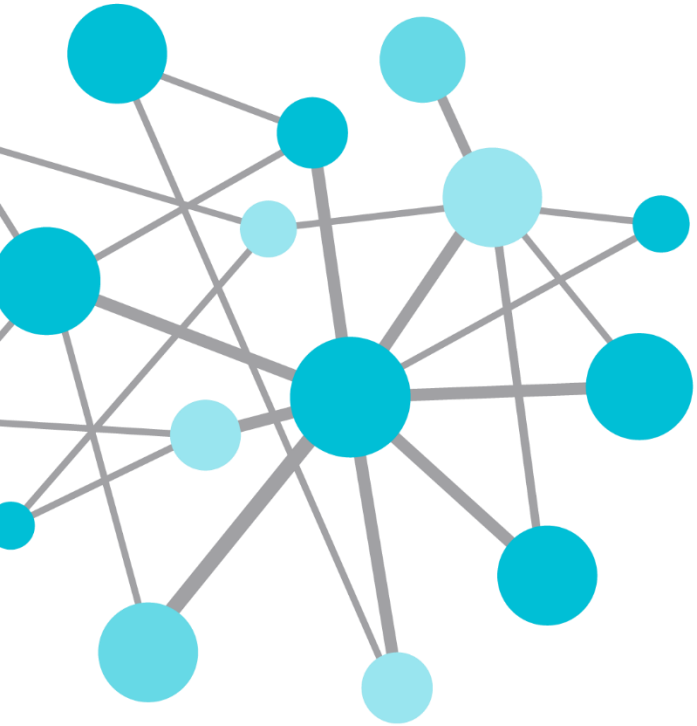

Biogen Idec The Path to a Unified Data Infrastructure

Presented by **Gus Green**

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Agenda

- Introduction
  - About Biogen Idec
  - RTP PI System Overview 2011
  - Problem Statement
- Solution
  - Upgraded Architecture
  - OSD Facility/Cambridge Addition
  - PI Advanced Computing Engine (PI ACE) Calculations for Real Time Monitoring
  - PI Asset Framework (PI AF) for ELE Integration
  - PI WebParts for User Convenience
- Future
  - PI Interface for Emerson DeltaV Batch (EMDVB) for Reporting Solution
- Conclusion

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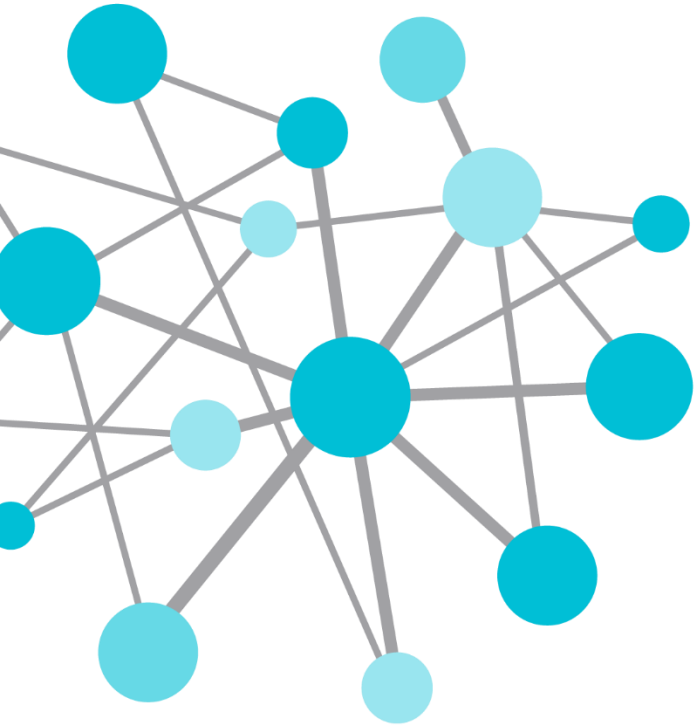

Introduction

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Biogen Idec

- Who We Are
  - Neurodegenerative Diseases, Hemophilia and Auto-Immune Disorders
  - AVONEX®, TYSABRI®, TECFIDERA®, RITUXAN® (partnered with Roche)
  - Strengths in Biologics
  - Small Molecule Development
  - Original PI Data circa 2001
- Global Footprint
  - Headquartered in Cambridge, MA
  - Manufacturing in Cambridge, Research Triangle Park (RTP) and Hillerød
  - Oral Solid Dosage (OSD) Facility - RTP

