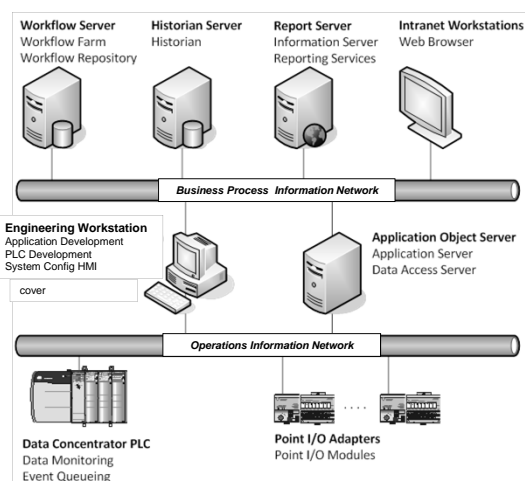
## Equipment Monitoring System - Overview





## System Architecture

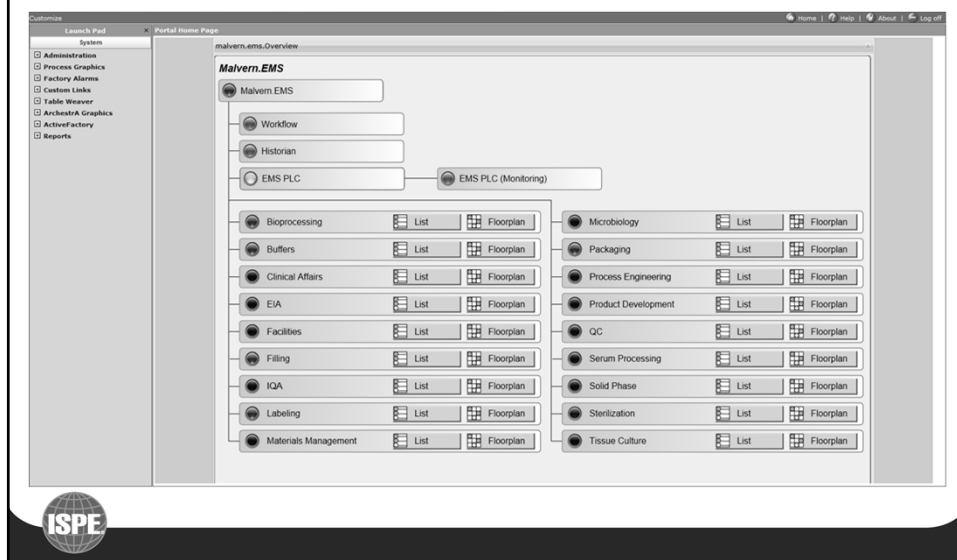
- The EMS consists of 4 servers, 1 engineering workstation, a data collection PLC, and 18 PLC Input / Output Panels.
- A dedicated Ethernet network was installed in Operations by FDI to enable communications between the data collection / Concentrator PLC, I/O panels, and the application server.
- FDI system users access the EMS via secured logon through their current workstations using web browsers.



