

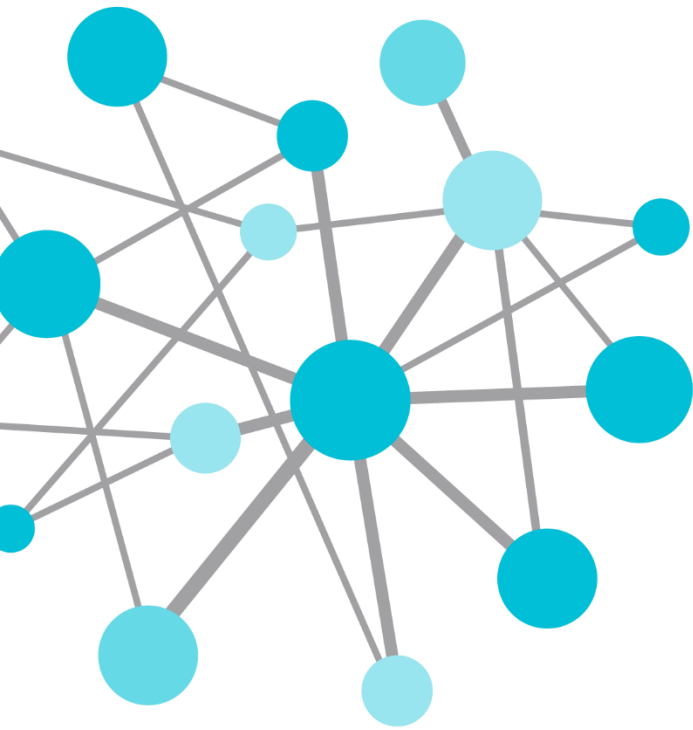


# Biogen Idec The Path to a Unified Data Infrastructure

Presented by **Gus Green**

# 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

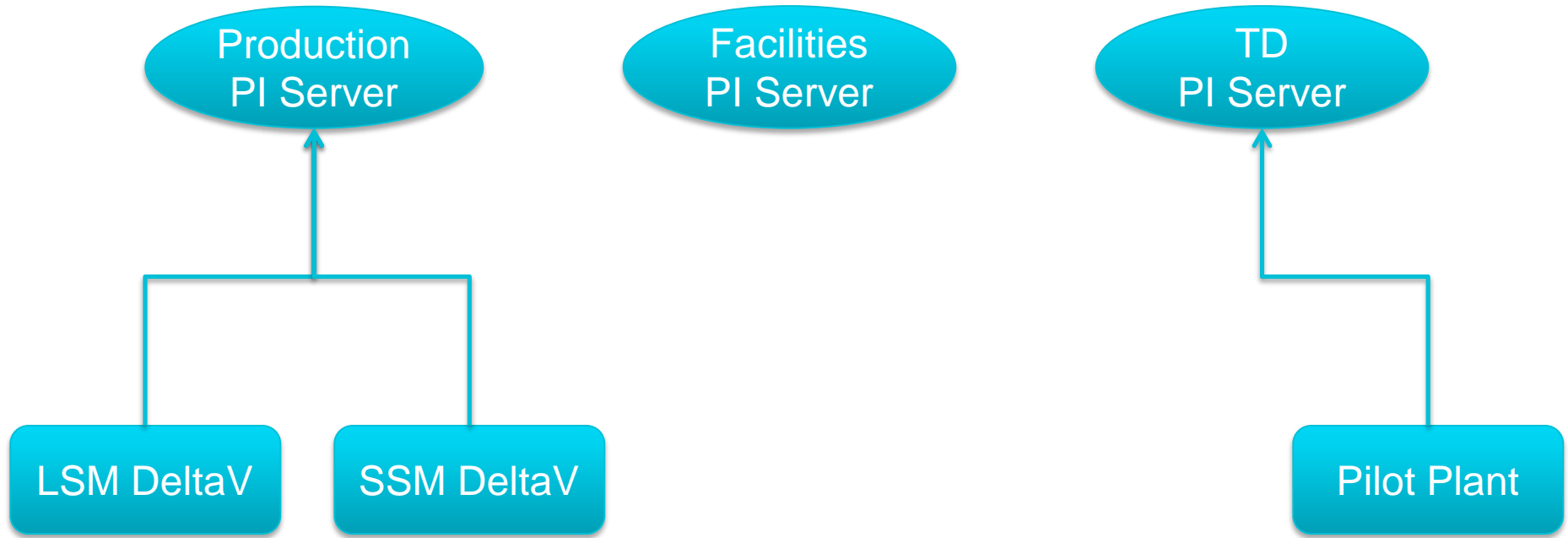


# Introduction

# Biogen Idec

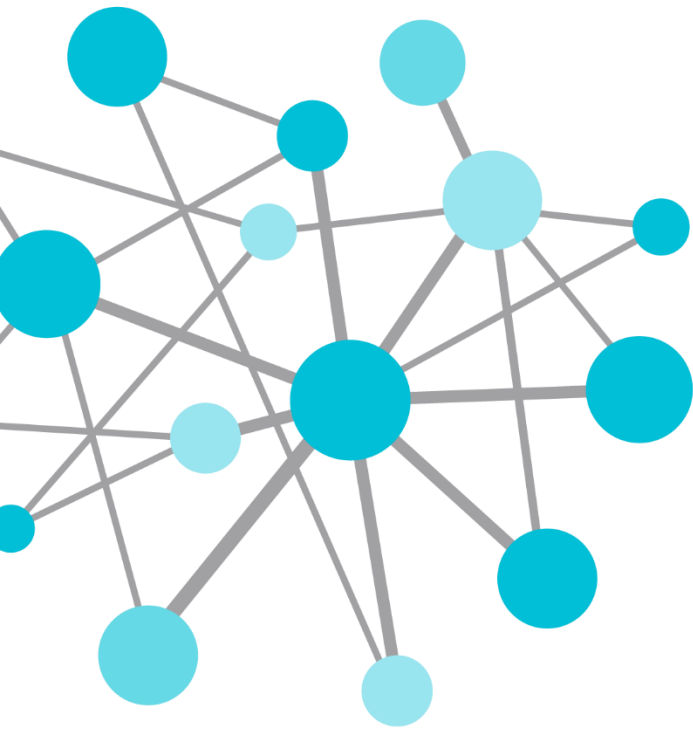
- Who We Are
  - Neurodegenerative Diseases, Hemophilia and Auto-Immune Disorders
  - AVONEX®, TYSABRI®, TECFIDERA®, RITUXAN® (partnered with Roche)
  - Strengths in Biologics
  - Small Molecule Development
  - Original PI Data circa 2001
- Global Footprint
  - Headquartered in Cambridge, MA
  - Manufacturing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