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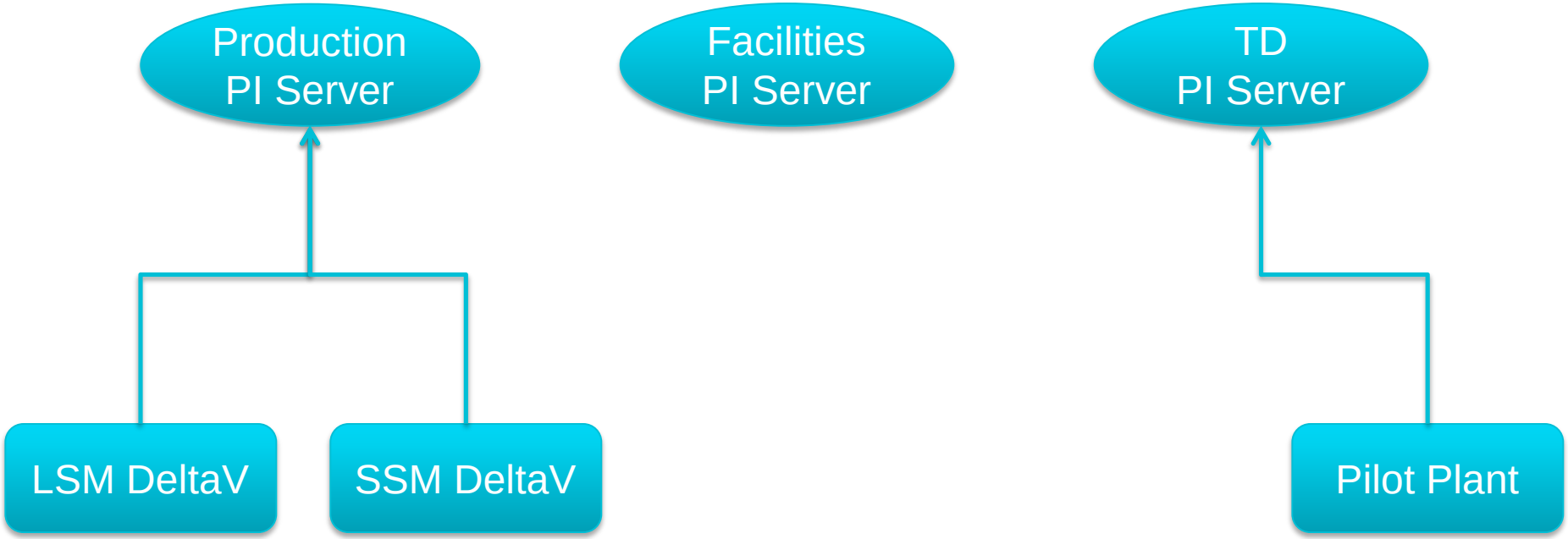
RTP PI System 2011



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Problem Statement

- PI System Not Current
  - Need to upgrade to PI System 2010
  - Need for new hardware
  - Many devices not connected – (Finesse DeltaV, Cedex, AKTA)

- PI System Under Utilized
  - Manufacturing Sciences (MS) and Technical Development (TD) access PI Data through PI DataLink
  - PI ProcessBook used to access production and facilities data for ad-hoc trending
  - SBOL in place for multivariate analysis of manufacturing data

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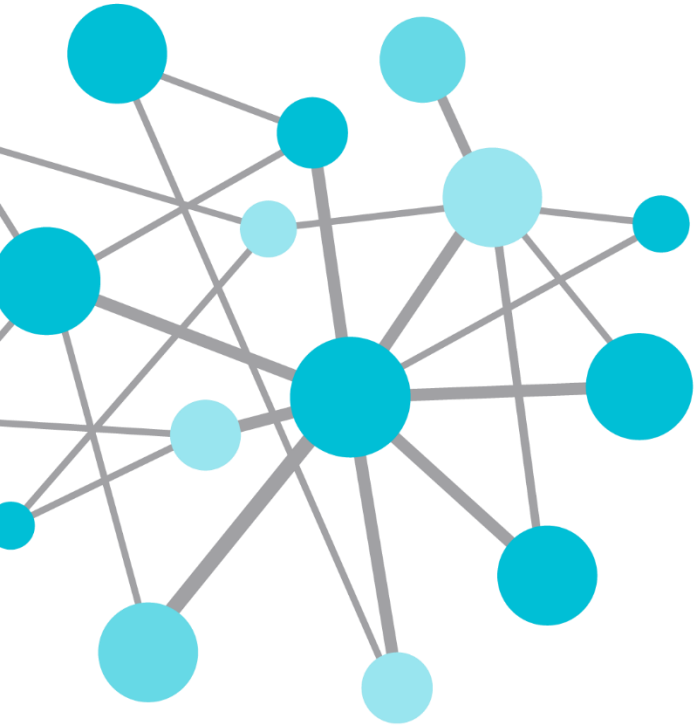