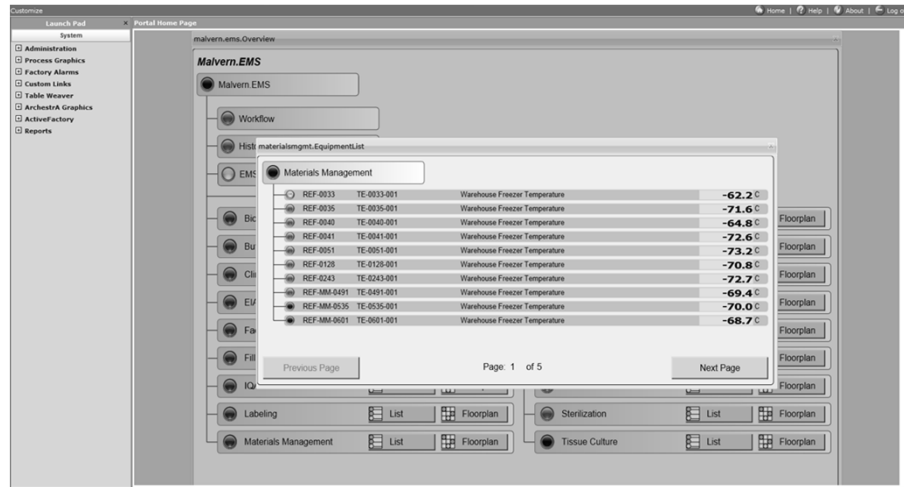
## User Navigation - Main Page



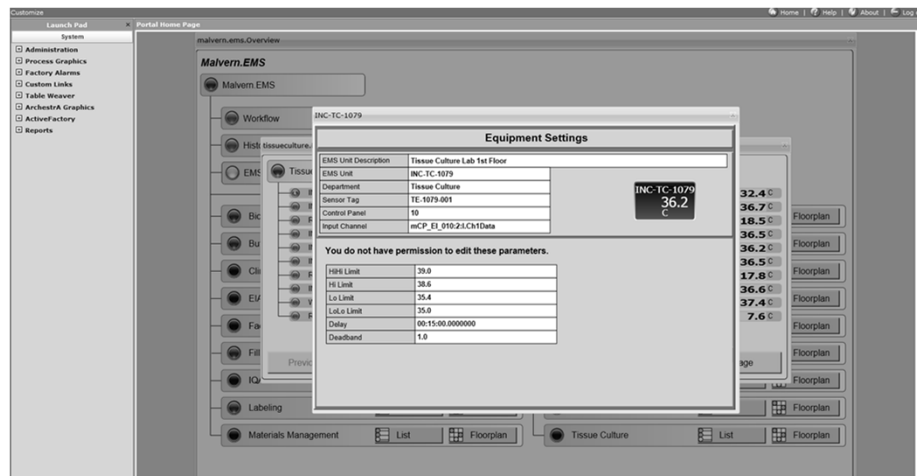
## Department Overview



## Equipment List

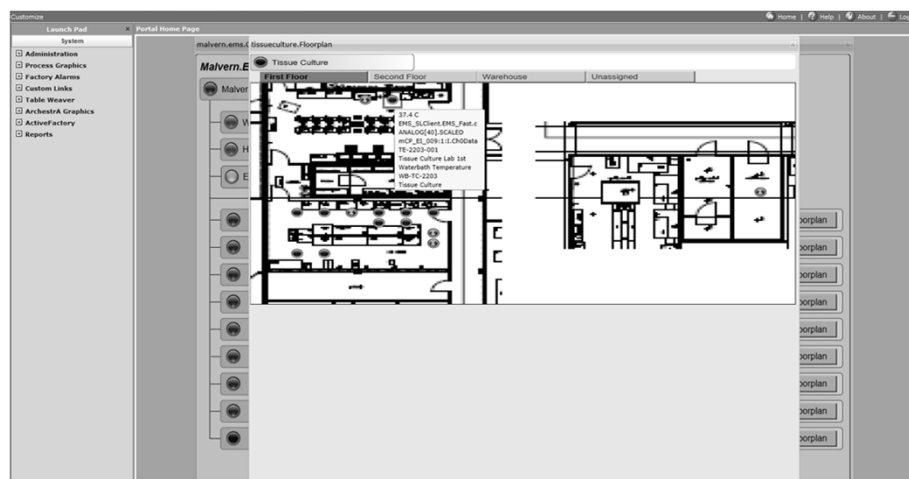


## Equipment Settings





## Equipment Floorplan



## Workflow Forms

### EMS Event Form

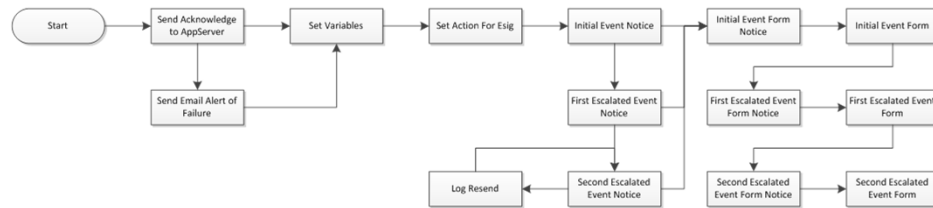
- This form is used to sign for a specific event, including both equipment monitoring events and system alarm events.
- Notified users comment and sign-off on all notifications
- Information captured by exception in Dept. Summary Reports

### EMS Department Summary Report Form

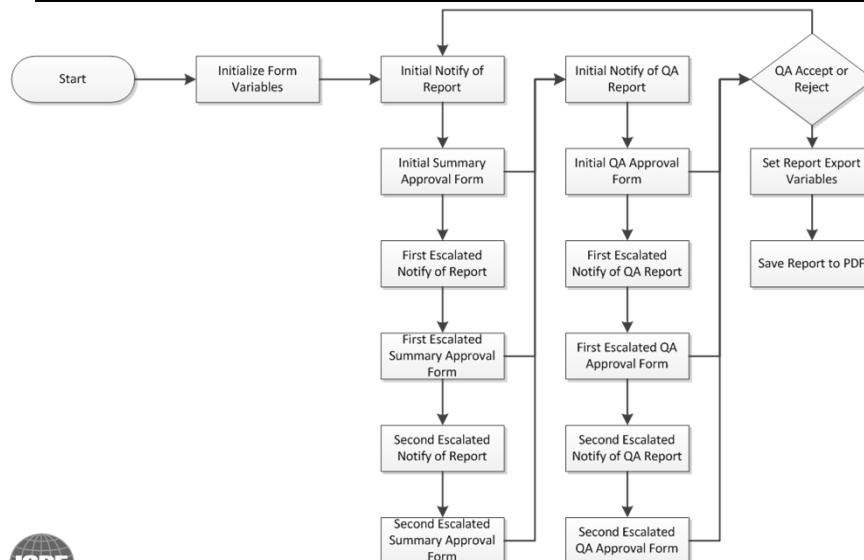
- This form is used to approve / sign for a monthly summary of events at both department and QA levels.
- This Summary Report replaces the manually generated equipment temperature logs and chart recorder graphs.



## Flow Chart - EMS Analog Event



## Flow Chart - EMS Event Summary Report



## EMS Summary Report for Approval

FUJIREBIO Diagnostics, Inc.		EMS Event Summary Report					