# RTP PI System 2011



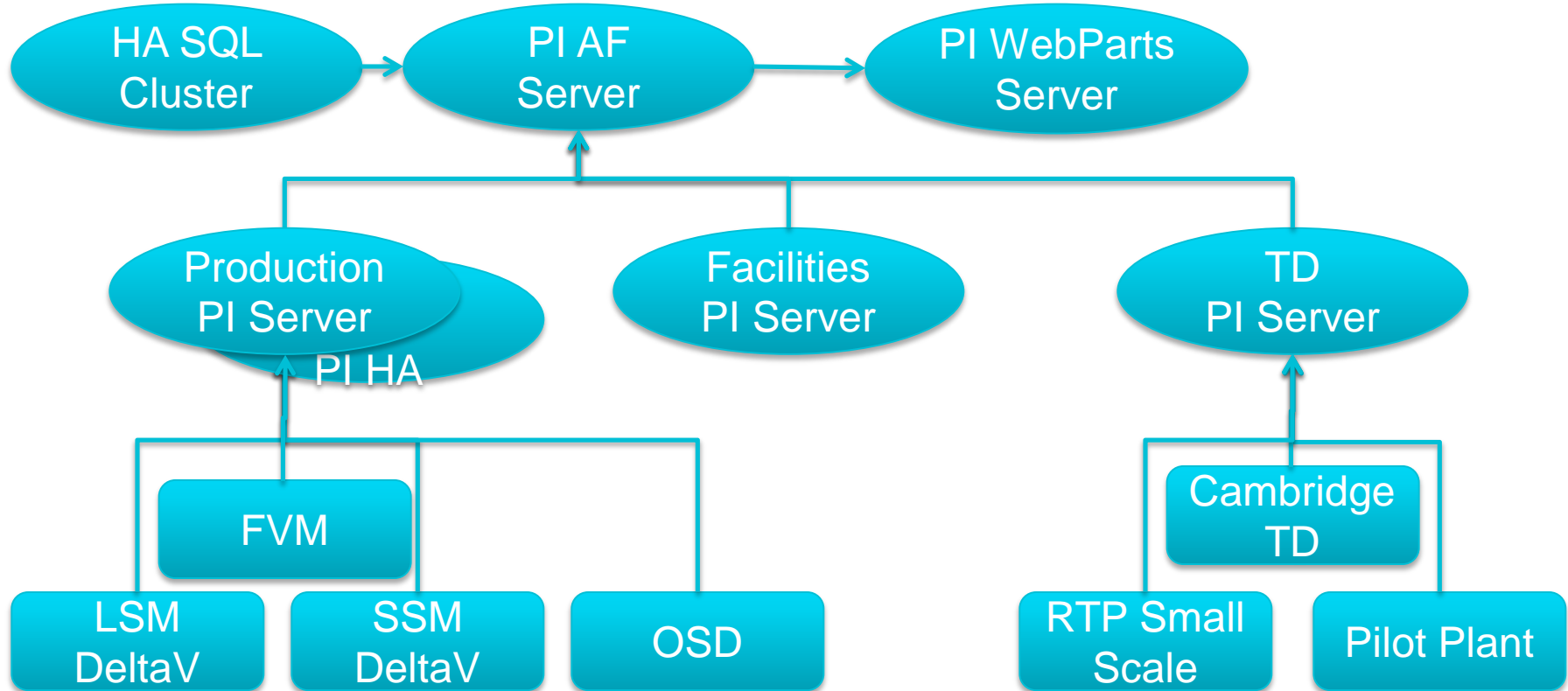
# Problem Statement

- 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



# Solution

# RTP PI System - Today





# Development Server

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

# Remote Locations

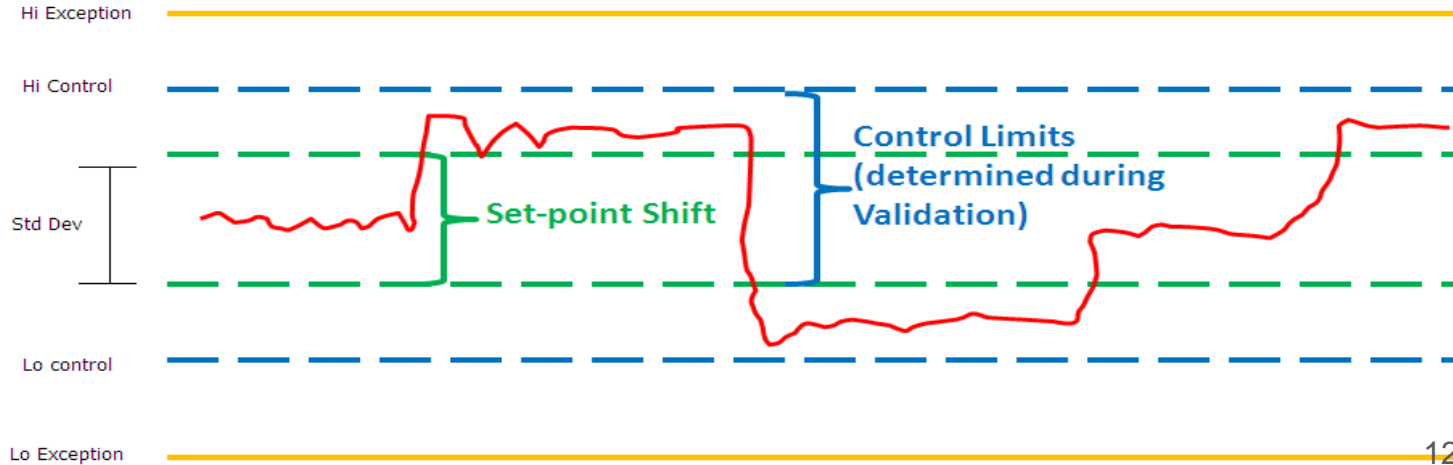
- Cambridge Facility
  - Originally PI Users for Manufacturing and Pilot Plant but only 1 PI Server
  - Migrated data to RTP TD PI Server
  - Used redundant interface nodes in Cambridge to push data over WAN
  - Supported by PI Admin in Cambridge and RTP PI Admin remotely
- OSD Facility
  - No PI System – 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!**

# PI ACE Calculations

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

# 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

# Chamber Monitoring

- Custom VB App
- Used for configuration

The screenshot displays the RTM Admin Tool interface. On the left, a list of modules is shown, with '20-FZ-8001-T' selected. The main area on the right shows the configuration for the selected module, organized into a table with three columns: 'Selected Module(s)', 'Value', and 'Modify'.