Solution

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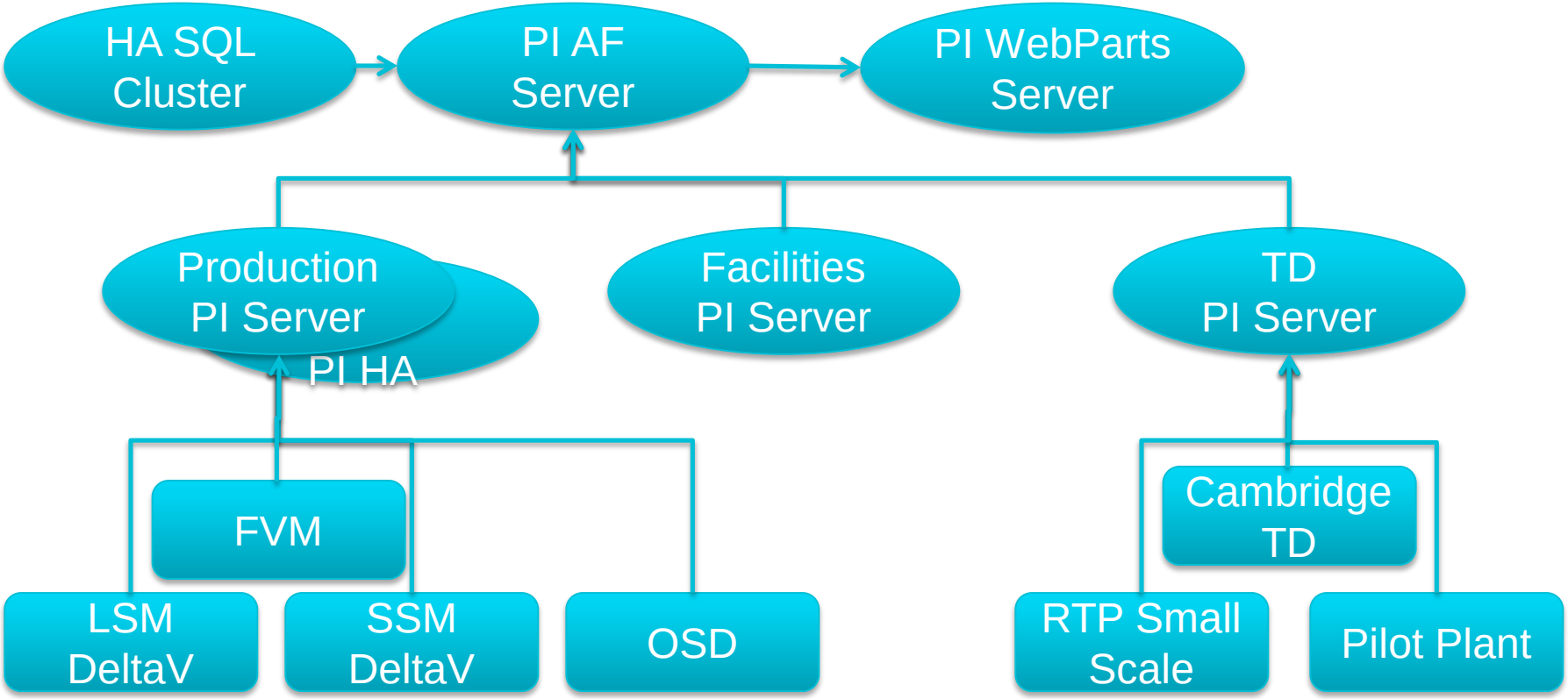
RTP PI System - Today



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Development Server

- Virtualization
  - Built ESXi host
  - Development server useful to experiment before applying to production
  - Trial run for server virtualization

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Remote Locations

- Cambridge Facility
  - Originally PI Users for Manufacturing and Pilot Plant but only 1 PI Server
  - Migrated data to RTP TD PI Server
  - Used redundant interface nodes in Cambridge to push data over WAN
  - Supported by PI Admin in Cambridge and RTP PI Admin remotely

- OSD Facility
  - No PI System – inherited Wonderware historian for original equipment
  - Build out of new tablet suite using equipment of different control platforms
  - Used redundant interface nodes to push data over direct link to RTP
  - Cost for OSD PI Server ~$160k
  - Cost for redundant interface nodes and extra tags ~$30k
  - RTP Engineering to support due to proximity
  - Savings of $130k in licensing and 1 headcount!

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PI ACE Calculations

- Chamber Monitoring Project
- Differential Pressure Monitoring Project
- Chromatography Trend Analysis Project

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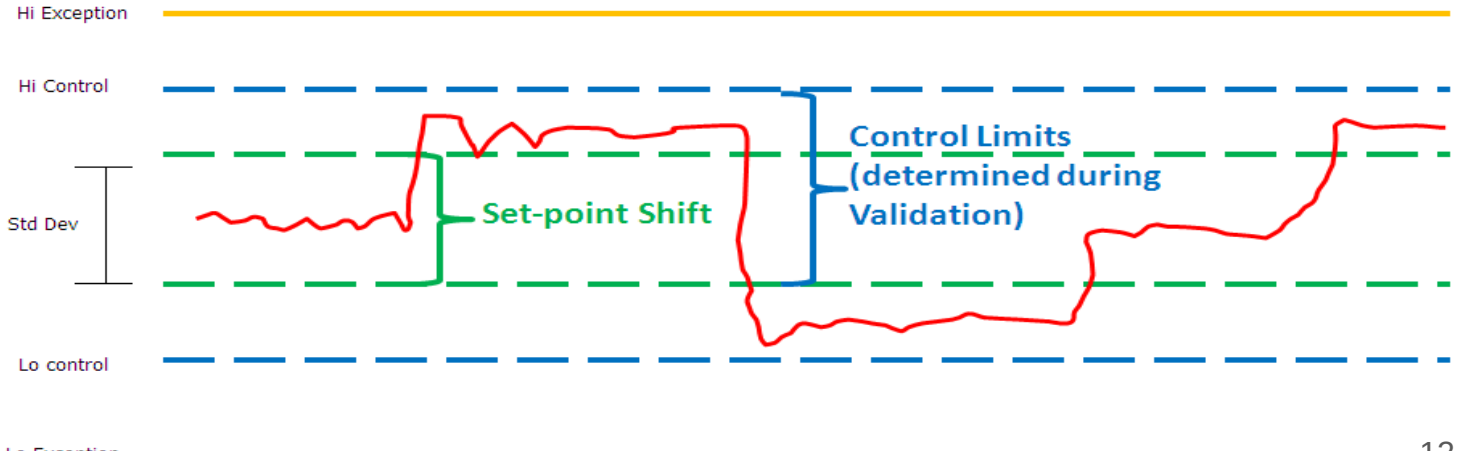
Chamber Monitoring Project