Year and Month		March 2012					
Department		Filling					
Dept. Approval		Weeks, Bill at 4/5/2012 11:27:37 AM Installation/commissioning test					
QA Approval		Weeks, Bill at 4/5/2012 11:28:30 AM Installation/commissioning test					
Event Time	Environment Variable And Location	Event Type	Value	Limit	Ack'd By / Time	Signed By / Time	Comment
3/12/2012 2:30:24 PM	REF-FB1-2031	High Warning	327.7	327.7	Zimmer, Josh 5:38:38 PM 4/4/2012		
3/12/2012 2:30:24 PM	REF-FB1-2031	High Excursion	327.7	327.7	Zimmer, Josh 5:38:37 PM 4/4/2012		
3/17/2012 8:04:23 AM	REF-FB1-2031	High Warning	7.5	7.5	Weeks, Bill 2:51:38 PM 4/5/2012	Weeks, Bill 10:54:02 AM 4/5/2012	Installation/commissioning test event - not real data
3/17/2012 9:23:15 AM	REF-FB1-2031	High Excursion	9	9			
3/17/2012 9:03:47 AM	REF-FB1-2031	Low Excursion	0	0			
3/17/2012 9:03:47 AM	REF-FB1-2031	Low Warning	0	0	Weeks, Bill 4:08:30 PM 4/5/2012		
3/17/2012 7:53:59 AM	REF-FB1-2031	Fault					