Selected Module(s)	Value	Modify
Allowed Std Dev	1.0771	
Low Control Limit	-80	
Low Exception Limit	-80	
High Control Limit	-70	
High Exception Limit	-60	
In Service	1	
Allowed Flatline Dur	6	
Class	B	
Trend Rev Avg	-71.9	
Allowed Avg Shift	1.5	
Allowed HIExcep Dur	86400	
Allowed LoExcep Dur	86400	
Allowed LoCtrl Dur	432000	
Allowed HICtrl Dur	432000	
Allowed Std Dev Dur	1296000	
ReCalc Enable	False	
Input Tag	\\.\ -- .B24QC.A002AA	
Parameter load TS	1/22/2014 10:25:44 AM	
Alarm   TS		
Calc Start TS	1/22/2014 10:25:44 AM	
VB ALM TS	1386971407.01563	
VB ALM	1	
VB EF Audit Template	RTM_Audit_Trail_Freezer	

At the bottom of the interface, there are 'Refresh' and 'Modify' buttons.

# Chamber Monitoring – PI AF

The screenshot displays the PI System Explorer interface. On the left, a tree view shows the hierarchy: Elements > RTP > AI > 22-CR-1010-T. The main pane shows the details for 22-CR-1010-T, including a table of attributes and their values.

Name	Value
Avg	4
AvgShftAllow	0.25
Class	8
Element_InputTag	\\.../AI1/PV/CV
HiCntrlAlarm	6.1
HiExcpAlarm	8
Input	3.915728
Input_Alarm	No Alarms
Last_Alarm_TS	
Last_Param_Load_TS	1/27/2014 12:20:03 PM
Last_Startup_TS	1/27/2014 12:20:03 PM
LoCntrlAlarm	2.9
LoExcpAlarm	2
Recalc	False
Service	1
Std_Dev	0.3233
Time_Duration_AvgStdDev	1296000 s
Time_Duration_HiCntrl	3600 s
Time_Duration_HiExcep	360 s
Time_Duration_LoCntrl	3600 s
Time_Duration_LoExcep	3600 s
TimehFlatLine	6 h
VB_Alarm	6
VB_Alarm_TS	1390842910.5
VB_EF_Template	RTM_Audt_Tral_Freezer

# Chamber Monitoring – PI Notifications

RTPBiogenIdecPIAlarms@Biogenidec.com

ent: Tue 2/18/2014 9:46 PM

0:

**RTM Point:** 21-FZ-2004-T

**RTM Point Desc:** PI Tag: 2004-TI-02/A11/PV.CV

**Alarm Value:** Lo Control Alarm | Range -200 to -164 | 2/18/2014 9:46:00 PM

**Alarm Time:** 2/18/2014 9:44:52 PM Eastern Standard Time (GMT-05:00:00)

**Alarm:** Low Control

**Actions:**

[Acknowledge With Comment](#)

**Equipment Value Trend:**

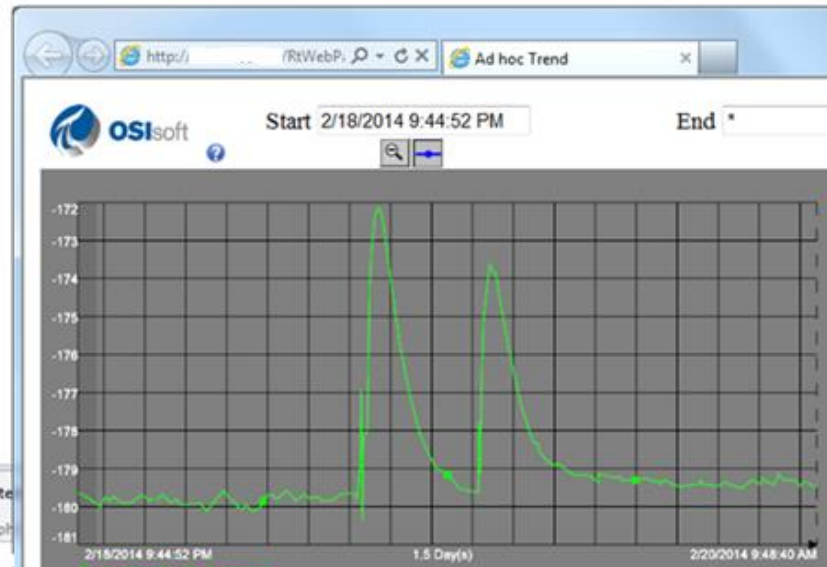
[Equipment Value Trend](#)

**Equipment Alarm Trend:**

[Instant PI WebParts Trend](#)

Click on a photo to see social network update

Connect to social networks to show profile pic





# 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.

The screenshot shows the 'MyPI Viewer' interface. On the left is a tree view with nodes: (None) (1), Test Notification, Differential Pressure (201), Freezer Real Time Monitoring (237), and Interface Failure (48). The main area displays an 'Options' panel with 'View Notifications' set to 'Active'. Below this is a table with the following columns: Start Time, End Time, Duration, State, Priority, Acknowledged, Action, Contact, Contact Method, and Comment.