- Configuration done through custom VB.NET application
- Calculations done through VB.NET
- Notifications sent to validation associates when process value starting to deviate
  - High and Low Control Limits, Std Deviation and Floating Average Shifts trigger alarms
  - Use email links to acknowledge alarms or view trends



Chamber Monitoring Project

- Added Compliance/Reduction in Resources
  - Real-time alarm monitoring
  - Real-time Notifications to trigger investigation
  - In validation now
  - Currently = manual trend review (4hrs * 200 chambers = 800hrs/year)
  - Future = Real Time review by PI System and only time needed is to investigate exceptions

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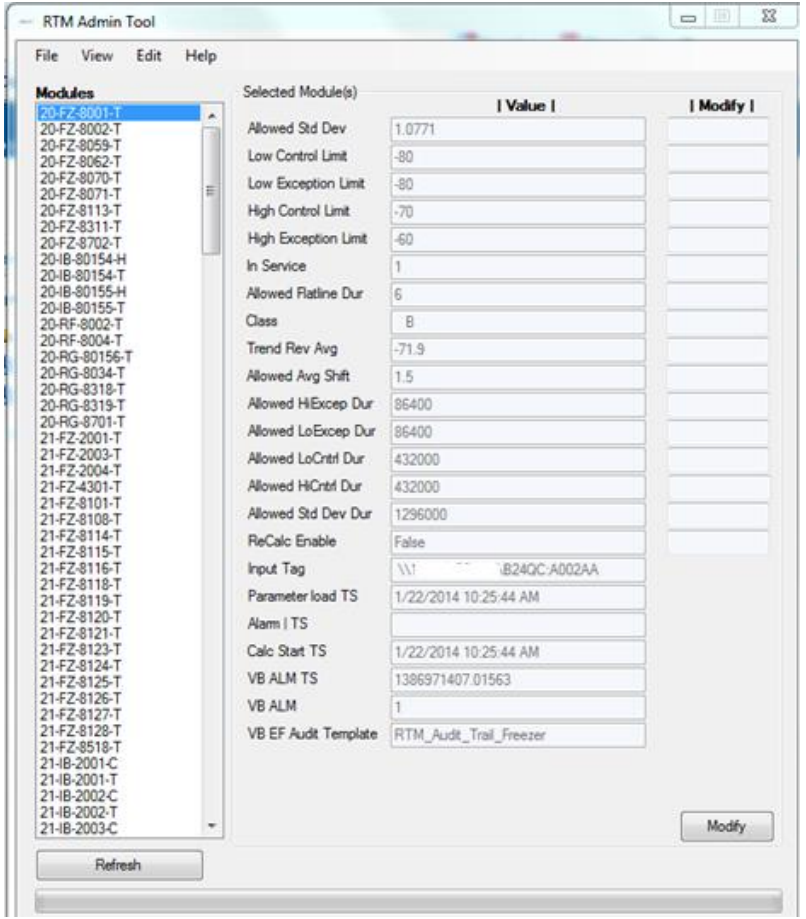
Chamber Monitoring

- Custom VB App
- Used for configuration



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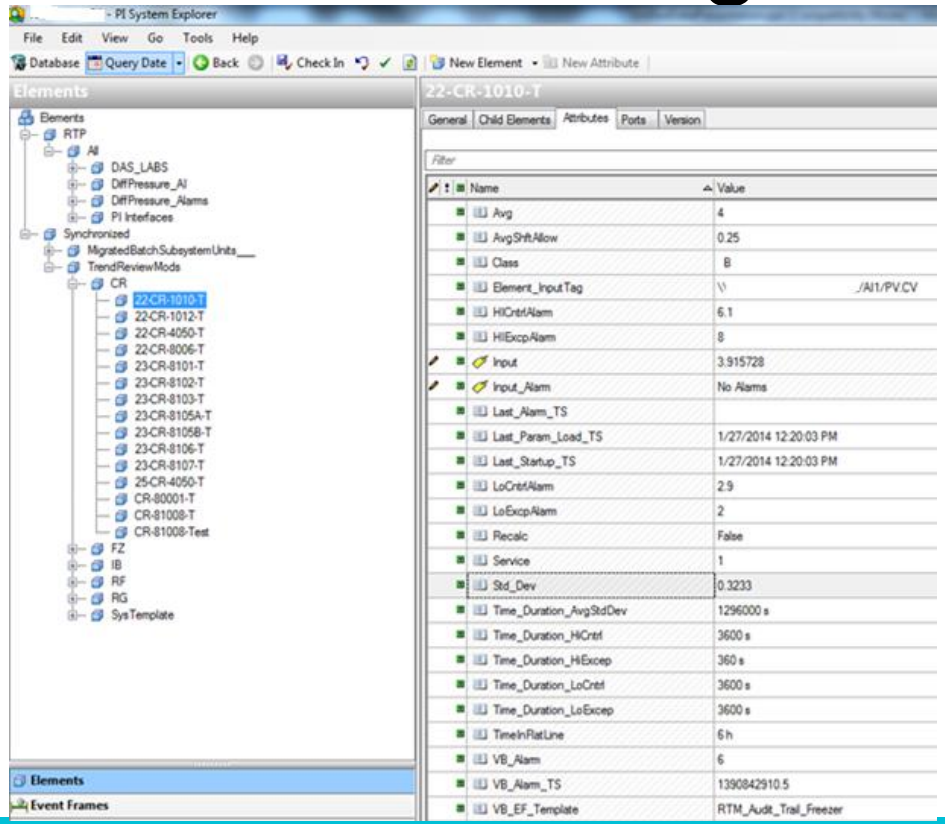
Chamber Monitoring – PI AF