Printed on: 6/5/2012 12:32:59 PM      Printed by: FUJIREBIO\KovacsK      Page 1 of 1

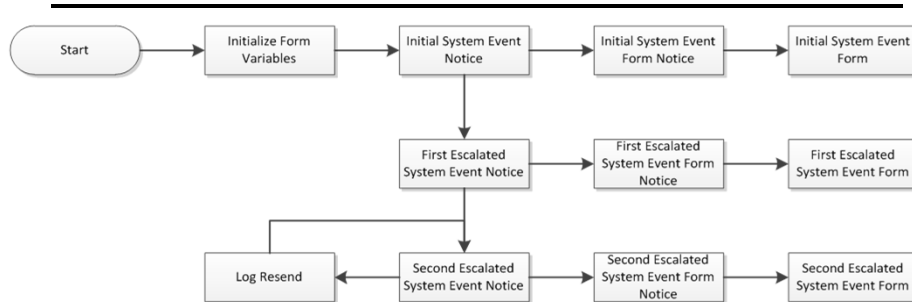


## Workflow - EMS System Event

- Handles response to system events, such as detecting a communication failure between the Application Object Server (AOS) and the PLC.
- Notification of the event is emailed to designated user ("initial actor").
- An acknowledgement (email reply) is required.
- Two levels of escalation are configured (1<sup>st</sup> & 2<sup>nd</sup> actors)
- Once one of the three actors has responded to the notice, they will receive an email notice that the electronic signature form is in their Workflow inbox.
- Once the form is completed with comments and signed, the workflow is complete.



## Flow Chart - EMS System Event

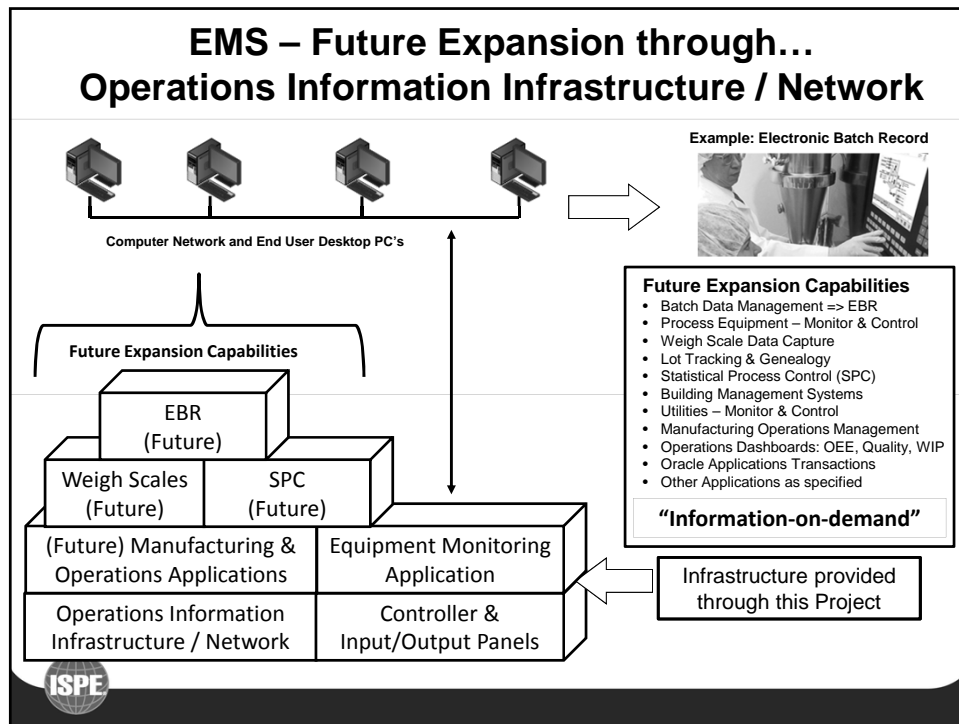


## Security Matrix

The following table maps FDI Active Directory groups to defined roles. Users can be members of more than one of these groups. Group membership is configured by IT in the Windows Active Directory.