Start Time	End Time	Duration	State	Priority	Acknowledged	Action	Contact	Contact Method	Comment
12/11/2012 10...	Active	Active	Critical	High	Yes				
12/11/2012 ...						Notification ma...	Matthew Good...		Alarm acknowledged by MG.
12/11/2012 ...						State unchang...			
12/11/2012 ...						State unchang...			
12/11/2012 ...						State unchang...			
12/11/2012 ...						State unchang...			
12/11/2012 ...						State unchang...			

Red arrows point from a legend box at the bottom to specific cells in the table: one to the 'Acknowledged' column of the first row, one to the 'Contact' column of the second row, and one to the 'Comment' column of the second row.

1) Proof of acknowledgement  
2) User who acknowledged  
3) User's comment.

# 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

# 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

# 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.)

# ELE Integration

The screenshot displays the ELE Integration software interface. On the left, a hierarchical tree structure shows the following elements:

- Elements
  - Area Elements
    - CAM TD Lab
    - RTP MS Lab
    - RTP TD Lab
    - TD Lab
      - Cell\_Culture
        - Finesse
          - V1**
          - V2 - 250L
          - V3 - 1000L
          - V4 - 200LCR
          - V5 - 50L
          - V6 - 250L
        - Stainless
        - Harvest
        - Purification

On the right, the 'General' tab is selected, showing a table of attributes for the 'Finesse V1' element:


Name	Value
Agitation	0
AirOverlay	0.602069079875946
AirSparge	0
CO2Sparge	0
Description	V1 - 50L Sub
Display	\\10.0.0.1\TD_CC_Finesse_V1.svg
DO	Bad Input
O2Sparge	0
pH	7.953156
Pressure	Bad Input
TankName	Bioreactor 1
Temp	23.17217
Vessel Weight	8.111657

# 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)

# PI WebParts

RTP PI Web Data


 Labs This Site ▾

Home GasGardXL Support Equipment LSM SSM FVM DAS RTM **TD\_Lab**

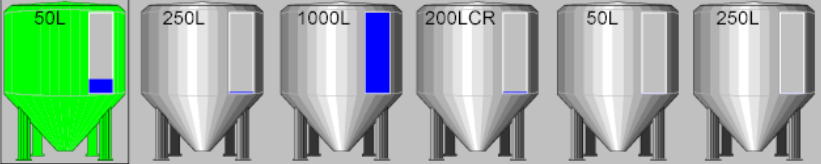
View All Site Content  
Documents  
Lists  
Discussions  
Sites  
People and Groups  
Recycle Bin