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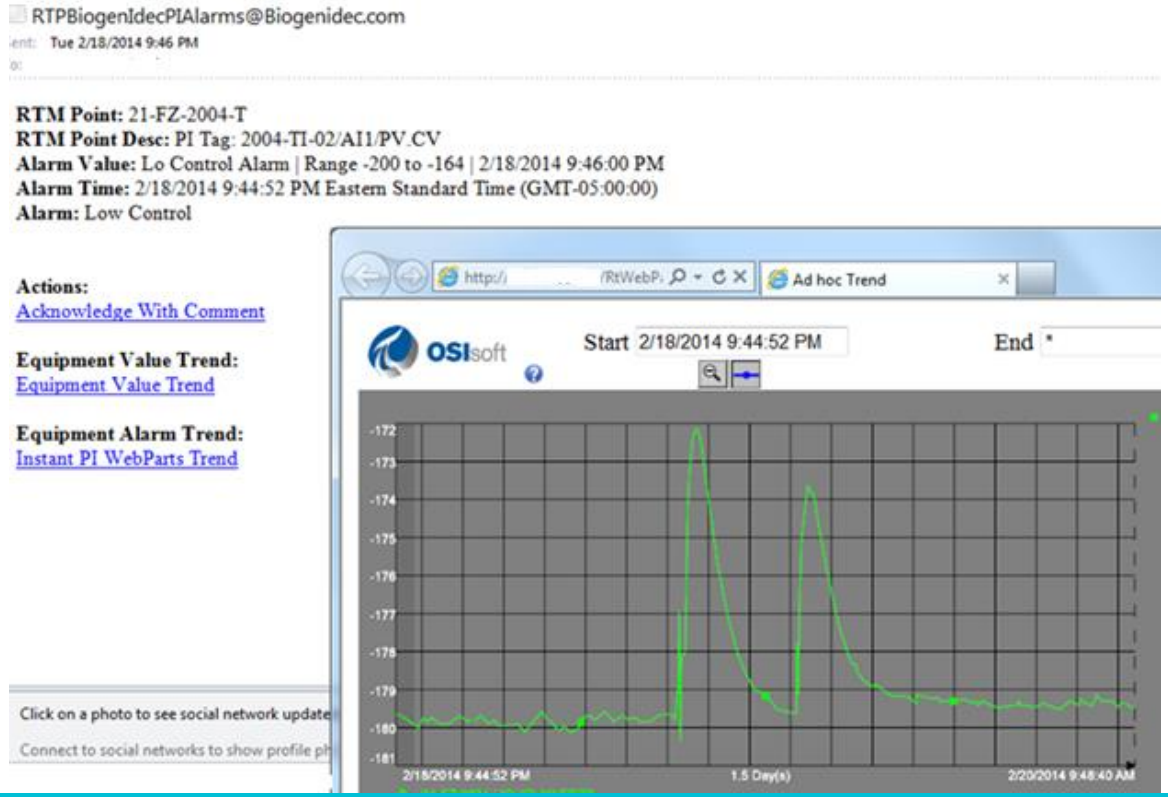
Chamber Monitoring – PI Notifications



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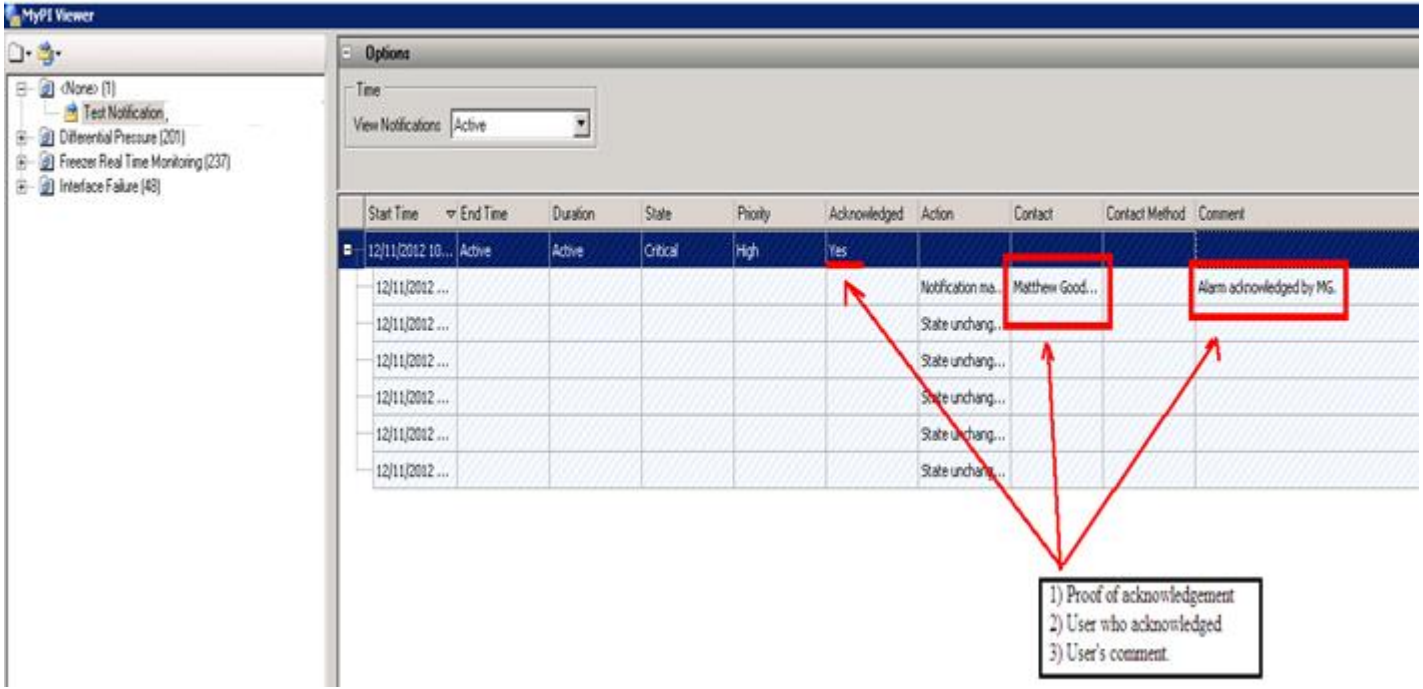
Chamber Monitoring – PI Notifications