Group	Roles						
	WIS_View	Sign_Event	Sign_Summary	AOS_View	AOS_Edit	Sys_Config	Sys_Alert
FDIEMS_Users	✓			✓			
FDIEMS_CanSignEvent		✓					
FDIEMS_CanSignSummary			✓				
FDIEMS_Engineers	✓			✓	✓		
FDIEMS_Admins	✓			✓	✓	✓	✓

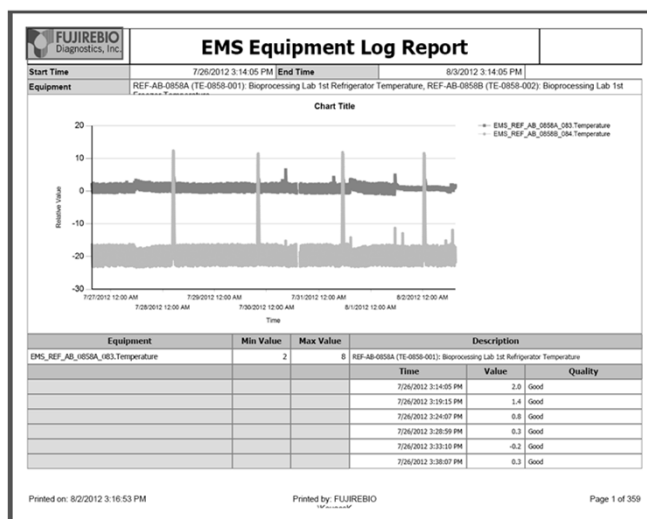




### Added System Benefits

- Ability to observe historical data and save graphs for each piece of equipment.
  - Obtain information for better understanding of processes
  - Ability to analyze equipment operations:
    - Better controller tuning for more efficient operations
    - Able to better see impact of equipment cycling during 7 day / 24 hour operations
- As an Operations Information Infrastructure, this system is already being used to provide data input for continuous improvement.
  - Future expectations include process analysis and improvements through a Process Analytical Technology (PAT) Framework.

## Example Report – Equipment Analysis



## Project Success Principals: Team Involvement

**CPER Requisitioner**  
Joe Ricci

**PM and Tech Adviser**  
Ken Kovacs

**Project Advisers**  
Steve D. & Harry H.

**IT Validation**  
Kat Ross

**System Admin**  
Josh Zimmer

**Project Kickoff / Finalize URS**  
IT - Mfg / Ops – QA / QC  
Facilities - Project Team

**Operations Personnel**  
25 individuals interviewed  
for input to develop URS

**Final Equipment ID & Survey**  
Ken K. - Josh Z. - ITS, Inc. - Steve Dunn  
Harry Hughes - Horace Marsh - Mike Spuglio

### Implementation/Start-up – Phased Approach

1. Warehouse
2. 2<sup>nd</sup> Floor – Product Dev. & Process Engr.
3. 1<sup>st</sup> Floor – Manufacturing

### User Community

69 different users trained and given  
secured access the system  
(out of a total of 185 site employees)