RTP PI Web Data > Labs

Lab Live Data

 TD LAB PI Graphic

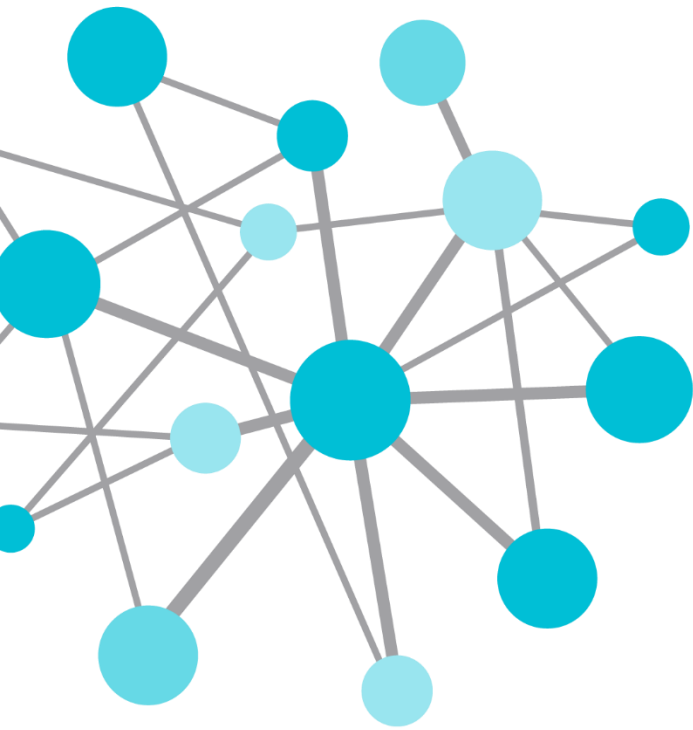
**Finesse Subs**



	50L	250L	1000L	200LCR	50L	250L
Temp	23.00	23.00	27.00	23.00	23.00	24.00
pH	8.00	Bad Input	Bad Input	Bad Input	8.00	0.00
DO	Bad Input	Bad Input	Bad Input	Bad Input	Bad Input	Bad Input
Weight	8.00	4.00	1199.00	3.00	-1.00	-9.00

**TD LAB AF Elements**

- Area Elements
  - CAM TD Lab
  - RTP MS Lab
  - RTP TD Lab
    - Pilot Scale
    - Small Scale
    - TD Lab
      - Cell\_Culture
        - Finesse**
        - Stainless
        - Harvest
        - Purification

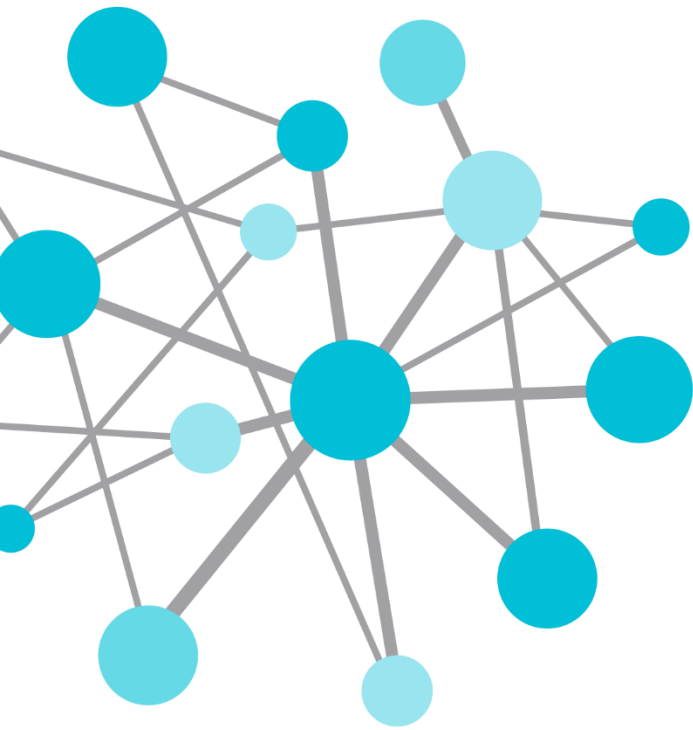


# Future



# 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



# Conclusion

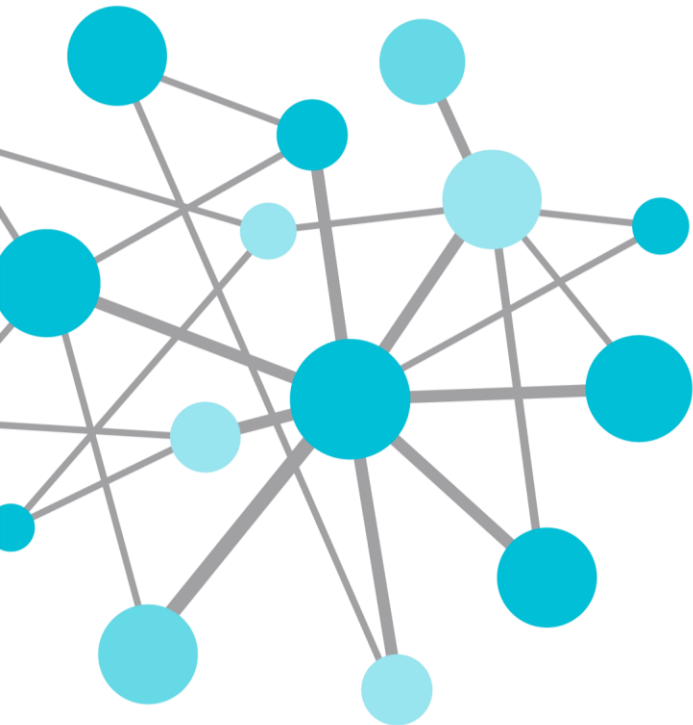
# Conclusion

- 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.

# Gus Green

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- Biogen Idec



THANK  
YOU

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