- Once the alarm has been acknowledged, the alarm status is updated with the user who acknowledged it and their associated comment if one was left.



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Differential Pressure Monitoring Project

- Maintenance Report
  - Monthly report – used to spend hours trying to figure out why each DP alarm triggered and how affected facility
- Operation
  - Operates similar to the chamber calculations.
  - Standard Deviation and Floating Average Shifts trigger alarms.
  - Notifications to trigger Maintenance Department
- Added Compliance
  - Real-time alarm monitoring
  - Real-time Notifications to trigger investigation immediately
  - Eliminates manual trend review a month later
  - Cost is still there but investigation is more accurate since its real-time

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Chromatography Trend Analysis Project

- Current setup
  - Use PI DataLink to pull in data for batch, manually enter batch information to pull in correct dataset
  - Very complex excel sheets created using macros and formulas that execute calculations
- PI Event Frames
  - Event frame for recipe with sub-event frames for unit procedures are created from data retrieved through EMDVB interface to production batch historian
  - PI ACE Manager searches through PI AF SDK for attributes from event frames to run calculations on dataset
  - New event frames are generated to contain calculation results to allow data to be organized in one place
- Data Analysis
  - Calculations built using VB.NET
  - Various calculations are performed on dataset of sample values based on interval
  - All calculation results stored within event frame attributes

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ELE Integration

- Electronic Lab Environment
  - Solution for Electronic Notebook to keep all experiment data in one place
  - Used PI Server to integrate all equipment data so ELE only connected to one source
  - Built PI AF structure using templates for bioreactors
  - Connects to PI Server through PI Web Services and PI AF SDK
  - User enters Bioreactor ID and sample ID so ELE can pull a snapshot of Bioreactor data at sample time as well as data from sample equipment (Cedex, BGA, etc.)

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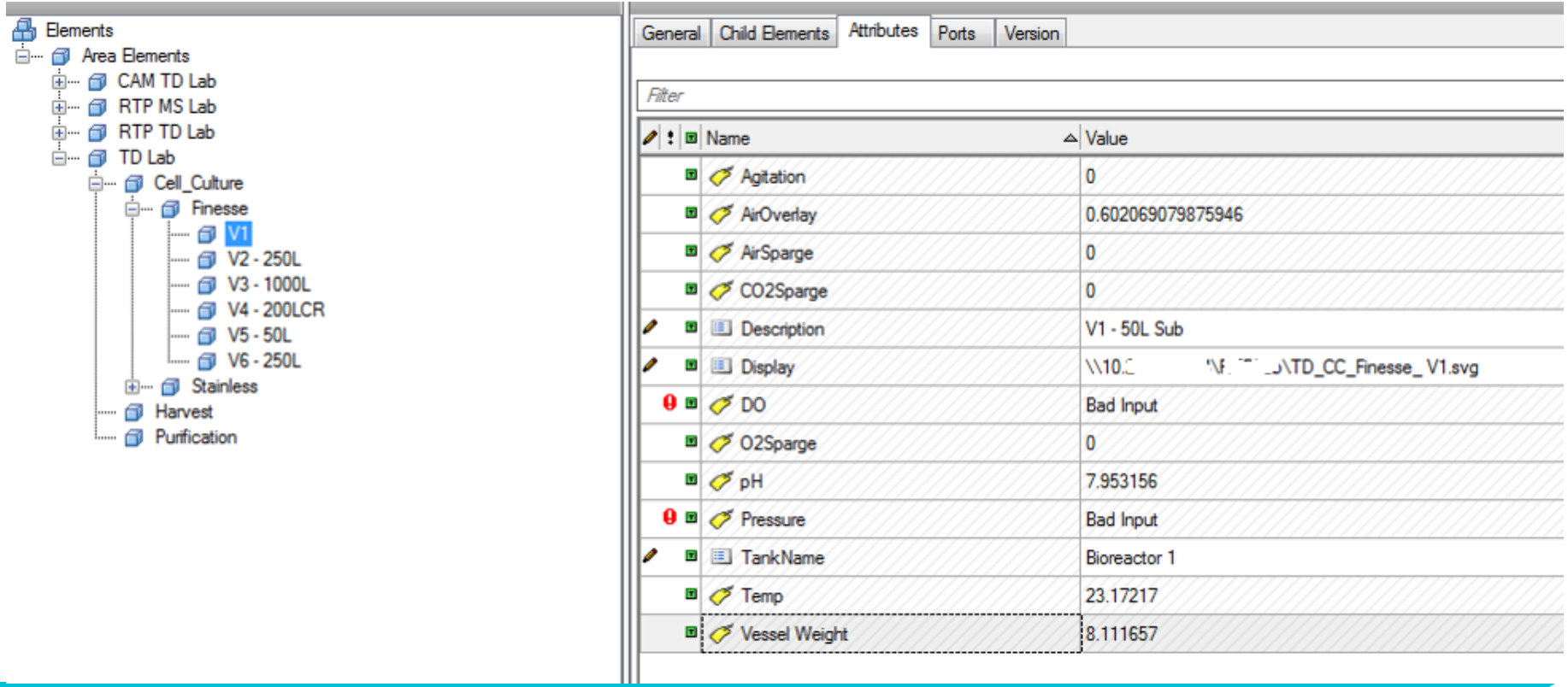
ELE Integration