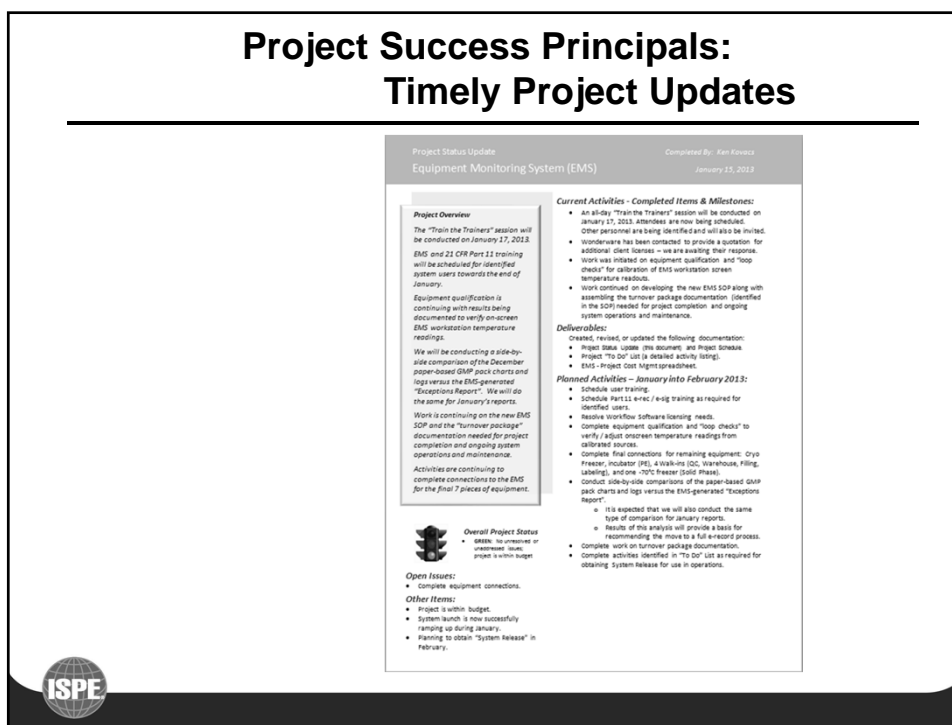
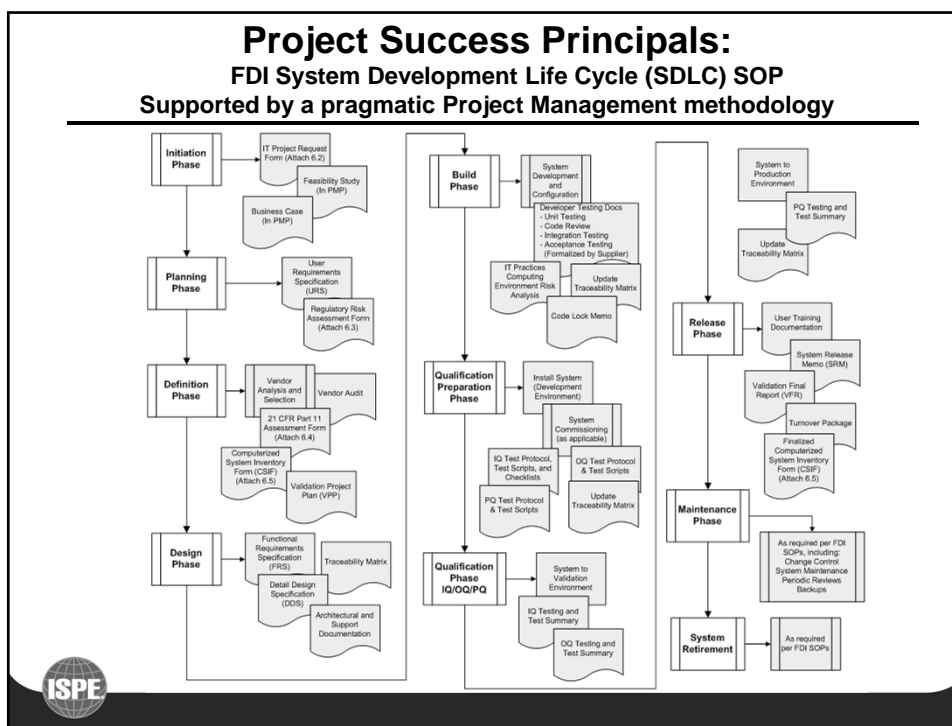
### System Implementation Resources