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PI WebParts

- PI WebParts provide quick view from anywhere
  - With any VPN connection to the Biogen Idec network the data is available
- PI WebParts used to provide snapshot of critical values
  - Users define critical process values
- Eliminates need for many remote access licenses
  - Most users want to quickly view values and do not need full access to system
  - Maintain only 1 or 2 remote DeltaV sessions per Finesse system
  - DeltaV Operator or Pro Station licenses ~$12k, Web Parts $475
  - Eliminates need to VPN onto the Manufacturing Control Network (MCN)

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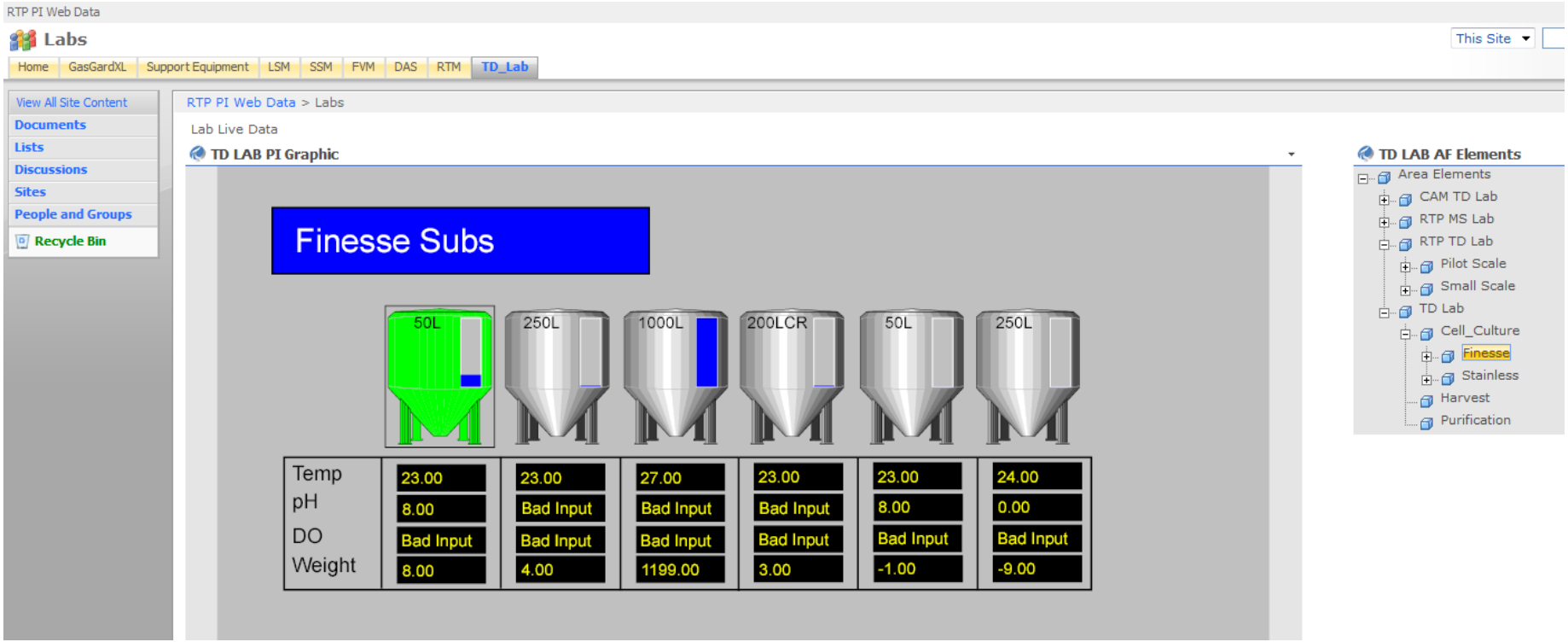
PI WebParts



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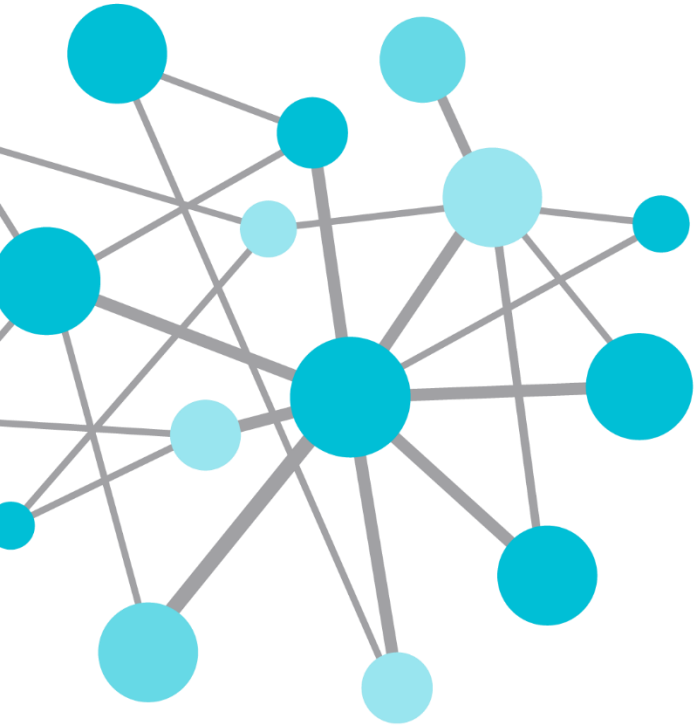

Future

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EMDVB for Reporting Solution

- Current batch reporting issues
  - Use DeltaV Batch Historian which only holds 30 days of batches
  - Combine with PI Batches to evaluate exceptions over time
  - PI Batch triggers difficult to locate to prevent false exceptions

- EMDVB Solution
  - Pull all critical batch data into PI Server
  - Enables users to view continuous archive – much longer than 30 days
  - All data in one place – PI Server
  - Store DeltaV alarms for exception based reporting

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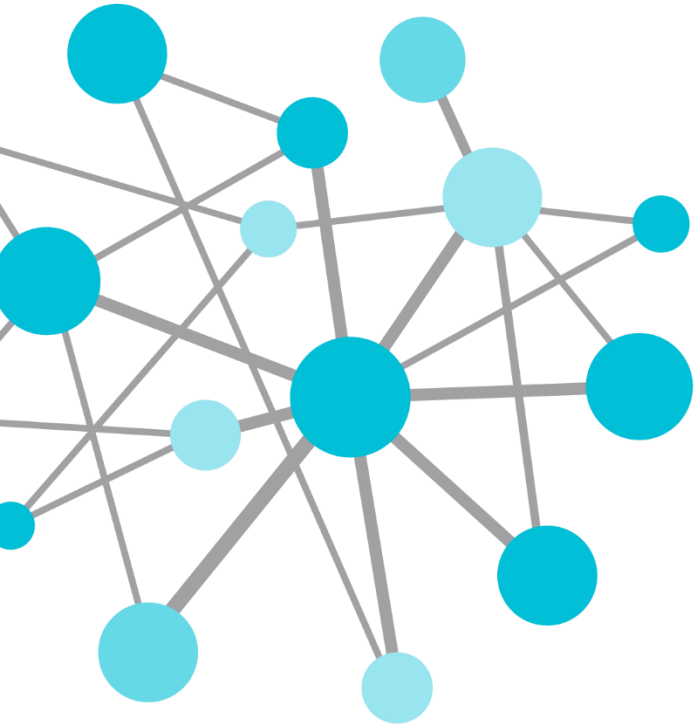

Conclusion

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Conclusion

- Infrastructure in place
  - Upgraded to PI System 2010 and added functionality
  - Added approximately ~25000 tags to system
  - Increased footprint in other locations

- Increased user interaction
  - Added many users from TD and MS areas
  - Added user's solutions to drive value from PI System
  - Added new ways to access data

By unifying data onto one platform we are now turning our data into information we can use.

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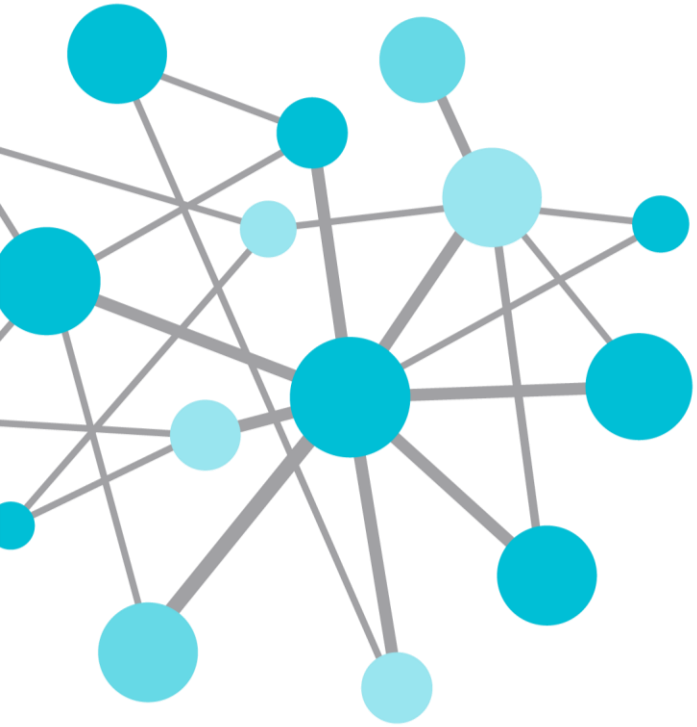

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