- System integrator: EZSoft, Inc.
- Wonderware / Invensys, Inc.
- Rockwell Automation, Inc.
- Network communications: TTM, Inc.
- Electrical contractor: D.J. Harris Electrical Construction, Inc.
- Instrumentation services: Instrumentation Technical Services, Inc.
- Temperature sensors: Industrial Controls, Inc.
- Instrumentation / interface installation: Cook's Service Co.
- Also: Rumsey Electric, Allied Wire & Cable, Neal Systems, Inc., Honeywell, SAS, Inc. & others

### Project Completion

1. Qualification / Validation / Calibration
2. Training
3. Run in parallel w/ paper records
4. Acceptance & Final Turnover





## Project Success Principals:

---

- Managing activities and deliverables through documented
  - Project Management Plan (PMP)
  - SDLC & System Validation Master Plan (SVMP)
- Understanding and documenting user requirements (URS)
- Ongoing user and team involvement
- Frequent communications w/ user groups
- Weekly schedule updates
- Continuous cost management
  - DIY & periodic reconcile w/ accounting
- Periodic meetings with System Integrator & other service companies, formalized through:
  - Meeting Agendas
  - Meeting Minutes, Notes, and Agreements



## Project Success Principals:

---

- Internal group discussion meetings prior to routing complex documents for approvals (such as FRS and DDS)
- Understand complexity of integration
  - disparate systems, equipment, and instrumentation
  - to generate appropriate design solutions
  - software licensing & impact on design
- Risk Analysis & Mitigation
  - Pay attention to the details
  - Utilize available guidance and tools (FMEA, Risk-based validation)
- Training: User, Administration, and Support Personnel
- *Acknowledge and thank contributors and team participants*





## Project Success Principals: Risk Analysis & Mitigation

- Risk Management addressed in PMP
  - Risk Identification (Regulatory, Business, Technology)
  - Risk Analysis
    - “...a justified and documented risk assessment and a determination of the potential of the system to affect product quality and safety, and record integrity”.
    - FDA Guidance for Industry: Part 11, Electronic Records; Electronic Signatures – Scope and Application
    - GAMP 5, Chapter 5 - “Quality Risk Management”, Appendix M3 – Science Based Quality Risk Management
  - Risk Mitigation
- Technology Implementation Risk:
 

Lower Risk

↗

Higher Risk

- New Technology/ New System
  - New Technology/ Existing System
  - Existing Technology/ New System
  - Existing Technology/ Existing System
- Acknowledge “Risk” in schedule and in funding



## EMS Project References

- FDI SOPs
  - IT / CSV: SDLC, Security, Backup and Retrieval
  - QE: Calibration, Configuration Management, Document Control
  - QA: Validation, Manual Data Logging, Change Control, Training
  - New: Equipment Monitoring System Operation
- Documentation
  - Available via secured access to MS SharePoint intranet site
  - EMS User's Manual and EMS Administrator's Manual (also used for training)
  - Design, build, and install docs and drawings (both FDI and System Integrator (SI) generated)
  - Project Management Plan (PMP) and project support documentation (by FDI)
  - System Validation Master Plan (SVMP by FDI)
  - SDLC documentation per PMP & SVMP (both FDI and SI generated)
  - Vendor's, supplier's, and equipment manufacturer's product documentation and manuals
- Standards and Guidance
  - ANSI/ISA-5.1-2009, Instrumentation Symbols and Identification
  - ANSI/ISA-95.00.01-2000, Enterprise-Control System Integration Part 1: Models and Terminology
  - ANSI/ISA-95.00.03-2005, Enterprise-Control System Integration, Part 3: Models of Manufacturing Operations Management
  - GAMP 5, A Risk-Based Approach to Compliant GxP Computerized Systems
  - GAMP GPG: Manufacturing Execution Systems – A Strategic and Program Mgmt Approach



## Questions / Discussion

---

### Equipment Monitoring System (EMS) Project Overview

*"Implementing an Operations Information Infrastructure"*



Fujirebio Diagnostics, Inc. contact:  
Ken Kovacs, Quality Business Systems Manager  
Email: [kovacsk@fdi.com](mailto:kovacsk@fdi.com)

